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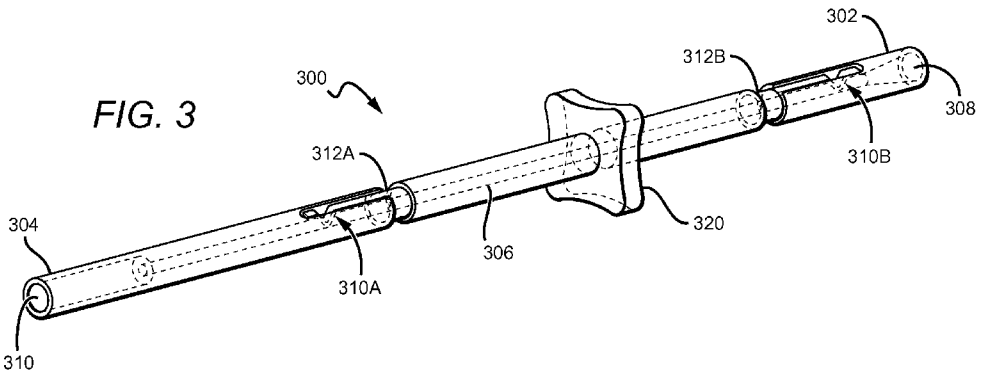
FIG. 3



(57) Abstract: Disclosed herein is a system for transferring brachytherapy elements to a needle, such as seeds, connectors, spacers, and strands. The system comprises a transfer device and, optionally, a stylet and a rack configured to hold one or more transfer devices.

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NEW PCT APPLICATION

Titled:

BRACHYTHERAPY ELEMENT TRANSFER SYSTEM

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BRACHYTHERAPY ELEMENT TRANSFER SYSTEM

[0001] This application claims benefit of priority to U.S. Provisional Application No. 60/892,079, entitled "Brachytherapy Element Transfer System," filed February 28, 2007, the disclosure of which is incorporated herein by reference in its entirety.

[0002] Victims of cancer are often treated using chemotherapy and/or radiation therapy. Chemotherapy is the treatment of cancer using drugs that destroy cancer cells. Radiation therapy is the use of a type of energy, called ionizing radiation, to destroy cancer cells.

[0003] Brachytherapy is one type of radiation therapy used to treat cancer. Brachytherapy involves placing a small amount of radioactive material inside the body, near the cancer cells or tumor. Unlike external radiation treatment such as electron beam irradiation, brachytherapy enables a doctor to use a higher total dose of radiation to treat a small area in a shorter amount of time. Brachytherapy may be temporary or permanent. In temporary brachytherapy, radioactive material is placed near the cancer cells or tumor for a fixed period of time, and then withdrawn. In permanent brachytherapy, radioactive material in the form of "seeds" is permanently placed near the cancer cells or tumor. Although the seeds remain in the body permanently, the radiation levels of the seeds drop off over time.

[0004] Brachytherapy has been used in the treatment of numerous types of cancer, including cervical, breast, lung, head and neck, and prostate. For example, prostate cancer may be treated using radioactive seeds, such as Pd^{103} or I^{125} seeds. Depending on

the prostate size and aggressiveness of the cancer, a health care provider can determine the number and positioning of the radioactive seeds needed to deliver a sufficient amount of radiation to kill the cancerous cells. In certain brachytherapy delivery systems, the requisite number of radioactive seeds, separated by bio-absorbable spacers and/or bio-absorbable connectors, are loaded into brachytherapy needles and inserted into the prostate. Once the tip of the needle has been placed in its proper position, the needle is withdrawn, leaving a pattern of seeds, spacers and/or connectors.

[0005] Proper seed placement and seed retention at the implantation site influence the success or failure of a brachytherapy procedure. Certain seed implantation devices and methods often provide variable seed spacing and dosimetric patterns during and after implantation. Loose seeds, especially those that are extra-capsular (located outside the capsule of the prostate), tend to migrate within the patient, and as a result, may not provide radiation where needed and may sometimes cause damage to other radiation-sensitive areas of the body. In addition, the manual loading of seeds and spacers into the brachytherapy needle can be a laborious and time-consuming task.

[0006] As a result of the above, "stranded" seeds have been developed. Stranded seeds are connected together by connective material to form a strand. The seeds in a particular strand may be spaced apart by a predetermined interval to create a desired dosing level. By varying the spacing of seeds and the lengths of strands, strands can be formed with different desired dosing levels. It may be advantageous to provide pre-constructed strands packaged in accordance with a patient's particular dose plan. Such packaging is disclosed in PCT Application Publication No. WO 2007/047280, the

disclosure of which is incorporated herein by reference in its entirety as if fully set forth herein.

[0007] To facilitate the formation of strands of seeds, a brachytherapy seed deployment system has been disclosed in U.S. Patent Nos. 6,010,446; and 6,969,344 (the contents of each of which are incorporated by reference as if fully set forth herein) The system comprises a basic unit of at least two seeds and a connecting spacer joining the seeds to maintain proper spacing between the seeds. Further alternating connecting spacers and seeds may be connected to this basic unit to form a strand of seeds, each seed separated from adjacent seeds by the length of the connecting spacer. The length of the connecting spacers and the overall length of the strand may be varied to create a desired dosing level depending on patient needs. The connectors may be formed of solid rods of bioabsorbable material that degrade within 18-24 months after being inserted into the body.

[0008] Fig. 1 illustrates three components of an exemplary brachytherapy seed deployment system designed to provide seed spacing in 0.5 cm increments. Reference character **100** designates an exemplary 1 cm standard connector (which is the distance between the center of the seeds when they are seated in cups **101A** and **101B**), reference character **110** designates an exemplary 0.5 cm seed-to-seed connector having cups **111A** and **111B**, and reference character **120** designates an exemplary extension connector having 0.5 cm center-to-center seed spacing beyond 1 cm, with the extension feature **122** being configured to seat within cups **101A-B**, **111A-B**, and **121**. Used together, these components may form strands of certain lengths with certain seed spacings. Certain

devices can be used to assemble the strands in the operating room, such as the SourceLink™ manual loader and the QuickLink® delivery system.

[0009] To apply these strands to the cancer cells or tumor, a hollow tube delivery device such as a needle, catheter or applicator may first be inserted into the affected area. Strands are then placed in the delivery device the delivery device is drawn out and the strands are seated in the proper location. Alternatively, the strands may first be placed into the delivery device prior to the insertion of the delivery device into the body. X-rays, ultrasound or CT scans may be among the tools used to ensure that the seeds in the strands are properly placed.

[0010] The transfer of the radioactive elements (including stranded and loose seeds) to the hollow tube delivery device can be problematic. During the transfer, the healthcare provider may be unnecessarily exposed to radiation from the radioactive elements. Furthermore, strands can be damaged or dropped during transfer to the hollow tube delivery device. It could be desirable to provide a transfer device that at least partially shields the healthcare provider from radiation.

SUMMARY

[0011] According to one embodiment of the present disclosure, there is provided a brachytherapy element transfer device comprising a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device; and at least one gating feature disposed within said lumen, wherein said gating feature is configured to at least partially occlude said lumen. The term "communicate" means that the lumen

of the transfer device at least substantially aligns with the lumen of the lumen in the hollow cannula.

[0012] According to another embodiment of the present disclosure, there is provided a brachytherapy element transfer system comprising a plurality of brachytherapy element transfer devices comprising a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device; at least one stylet; and at least one device configured to hold the plurality of brachytherapy transfer devices in a configuration that is associated with a treatment plan for a patient.

[0013] According to another embodiment of the present disclosure, there is provided a method for implanting at least one brachytherapy element in a patient, comprising determining the brachytherapy needle loading configuration per the patient dose plan; inserting the at least one brachytherapy element into a brachytherapy element transfer device comprising a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device; placing the loaded brachytherapy element transfer device into a rack; repeating the foregoing steps until the rack contains at least substantially the entire patient dose plan; inserting a plurality of brachytherapy needles into the region in which the at least one brachytherapy element is to be implanted; placing the distal end of a loaded brachytherapy element transfer device against the proximal end of the brachytherapy needle; and, using a stylet, urging the at least one brachytherapy element from the brachytherapy element transfer device into the brachytherapy needle

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The drawings are illustrative of certain embodiments of the present invention, in which like characters represent like elements throughout the views of the drawings, and wherein:

[0015] FIG. **1** illustrates connecting spacers.

[0016] FIG. **2** illustrates one embodiment of an applicator needle transfer device in accordance with the present disclosure.

[0017] FIG. **3** illustrates another embodiment of an applicator needle transfer device in accordance with the present disclosure.

[0018] FIG. **4** illustrates one embodiment of a gating feature in accordance with the present disclosure.

[0019] FIG. **5** illustrates one embodiment of an implant needle transfer device in accordance with the present disclosure.

[0020] FIG. **6** illustrates another embodiment of an implant needle transfer device in accordance with the present disclosure.

[0021] FIG. **7** illustrates one embodiment of a rack configured to hold at least one transfer device in accordance with the present disclosure.

DESCRIPTION

[0022] The transfer device is used to transfer elements, such as radioactive and non-radioactive elements, including but not limited to radioactive seeds, such as BrachySource® I^{125}seeds and TheraSeed® Pd^{103} seeds. It should be noted that seeds comprising other radioactive material can be used as well, including but not limited to Cs^{131}, Au^{198}, Co^{60}, Ir^{192}, and combinations of any of the foregoing. Non-limiting examples of other elements include non-radioactive connectors, non-radioactive spacers, and assembled strands, such as assembled SourceLink® strands, configured for insertion into a medical device, for example a brachytherapy implant needle. According to various

embodiments, the transfer device will provide shielding and product protection during the transfer process. According to various embodiments, the transfer device can be used with loaders such as the QuickLoad™ and SourceLink™ manual loaders, the QuickLink® delivery system, with the ReadyLink® Delivery System (all of C. R. Bard, Inc., Covington, GA), and with manually assembled components.

[0023] The transfer device can be configured to transfer strands or loose components into various types of devices, for example needles, such as hubbed needles (so named for the hub at the proximal end) and applicator needles (designed for use with the Mick® Applicator (Mick Radio-Nuclear Instruments, Inc., Mt. Vernon, NY)). By way of non-limiting example, needles suitable for use with the transfer device include the Bard® BrachyStar® FastFill® Needle and the Bard® BrachyStar®Applicator Seed Implant Needle, respectively (C. R. Bard, Inc., Covington, GA). According to various embodiments, the transfer devices disclosed herein can be used with other types of needles and containers as well.

[0024] According to various embodiments, the transfer devices in accordance with the present disclosure can be provided in a number of different embodiments. For example, disclosed herein are transfer devices configured for use with both implant needles and applicator needles. According to various embodiments, the transfer devices disclosed herein may have at least one gating feature. The gating feature functions to retain the brachytherapy element within the transfer device during transfer of the element to the needle.

[0025] The present invention will now be described by reference to more detailed embodiments, with reference to the accompanying drawings. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0026] One embodiment of an applicator needle transfer device **200** is illustrated in Fig. 2, defined by a generally tubular member with proximal end **202** and distal end **204** that communicate with each other via a lumen **206** extending the entire length of the device. Lumen **206** has a funnel-shaped proximal end **208**. This funnel-shaped feature serves to axially align brachytherapy elements, such as a strand. In addition, the funnel-shaped feature **208** can be configured to mate with the QuickLink™ or SourceLink® loaders. That is, once a seeds and connectors are joined to form a strand by the loader, the proximal end **202** of the transfer device can receive the strand directly from the loader. The distal end **210** of lumen **206** is designed to fit the proximal end of an applicator needle hub, so that the axially aligned elements (in the form of, e.g., a strand) can be urged into the needle.

[0027] According to various embodiments, the device **200** can also comprise a stainless steel grip **320** (illustrated in Figure 3). The grip can be seamlessly brazed to the tubular member.

[0028] Fig. 3 illustrates another embodiment of an applicator needle transfer device in accordance with the present disclosure. The transfer device **300** has a proximal end **302**, a distal end **304**, a lumen **306**, and two gating features **310A** and **310B**. Gating

features **310A-B** are biased inwardly, so that they at least partially occlude lumen **306**. The gating feature is further illustrated in Fig. 4. It includes an occlusive feature **311**, an arm **315**, and a feature **313** that snaps into indentations **312A-B** (Fig. 3). The arm **315** is angled relative to the

longitudinal axis of gating feature **310** so that occlusive feature **311** is biased into lumen **306** (Fig. 3).

[0029] In operation, and by way of non-limiting example, a strand (not shown) is placed in funnel-shaped portion **308** of lumen **306**. The strand is gently urged into the gating feature **310B** via a stylet (not shown). Upon application of a certain amount of force, the gating feature is forced upward by the distal end of the strand, so that the gating feature no longer occludes lumen **206**. Once the entire strand is urged past gating feature **310B**, the stylet is withdrawn and the strand is locked between gating features **310A** and **310B**. The loaded transfer device can then be manipulated without concern that the strand will unintentionally depart the device. When the strand is ready to be urged into a needle, distal end **304** of the transfer device is placed over the proximal end of the needle (not shown). The stylet is introduced into proximal end **302**, forcing open gate **310B**, and urging the strand past gate **310A**.

[0030] Fig. 5 illustrates a transfer device **500** for an implant needle. Transfer device **500** includes a proximal end **502** and a distal end **504**. Lumen **506** has a funnel-shaped proximal portion **508**. The distal end **504** has a conical shape configured for placement in the hub at the proximal end of an implant needle (not shown).

[0031] Fig. 6 illustrates an embodiment of an implant needle transfer device **600**, comprising a proximal end **602**, a distal end **604**, a gripping feature **620**, gating features **610A** and **610B**, and features **612A** and **612B** configured for mounting the gating features. As with the applicator needle, although two gating features are shown, transfer devices having no gating features, or only a single gating feature, are also contemplated by the present disclosure.

[0032] According to various embodiments, the needles can be loaded either before implantation or after they have been placed into the patient (i.e., as part of an after-loading technique). In addition to transfer devices, the system for transferring radioactive elements can also comprise a rack configured to hold a given number of transfer devices during storage, steam sterilization and/or the implant procedure. The rack can have a hole pattern to mimic the hole pattern on standard needle templates used in the implant procedure, so that loaded transfer devices can be staged in such a way that there is a visual cue to the needles to be loaded. The rack can have blank areas where the hole positions can be marked (e.g. to number the holes A1, A2, etc.) to match the naming of the grid positions in a particular dose planning software system. An exemplary embodiment of such a rack is illustrated in Fig. 7. Rack **700** comprises a base plate **702**, a first guiding plate **706**, a second guiding plate **704**, and supporting columns **710A**, **710B**, and **710C** (and a fourth column, not shown). As illustrated, the rack **700** contains transfer devices **300** and **600** disposed in holes **708**.

[0033] According to various embodiments, a stylet is used with the transfer devices disclosed herein. According to various embodiments, when the transfer device is mated to a needle in the after-loader technique, a stylet is provided which is configured to allow

the strand to be implanted immediately, rather than pushing the strand out of the transfer device into the needle, removing the transfer device, and replacing the original needle stylet back into the implant needle. According to another embodiment, however, once the needle is loaded with the brachytherapy element, the transfer device can be withdrawn from the proximal end of the needle, and the needle stylet can be re-inserted to facilitate implantation of the brachytherapy element in the patient. According to various embodiments, the transfer device stylet is at least as long as the combined length of the transfer device and the needle.

[0034] The transfer devices disclosed herein can be made from a variety of materials. According to various embodiments, the transfer devices are machined from stainless steel. The transfer devices can have any size suitable for their intended purpose. According to various embodiments, an exemplary transfer device can have a length ranging from 5 to 25 cm, for example 7 to 20 cm, including 10 to 15 cm, for example 13 to 15 cm, such as 14 cm. The transfer devices can have an outside diameter ranging from 0.1 to 1 cm, such as 0.3 to 0.7 cm, for example 0.5 cm. The internal lumen can have any diameter configured for receiving brachytherapy elements, including radioactive seeds and non-radioactive connectors/spacers. According to various embodiments, the internal diameter ranges from 1 to 3 mm.

[0035] The transfer devices disclosed herein are not limited in the way in which they can be used in medical procedures. For example, and with reference to a brachytherapy procedure, the healthcare provider would want to select the correct transfer device for the implant needle type used during the procedure (i.e., implant or applicator needle). A needle loading configuration is determined with reference to the patient's dose plan, and

the configuration is prepared per typical protocol. The prepared seed load configuration is then transferred into the transfer device, either manually or via a loading system outlet adaptor.

[0036] Next, the transfer device can be placed in a rack, such as rack **700** (Fig. 7). According to various embodiments, the hole positions on the rack may be labeled to correspond to the numbering system used in the needle template and/or dose planning software.

[0037] According to various embodiments, the foregoing steps can be repeated until all the needle loads have been prepared and transferred into the transfer devices and placed in the rack. Next, under ultrasonic guidance, a plurality of needles are located in the desired treatment area (e.g., the prostate gland, or any other tissue to be treated). The transfer device corresponding to a particular needle is removed from the rack to implant the desired needle. The distal end of the transfer device is inserted into or onto the proximal end of the needle. A stylet is employed to push the needle load through the transfer device and into the needle. Once it has been verified that the needle load is at the needle tip, the stylet is held in position while pulling back on the needle/transfer device assembly to place the needle load where desired. The stylet/transfer device/needle assembly is then removed.

[0038] According to various embodiments, the transfer devices can be loaded by a pharmacy according to a particular patient's dose plan. The loaded devices can then be shipped to the facility that will implant the brachytherapy elements into the patient.

[0039] The particulars shown herein are by way of example and for purposes of illustrative discussion of the various embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description making apparent to those skilled in the art how several forms of the invention may be embodied in practice.

[0040] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The terminology used in the description of the invention herein is for describing particular embodiments only and is not intended to be limiting of the invention. As used in the description of the invention and the appended claims, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. All publications, patent applications, patents, and other references mentioned herein are expressly incorporated by reference in their entirety.

[0041] Also, unless otherwise indicated, all numbers expressing quantities of physical parameters and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to

limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should be construed in light of the number of significant digits and ordinary rounding approaches.

[0042] Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Numerical ranges given throughout this specification will include every narrower numerical range that falls within such broader numerical range, as if such narrower numerical ranges were all expressly written herein.

What is claimed is:

1. A brachytherapy element transfer device comprising:

a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device; and

at least one gating feature disposed within said lumen, wherein said gating feature is configured to at least partially occlude said lumen.

2. The brachytherapy element transfer device according to Claim 1, wherein said at least one gating feature is capable of being urged into a non-occlusive position by application of a pre-determined force.

3. The brachytherapy element transfer device according to Claim 2, wherein said force is applied via a stylet urged against said brachytherapy element, which in turn is urged into said gating feature.

4. The brachytherapy element transfer device according to Claim 1, comprising two gating features.

5. The brachytherapy element transfer device according to Claim 4, wherein the first gating feature is positioned proximate to the distal end of said cannula, and the second gating feature is positioned proximate to the proximal end of said cannula.

6. The brachytherapy element transfer device according to Claim 1, wherein said brachytherapy device is a brachytherapy needle.

7. The brachytherapy element transfer device according to Claim 6, wherein said brachytherapy needle is a hubbed brachytherapy needle.

8. The brachytherapy element transfer device according to Claim 1, further comprising a gripping feature.

9. The brachytherapy element transfer device according to Claim 8, wherein said gripping feature is disposed about the outer diameter of said cannula

10. The brachytherapy element transfer device according to Claim 1, wherein said device is at least partially constructed from stainless steel.

11. A brachytherapy element transfer system comprising:

a plurality of brachytherapy element transfer devices comprising a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device;

at least one stylet; and

at least one device configured to hold the plurality of brachytherapy transfer devices in a configuration that is associated with a treatment plan for a patient.

12. The brachytherapy element transfer system according to Claim 11, wherein said plurality of brachytherapy transfer devices each comprise at least one gating feature capable of being urged into a non-occlusive position by application of a pre-determined force.

13. The brachytherapy element transfer system according to Claim 12, wherein said force is applied via a stylet urged against said brachytherapy element, which in turn is urged into said gating feature

14. The brachytherapy element transfer device according to Claim 11, wherein at least one of said plurality of brachytherapy transfer devices comprises two gating features.

15. The brachytherapy element transfer system according to Claim 14, wherein the first gating feature is positioned proximate to the distal end of said cannula, and the second gating feature is positioned proximate to the proximal end of said cannula

16. The brachytherapy element transfer system according to Claim 11, wherein said brachytherapy device is a brachytherapy needle.

17. The brachytherapy element transfer system according to Claim 16, wherein said brachytherapy needle is a hubbed brachytherapy needle.

18. A method for implanting at least one brachytherapy element in a patient, comprising:

a. determining the brachytherapy needle loading configuration per the patient dose plan;

b. inserting the at least one brachytherapy element into a brachytherapy element transfer device comprising a hollow cannula defining a lumen, wherein said cannula has a proximal end and a distal end, said distal end being configured to communicate with the proximal end of a brachytherapy device;

c. placing the loaded brachytherapy element transfer device into a rack;

d. repeating steps a-c until the rack contains at least substantially the entire patient dose plan;

e. inserting a plurality of brachytherapy needles into the region in which the at least one brachytherapy element is to be implanted;

f. placing the distal end of a loaded brachytherapy element transfer device against the proximal end of the brachytherapy needle; and

g. using a stylet, urging the at least one brachytherapy element from the brachytherapy element transfer device into the brachytherapy needle.

19. The method according to Claim 18, further comprising holding the stylet in position while withdrawing the brachytherapy needle from the patient, thereby depositing the at least on brachytherapy element in the patient.

20. The method according to Claim 18, wherein the rack holds the plurality of brachytherapy element transfer devices in a configuration corresponding to the patient dose plan.

FIG. 1

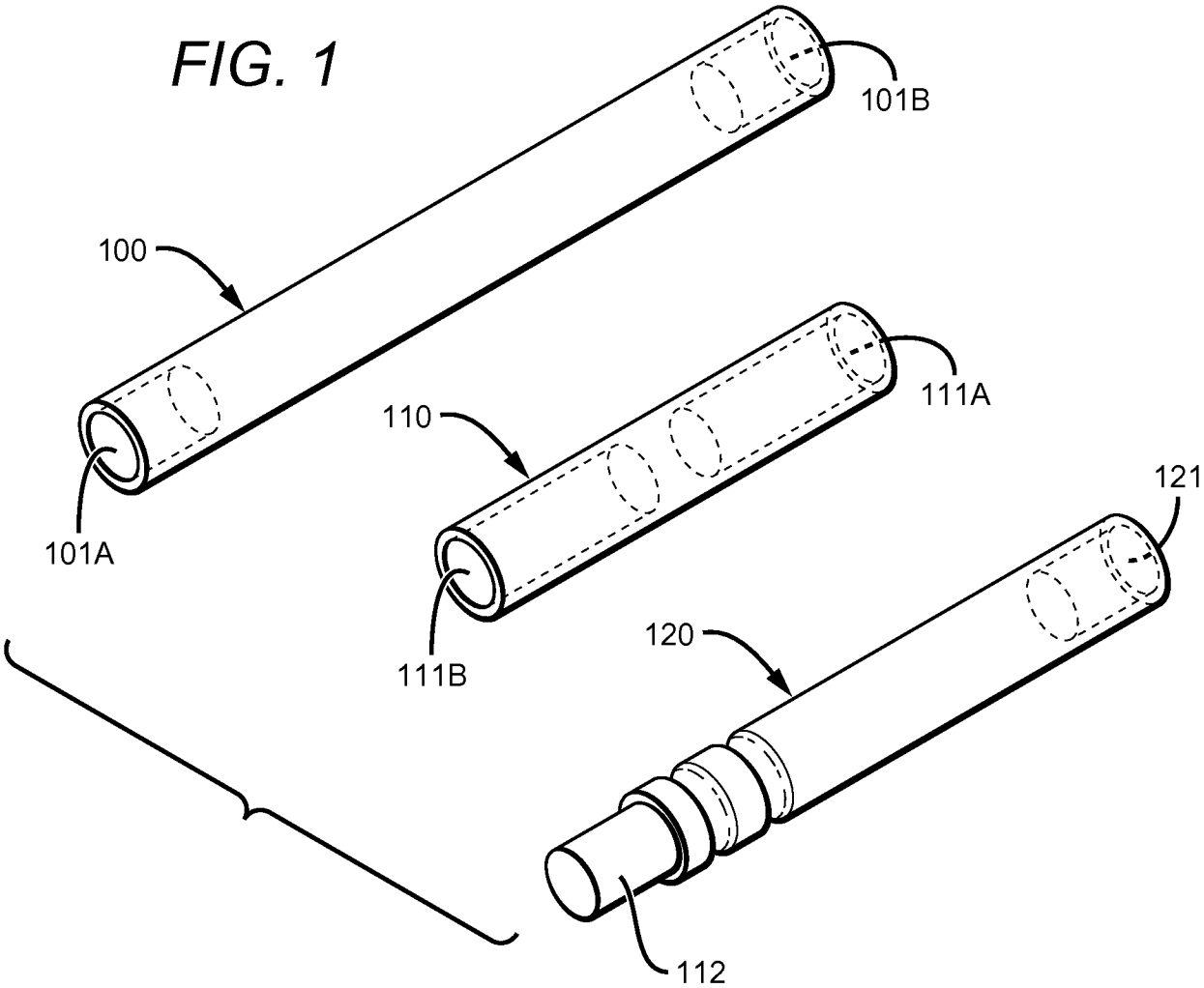
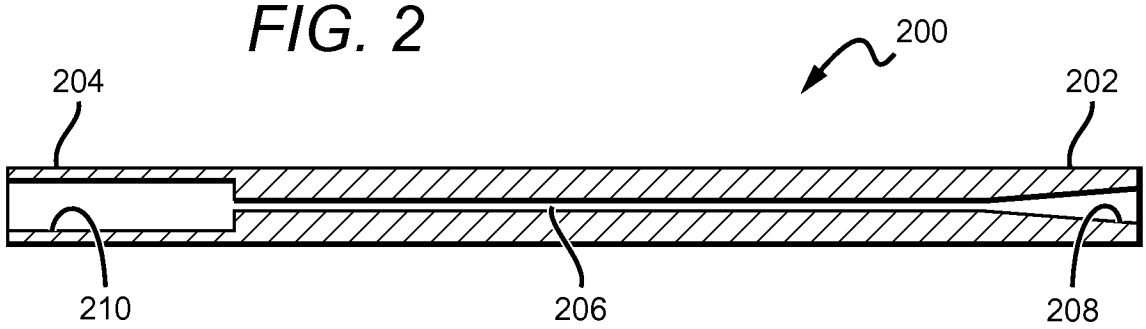
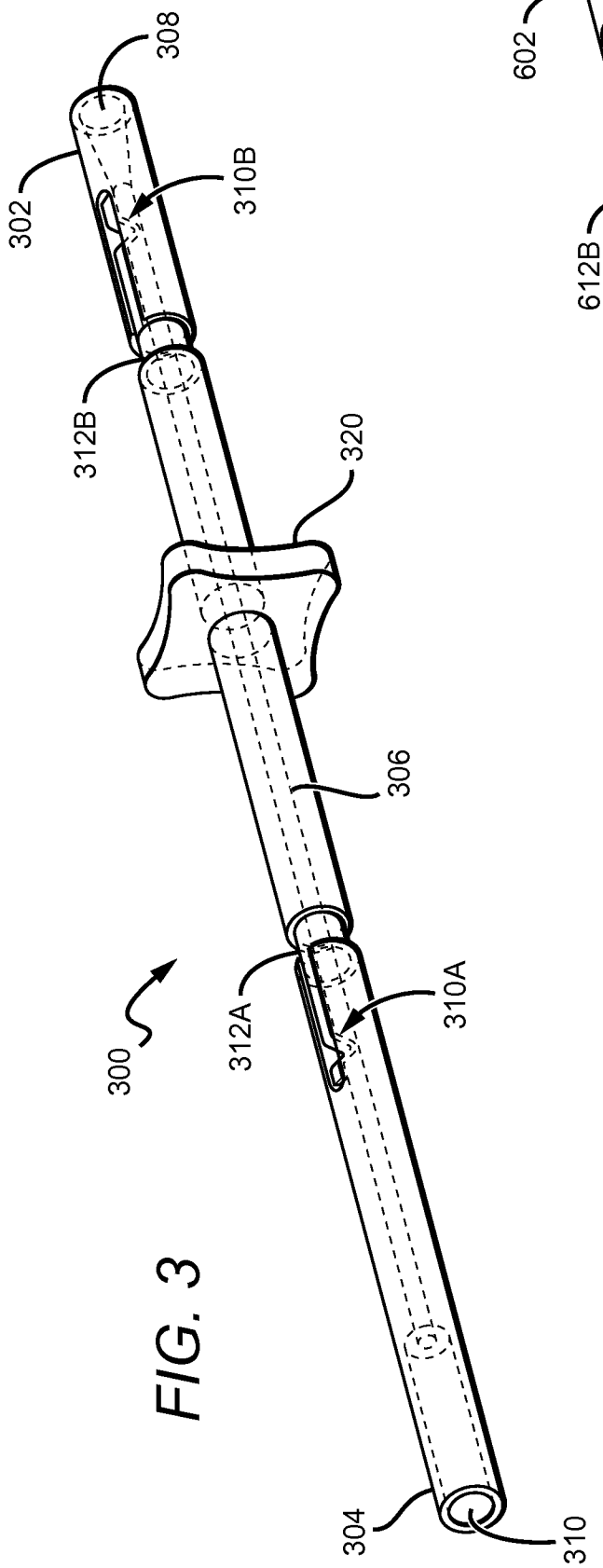


FIG. 2

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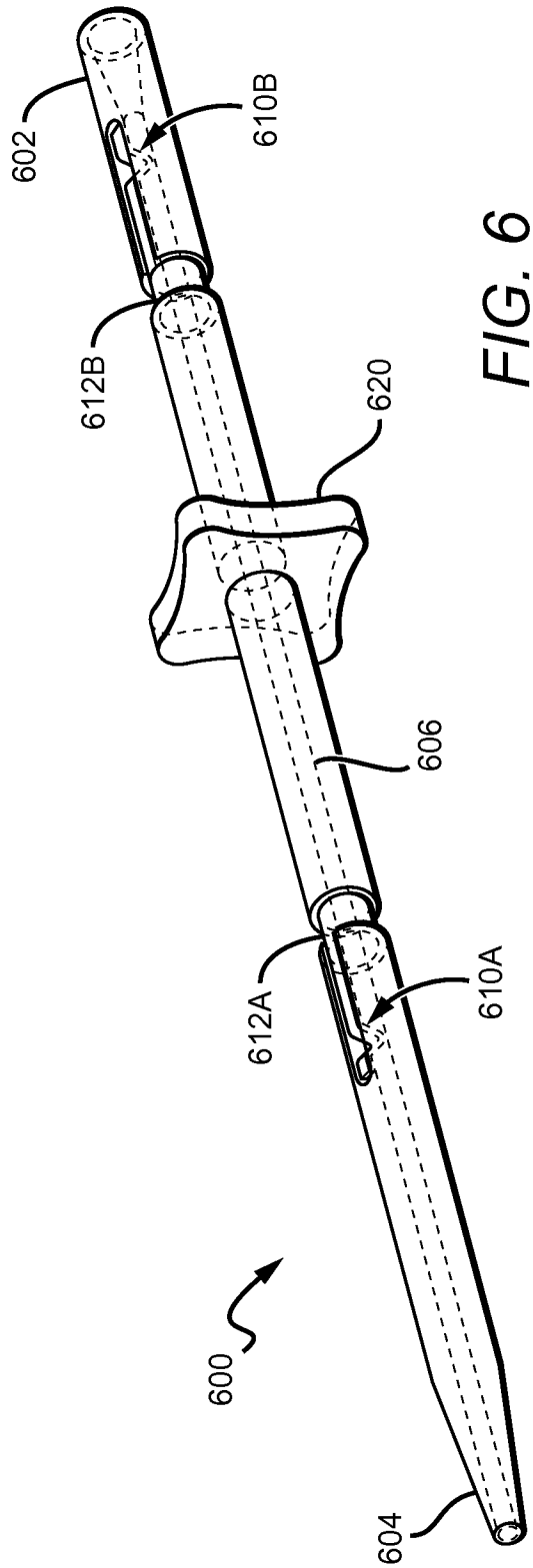
302
310B
312B
320
306
312A
310A
300
304
310

FIG. 3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604

FIG. 6

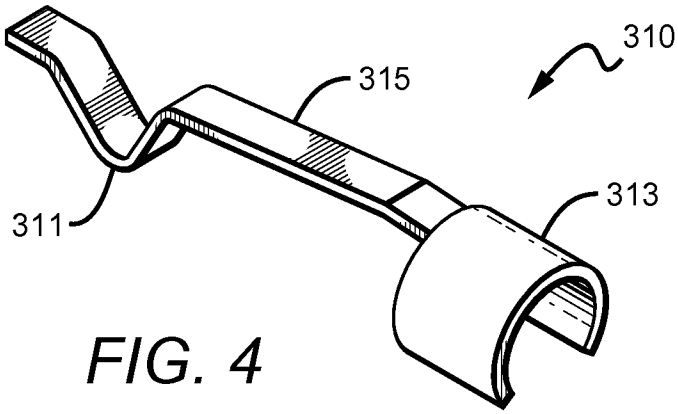

FIG. 4

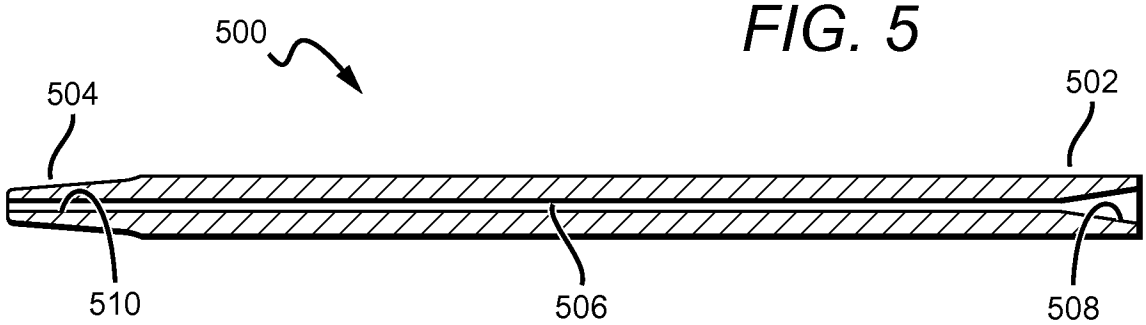

FIG. 5

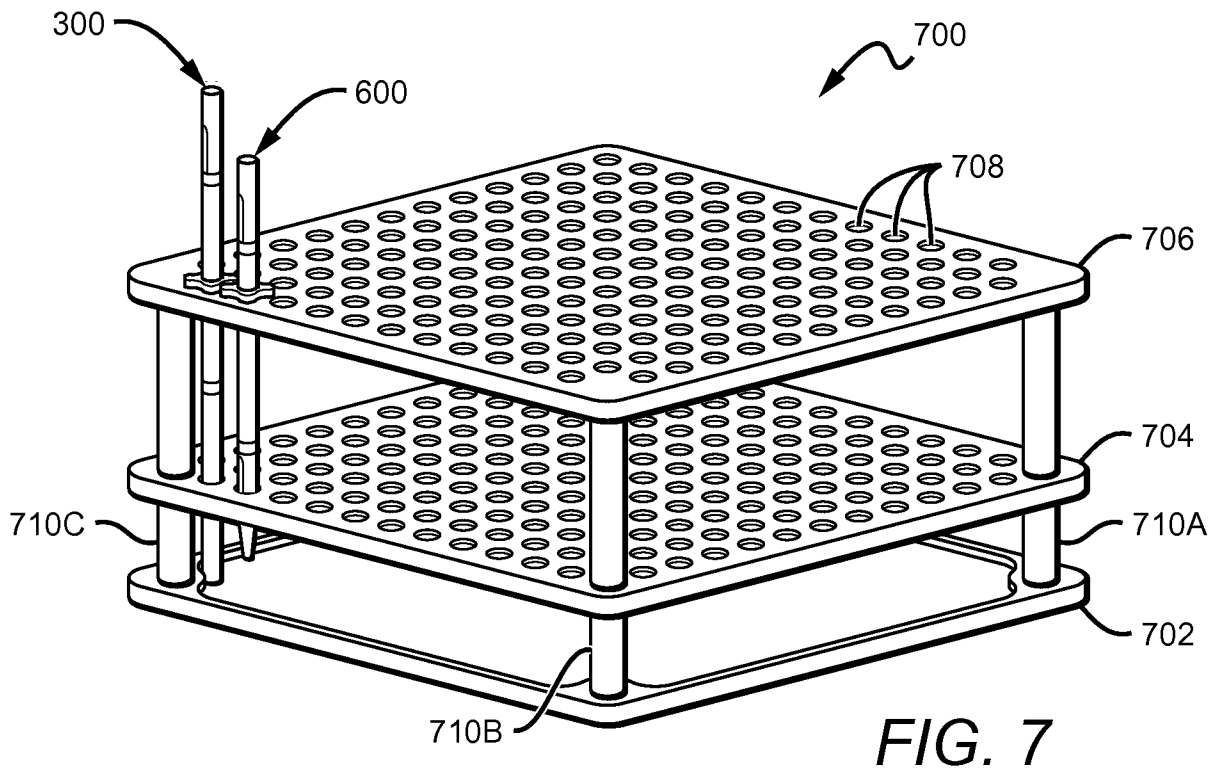

FIG. 7