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(54) Title: DELIVERY SYSTEMS, NEEDLE ASSEMBLIES AND METHODS OF DELIVERING COMPONENTS

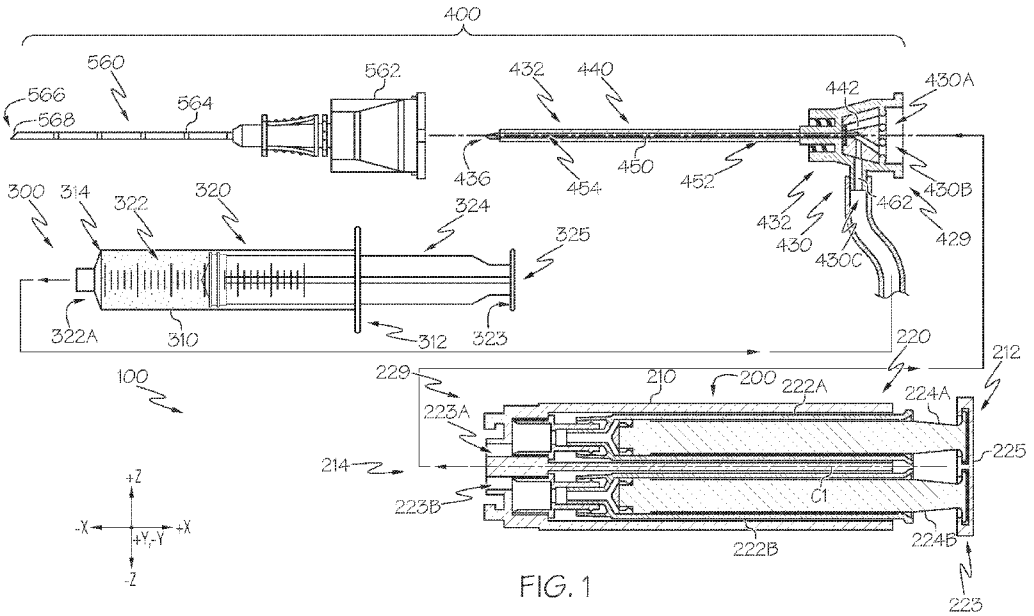


FIG. 1

(57) Abstract: A needle assembly includes an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction. The needle assembly further includes an inner cannula disposed within the outer lumen and including an inner lumen defining a second channel and having a plurality of inner lumen ports, the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, and each of the plurality of inner rings being spaced from one another in the longitudinal direction. The plurality of outer rings and the plurality of inner rings are aligned in the longitudinal direction.

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DELIVERY SYSTEMS, NEEDLE ASSEMBLIES AND METHODS OF DELIVERING COMPONENTS

TECHNICAL FIELD

[0001] The present disclosure relates to needle assemblies, and, more particularly, to coaxial needle assemblies for delivering components.

BACKGROUND

[0002] Radiation therapy is a commonly used treatment for cancer, but can result in negative effects on surrounding healthy tissues. In an effort to mitigate these effects, hydrogel spacers may be inserted into a target site in order to create a space between the radiation source and healthy tissue positioned at the target site. However, current methods for delivering hydrogel spacers can be time-consuming and require a plurality of punctures, which may increase the risk of complications during a radiation procedure. Accordingly, a need exists for a needle assembly and an improved method for delivering hydrogel spacers that is efficient and minimally invasive.

SUMMARY

[0003] An object of the present disclosure is to provide a needle assembly for delivering hydrogel spacers to a target site undergoing radiation treatment.

[0004] In one aspect, a needle assembly is disclosed. The needle assembly includes an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction. The needle assembly further includes an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, with the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, and each of the plurality of inner rings being spaced from one another in the longitudinal direction. The plurality of outer rings and the plurality of inner rings are aligned in the longitudinal direction.

[0005] In another aspect, a delivery system is disclosed. The delivery system includes a dual chamber applicator comprising a first component chamber containing a first component and a second component chamber containing a second component. The delivery system further

includes a needle assembly coupled to the dual chamber applicator, the needle assembly including an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction. The needle assembly further includes an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, with the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, and each of the plurality of inner rings being spaced from one another in the longitudinal direction. The first component chamber is fluidly coupled to the first channel and the second component chamber is fluidly coupled to the second channel, such that the first component chamber provides the first component to the first channel and the second component chamber provides the second component to the second channel.

[0006] In yet another aspect, a method of operating a delivery system is disclosed. The method includes coupling a dual chamber applicator to a needle assembly such that a first component chamber containing a first component of the dual chamber applicator is fluidly coupled to a first channel defined by an outer lumen of the needle assembly and a second component chamber containing a second component of the dual chamber applicator is fluidly coupled to a second channel defined by an inner lumen of the needle assembly, wherein the outer lumen of the needle assembly includes a plurality of outer lumen ports arranged in a plurality of outer rings and the inner lumen of the needle assembly includes a plurality of inner lumen ports arranged in a plurality of inner rings, deploying the first component to the first channel and the second component to the second channel, and deploying a resultant mixture of the first component and the second component to a target site via the plurality of outer lumen ports. The first component and the second component mix at a distal end of the needle assembly.

[0007] These and additional features provided by the embodiments described herein will be more fully understood in view of the following detailed description, in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The embodiments set forth in the drawings are illustrative and exemplary in nature and not intended to limit the subject matter defined by the claims. The following detailed description of the illustrative embodiments can be understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals and in which:

[0009] FIG. 1 depicts a side view of a delivery system including a dual chamber applicator, an auxiliary applicator, and a needle assembly having an elongate stylet, according to one or more embodiments shown and described herein;

[0010] FIG. 2A depicts a partial perspective view of the needle assembly of FIG. 1, according to one or more embodiments shown and described herein;

[0011] FIG. 2B depicts a partial side view of the needle assembly of FIG. 1, according to one or more embodiments shown and described herein; and

[0012] FIG. 3 depicts an illustrative flow diagram of a method of using a delivery system, according to one or more embodiments shown and described herein.

[0013] Reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate at least one embodiment of the present disclosure, and such exemplifications are not to be construed as limiting the scope of the present disclosure in any manner.

DETAILED DESCRIPTION

[0014] Embodiments disclosed herein relate to delivery systems and methods of using delivery systems. In some embodiments, the delivery system may include a dual chamber applicator and a needle assembly, with the dual chamber applicator being fluidly coupled to the needle assembly. The dual chamber applicator may include a first component chamber and a second component chamber, with the first component chamber being fluidly coupled to a first channel of the needle assembly and the second component chamber being fluidly coupled to a second channel of the needle assembly. In operation, the dual chamber applicator may be engaged to deploy a first component to the first channel (e.g., via the first component chamber) and a second component to the second channel (e.g., via the second component chamber). In these embodiments, the needle assembly may further include a plurality inner lumen ports positioned

circumferentially about the second channel and a plurality of outer lumen ports positioned about the first channel, with the plurality of inner points fluidly coupling the first channel to the second channel and the plurality of outer lumen ports fluidly coupling the first channel to a target site. Accordingly, as the second component flows through the second channel, the second component may pass through the plurality of inner points such that the second component enters the first channel and mixes with the first component. In these embodiments, the mixture of the first component and the second component may be deployed to the target site.

[0015] As will be described in additional detail herein, the plurality of inner lumen ports may be arranged in a plurality of inner rings, while the plurality of outer lumen ports may be arranged in a plurality of outer rings, such that each of the plurality of inner lumen ports is aligned with at least one of the plurality of outer lumen ports in a longitudinal direction. By stacking the plurality of outer rings and the plurality of inner rings in this manner, it may be possible to increase the number of ports provided on the needle assembly without increasing the diameter of the needle assembly. Additionally, the stacked port arrangement allows for more even distribution of a component (e.g., fluid) across the target site, which may effectively reduce the risk of clogging or blockages forming within the needle assembly as compared to other commonly use port configuration (e.g., spiral, linear, etc.).

[0016] Embodiments of delivery systems, needle assemblies, and methods using delivery systems will now be described in more detail herein with reference to the drawings, and where like numbers refer to like structures.

[0017] Turning now to the drawings, FIG. 1 depicts an illustrative delivery system 100 according to various embodiments. The delivery system 100, in accordance with an aspect of the present invention, may be for use in a spacer delivery procedure whereby a multi-component spacer (e.g., a hydrogel) is delivered to a site that has been prepped via a hydro-dissection procedure. The delivery system 100 generally includes a dual chamber applicator 200, an auxiliary applicator 300, and/or a needle assembly 400. The various components for the delivery system 100 are couplable together for the purposes of delivering a dual component mixture (e.g., a dual component hydrogel) and an additional material (e.g., saline or other hydro-dissection solution, or the like), as indicated by the dashed lines in FIG. 1 and described herein.

[0018] The dual chamber applicator 200 generally includes a body 210 having a proximal end 212 and a distal end 214 spaced a distance apart from the proximal end 212. The body 210

also defines a pair of syringes 220. The dual chamber applicator 200 is configured to separately carry each of a first component, such as a first precursor material of a multi-component hydrogel, and a second component, such as a second precursor material of the multi-component hydrogel.Illustrative examples of first component include, but are not limited to, albumin, polyethylenimine (PEI), an amine containing polyethylene glycol (PEG) or protein, or the like. Illustrative examples of second component include, but are not limited to, an *N*-hydroxysuccinimide (NHS) ester component such as PEG-(SS)2, PEG-(SS)4, PEG-(SS)8, PEG-(SG)4, PEG-(SG)8, and/or the like. In the present embodiment, the first component and the second component are combined and mixed within the needle assembly 400, as will be described in greater detail herein.

[0019] The pair of syringes 220 includes an actuator 223, a first component chamber 222A, and a second component chamber 222B. The first component chamber 222A may be, for example, a cylindrical tube that is configured to carry the first precursor material of the hydrogel spacer. The first component chamber 222A has a first output port 223A (e.g., a first component port). The second component chamber 222B also may be, for example, a cylindrical tube that is configured to carry the second precursor material of the hydrogel spacer. The second component chamber 222B has a second output port 223B (e.g., a second component port). In some aspects, the first component chamber 222A and the second component chamber 222B are arranged in a substantially longitudinally parallel arrangement.

[0020] In some aspects, the actuator 223 includes a first piston 224A, a second piston 224B, and a handle 225. The handle 225 is in the form of a link member that perpendicularly extends between, and is connected to, each of the first piston 224A and the second piston 224B to facilitate simultaneous movement of the first piston 224A and the second piston 224B with the depression or retraction of the handle 225. The first piston 224A is in the form of a plunger that is positioned in the first component chamber 222A proximal to the first sealant component. The second piston 224B is in the form of a plunger that is positioned in the second component chamber 222B proximal to the second sealant component.

[0021] Referring still to FIG. 1, the first output port 223A of the first component chamber 222A and the second output port 223B of the second component chamber 222B may be arranged within the distal end 214 of the body 210 of the dual chamber applicator 200. The first output port 223A and the second output port 223B are generally component outputs, such as fluid outputs, that are aligned with outer lumen ports of other components, as will be described herein, such that

the first component and the second component can be dispensed from and/or received within the respective component chamber 222A, 222B. For example, in some aspects the first output port 223A may be concentrically aligned with the first component chamber 222A and the second output port 223B may be concentrically aligned with the second component chamber 222B. However, in other aspects, such as the aspect depicted in FIG. 1, the first output port 223A may be located radially inward of a central area of the second component chamber 222B such that the first output port 223A and the second output port 223B are as close as possible to a central axis C1 of the body 210 of the dual chamber applicator to facilitate alignment with the other components of the delivery system 100 described herein.

[0022] In these embodiments, the body 210 of the dual chamber applicator may further include a connection mechanism 229 for connecting the dual chamber applicator 200 to the needle assembly 400. For example, in some embodiments, the body 210 of the dual chamber applicator 200 may include a quarter turn connector or other connector integrated with the distal end 214 of the dual chamber applicator 200. In some embodiments, various components of the connection mechanism 229 are integrated with the body 210 such that the connection mechanism 229 and the body 210 are a single monolithic piece. However, it should be understood that this is merely illustrative and the various components of the connection mechanism 229 may be separate pieces that are permanently or semi-permanently joined with the body 210 of the dual chamber applicator 200 (e.g., permanently or semi-permanently joined with the dual chamber applicator 200).

[0023] The connection mechanism 229 may be generally located at the distal end 214 of the body 210 of the dual chamber applicator 200 such that various components of the connection mechanism 229 are positioned adjacent the first output port 223A and the second output port 223B. In these embodiments, the connection mechanism 229 may be generally shaped and sized to releasably interlock with a corresponding connection mechanism 429 of the needle assembly 400, as will be described in additional detail herein. When the needle assembly 400 is coupled to the dual chamber applicator 200, the ports thereof are aligned and sealed with the first output port 223A and the second output port 223B of the dual chamber applicator 200.

[0024] Referring still to FIG. 1, the auxiliary applicator 300 generally includes a body 310 having a proximal end 312 and a distal end 314 spaced a distance apart from the proximal end 312. The body 310 further defines a syringe 320, which may be used to carry a material, such as a hydro-dissection solution (e.g., saline or another hydro-dissection solution), an anesthetic solution, and/or the like.

[0025] In these embodiments, the syringe 320 further includes an actuator 323 and a saline chamber 322. The saline chamber 322 may be, for example, a cylindrical tube that is configured to carry the hydro-dissection solution, the anesthetic solution, and/or the like. In these embodiments, the saline chamber 322 may include an output port 322A.

[0026] In further aspects, the actuator 323 further includes a piston 324 and a handle 325. The handle 325 may be connected to the piston 324 at a proximal end thereof to facilitate movement of the piston 324 with the depression and/or retraction of the handle 325. In these embodiments, the piston 324 may take the form of a plunger that is positioned in the saline chamber 322 proximal to the hydro-dissection solution, the anesthetic solution, and/or the like.

[0027] The output port 322A of the saline chamber 322 may be arranged within the distal end 314 of the body 310 of the auxiliary applicator 300. In these embodiments, the output port 322A may be a component output, such as a fluid output, that is fluidly coupled to an auxiliary port of a hub of the needle assembly 400, as will be described in additional detail herein. By fluidly coupling the output port 322A of the saline chamber 322 of the auxiliary applicator 300 to the needle assembly 400, components, such as fluid, within the saline chamber 322 may be deliverable through the needle assembly 400.

[0028] Referring now to FIGS. 1, and 2A-2B, the needle assembly 400 is depicted (FIG. 1 depicts the needle assembly 400 in full, and FIGS. 2A-2B depict a distal portion of the needle assembly 400). In these embodiments, the needle assembly 400 generally includes a hub 430 and an elongate stylet 432 (e.g., an elongate hollow stylet) that extends distally (e.g., in the – x-direction as depicted in the coordinate axis of FIG. 1) from the hub 430. The elongate stylet 432 has a proximal end 434 and a distal end 436. As depicted most clearly in FIG. 1, the hub 430 is fixedly attached (e.g., through overmolding, adhesive and/or pressed fit) to the proximal end 434 of the elongate stylet 432. The hub 430 further includes a plurality of input ports (e.g., a first input port 430A, a second input port 430B, and/or the auxiliary input port 430C) of the needle assembly 400. Accordingly, the hub 430 may be configured for removable connection to the dual chamber applicator 200 via the corresponding connection mechanism 229 such that, when connected, the first input port 430A of the needle assembly 400 is aligned and sealed with the first output port 223A of the dual chamber applicator 200 and the second input port 430B of the needle assembly 400 is aligned and sealed with the second output port 223B of the dual chamber applicator 200, as described in greater detail herein. In addition, the hub 430 may include the auxiliary input port 430C for fluidly coupling the needle assembly 400 to the auxiliary applicator 300 (e.g., via tubing

or the like coupled between the output port 322A of the saline chamber 322 of the syringe 320 and the auxiliary input port 430C of the hub 430).

[0029] As most clearly depicted in FIGS. 2A and 2B, the elongate stylet 432 further includes an elongate cannula 440 that extends from the proximal end 434 to the distal end 436 of the elongate stylet 432. In these embodiments, the elongate stylet 432 may be a hollow stylet, such that the elongate cannula 440 includes an outer lumen 438 positioned concentrically within the elongate stylet 432 and extending from the proximal end 434 to the distal end 436 of the elongate stylet 432. Furthermore, the outer lumen 438 may define a first channel 442 that may be configured for receiving the first component (e.g. via the first input port 430A of the hub 430 coupled to the first output port 223A of the dual chamber applicator 200), as will be described in additional detail herein.

[0030] As further depicted in FIG. 2A, the distal end 436 of the elongate stylet 432 may include a closed distal end having a distal port 436A that allows for components, such as fluid, to be dispensed from the elongate cannula 440. In these embodiments, the distal end 436 of the elongate cannula 440 may be, for example, a blunt tip that avoids and/or reduces the chance of puncture of structures positioned at a target site. Although not depicted, it should be further appreciated that, in some embodiments, the distal end 436 of the elongate cannula 440 may include a needle tip that may be used to pierce tissue positioned at the target site.

[0031] Referring again to FIGS. 1 and 2A-2B, the elongate stylet 432 may further include an inner cannula 450 that is positioned coaxially within the outer lumen 438 of the elongate stylet 432 (and in turn, within the first channel 442 defined by the outer lumen 438). In these embodiments, the inner cannula 450 may include a proximal end 452 and a distal end 454, and may be positioned within the outer lumen 438 such that the distal end 454 of the inner cannula 450 is positioned proximally (e.g., in the + x-direction as depicted in the coordinate axes of FIGS. 2A-2B) of the distal end 436 of the elongate cannula 440. In these embodiments, the inner cannula 450 may further define an inner lumen 458 which is positioned concentrically within the inner cannula 450 and extends from the proximal end 452 to the distal end 454 of the inner cannula 450.

[0032] As most clearly depicted in FIGS. 2A and 2B, the inner lumen 458 may further define a second channel 462 that may be configured for receiving the second component (e.g., via the second input port 430B of the hub 430 coupled to the second output port 223B of the dual chamber applicator 200), as will be described in additional detail herein.

[0033] Referring still to FIGS. 1 and 2A-2B, the elongate cannula 440 and the inner cannula 450 may each include a plurality of ports that extend through the outer lumen 438 and the inner lumen 458, respectively. For example, the inner cannula 450 may include a plurality of inner lumen ports 464 and the elongate cannula 440 may include a plurality of outer lumen ports 448. In these embodiments, the plurality of inner lumen ports 464 may fluidly couple the inner lumen 458 to the outer lumen 438, such that components that pass through the second channel defined by the inner lumen 458 may flow out of the plurality of inner lumen ports 464 and mix with the components that flows through the first channel defined by the outer lumen 438. Similarly, the plurality of outer lumen ports 448 may expose the elongate stylet 432 to an external environment (e.g., a target site), such that components that pass through both the first channel defined by the outer lumen 438 and components that pass through the second channel defined by the inner lumen 458 may be deposited at the target site.

[0034] As most clearly depicted in FIGS. 2A and 2B, the plurality of inner lumen ports 464 may be arranged in a plurality of inner rings 465 that extend about the inner cannula 450 in a circumferential direction C. In these embodiments, each of the plurality of inner rings 465 may be spaced along a portion of the distal end 454 of the inner cannula 450 in a longitudinal direction (e.g., in the +/- x-direction as depicted in the coordinate axes of FIGS. 2A-2B). As depicted in FIGS. 2A and 2B, the plurality of inner rings 465 may be evenly spaced along the portion of the distal end 454 of the inner cannula 450. However, it should be appreciated that, in some embodiments, the plurality of inner rings 465 may be variably spaced in the longitudinal direction (e.g., having different lengths of space in the longitudinal direction between each adjacent inner ring of the plurality of inner rings 465) along the portion of the distal end of the inner cannula 450.

[0035] As further depicted in FIGS. 2A and 2B, the plurality of outer lumen ports 448 may similarly be arranged in a plurality of outer rings 449 that extend about the elongate cannula 440 in the circumferential direction. In these embodiments, each of the plurality of outer rings 449 may be spaced along a portion of the distal end 436 of the elongate stylet 432 in the longitudinal direction (e.g., in the +/- x-direction as depicted in the coordinate axes of FIGS. 2A-2B). As depicted in FIGS. 2A and 2B, the plurality of outer rings 449 may be evenly spaced along the portion of the distal end 436 of the elongate stylet 432. However, it should be appreciated that, in some embodiments, the plurality of outer rings 449 may be variably spaced in the longitudinal direction (e.g., having different lengths of space in the longitudinal direction between each adjacent outer ring of the plurality of outer rings 449) along the portion of the distal end of the

elongate stylet 432.

[0036] In the embodiments described herein, the plurality of outer rings 449 and the plurality of inner rings 465 are depicted as extending around the distal portion of the elongate cannula 440 and the inner cannula 450, respectively, in the circumferential direction. Furthermore, although the plurality of outer rings 449 and the plurality of inner rings 465 are depicted as including three outer lumen ports 448 and three inner lumen ports 464, respectively, it should be appreciated that the plurality of outer rings 449 and the plurality of inner rings 465 may include any number of ports without departing from the scope of the present disclosure. Accordingly, it should also be appreciated that the plurality of outer rings 449 and the plurality of inner rings 465 may include a different number of ports. For example, the plurality of outer rings 449 may include three outer lumen ports 448 while the plurality of inner rings 465 may include four inner lumen ports 464.

[0037] It should also be noted that, in some embodiments, each of the plurality of outer rings 449 and each of the plurality of inner rings 465 may include a different number of ports. For example, the plurality of outer rings 449 may include a first outer ring, a second outer ring, and a third outer ring, with the first outer ring including two ports, the second outer ring including three ports, and the third outer ring including four ports. Accordingly, it should be appreciated that the plurality of outer rings 449 and the plurality of inner rings 465 may include any combination of rings and/or ports without departing from the scope of the present disclosure.

[0038] Referring still to FIGS. 2A and 2B, in these embodiments, the plurality of inner rings 465 and the plurality of outer rings 449 may be positioned along the distal ends of the inner cannula 450 and the elongate stylet 432, respectively, such that each of the plurality of inner rings 465 is aligned with at least one of the plurality of outer rings 449, and vice versa. In these embodiments, the arrangement of the plurality of inner rings 465 and the plurality of outer rings 449 may be referred to as a "stacked" arrangement. That is, the plurality of inner rings 465 and the plurality of outer rings 449 may be staggered along the distal end of the inner cannula 450 and the elongate cannula 440, respectively. For example, as most clearly depicted in FIG. 2B, the inner cannula 450 may include four inner rings 465, such as a first inner ring 465a, a second inner ring 465b, a third inner ring 465c, and a fourth inner ring 465d. Similarly, the elongate cannula 440 may include four outer rings 449, including a first outer ring 449a, a second outer ring 449b, a third outer ring 449c, and a fourth outer ring 449d. As depicted in FIG. 2B, the first inner ring 465a may be positioned proximally to the first outer ring 449a (e.g., in the + x-direction as depicted

in the coordinate axis of FIG. 2B), the second inner ring 465b may be positioned between the first outer ring 449a and the second outer ring 449b, the third inner ring 465c may be positioned between the second outer ring 449b and the third outer ring 449c, the fourth inner ring 465d may be positioned between the third outer ring 449c and the fourth outer ring 449d and the fourth outer ring 449d may be positioned distally (e.g., in the – x-direction as depicted in the coordinate axis of FIG. 2B), such that each ring of the plurality of outer rings 449 is positioned adjacent an inner ring 465 of the plurality of inner rings 465.

[0039] Referring again to FIGS. 1 and 2A-2B, and as should be appreciated in view of the foregoing, the elongate stylet 432 may be configured to facilitate fluid communication with the plurality of output ports 223A, 223B of the dual chamber applicator 200 so as to receive the first and second components from the dual chamber applicator 200 and direct the two components to the distal end 436 of the elongate stylet for mixing and delivery to the target site. In addition, the elongate stylet 432 of the needle assembly 400 is configured to facilitate fluid communication with the output port 322A of the auxiliary applicator 300 so as to receive the contents of the auxiliary applicator 300 and direct the contents to the distal end 436 of the elongate stylet 432 for delivery to the target site.

[0040] For example, in these embodiments, when the auxiliary applicator 300 is coupled to the needle assembly 400, as has been described herein, the syringe 320 of the auxiliary applicator 300 may be depressed to deploy the contents of the saline chamber 322 into the elongate stylet 432, such that the contents of the saline chamber 322 are received by the outer lumen 438 and/or the inner lumen 458 of the elongate stylet and flow through the first channel 442 and/or second channel 462 towards the distal end 436 of the elongate stylet 432. Once the contents of the chamber reach the distal end 436 of the elongate stylet 432, the contents may be deployed via the plurality of outer lumen ports 448 and/or inner lumen ports 464 to the target site.

[0041] In these embodiments, the contents of the auxiliary applicator 300 may be a fluid, such as saline, that may serve a variety of purposes in preparing the target site for receiving the first and second components from the dual chamber applicator 200. For example, in some embodiments, the auxiliary applicator 300 may supply saline to the elongate stylet 432 to flush the needle assembly 400 and remove any debris present in the elongate stylet 432 in order to avoid clogging. Furthermore, in some embodiments, the auxiliary applicator 300 may provide saline, or any other similar fluid, to the elongate stylet 432 in order to create a space within the target site where the first and second components of the dual chamber applicator 200 may be deployed. For

example, by injecting saline into the target site via the auxiliary applicator 300, tissue at the target site may be expanded, which may allow for the needle assembly 400 to more easily access the target site while reducing the risk of injury to surrounding tissue. Additionally, supplying a fluid to the target site via the auxiliary applicator 300 may further help flush out and debris and/or fluid from the target site, which may improve visualization of the target site and minimize the risk of infection.

[0042] Referring still to FIGS. 1 and 2A-2B, the dual chamber applicator 200 may be similarly utilized to supply the first and second components to the elongate stylet 432 of the needle assembly, as has been described herein. In these embodiments, the dual chamber applicator 200 may be coupled to the needle assembly 400 such that the first output port 223A is fluidly coupled to the first channel 442 of the elongate stylet 432, while the second output port 223B is coupled to the second channel 462 of the elongate stylet 432. Accordingly, when the syringes 220 of the dual chamber applicator 200 are depressed, the first component chamber 222A may deploy the first component into the first channel 442, while the second component chamber 222B may deploy the second component into the second channel 462. Accordingly, it should be appreciated that the first channel 442 and the second channel 462 maintain a separation of the first component and the second component until the components reach the distal end 436 of the elongate stylet 432, thereby avoiding a situation where the components prematurely mix.

[0043] As described herein, the first component and the second component may traverse the first channel and the second channel, respectively, until the first component and second channel reach the distal end 436 of the elongate stylet 432. As the first component and the second component reach the distal end 436 of the elongate stylet 432, the second component may escape the second channel 462 via the inner lumen ports 464 of the inner lumen 458, such that the second component enters the first channel 442 and mixes with the first component. As the first component and second components mix, the mixture of components may continue to traverse the distal end 436 of the elongate stylet 432 until the mixture of components is deployed to the target site via the outer lumen ports 448 of the outer lumen 438.

[0044] Referring still to FIGS. 1 and 2A-2B, and as noted herein, the inner lumen ports 464 and the outer lumen ports 448 may be arranged in a plurality of inner rings 465 and a plurality of outer rings 449. In these embodiments, at least a first inner ring of the plurality of inner rings 465 may be positioned proximally (e.g., in the + x-direction as depicted in the coordinate axes of FIGS. 2A-2B) to at least a first outer ring of the plurality of outer rings 449. For example, in these

embodiments, it may be desirable for the first component and the second component to mix before entering the target site. By positioning at least the first inner ring of the plurality of inner rings 465 proximally to at least the first outer ring of the plurality of outer rings 449, it may be possible to ensure that neither the first component or the second component escape the elongate stylet without mixing, as the second component flowing through the second channel 462 may escape from at least the first inner ring of the plurality of inner rings 465 and mix with the first component prior to the first component being deployed from at least the first outer ring of the plurality of outer rings 449.

[0045] It should be noted that, in the embodiments provided herein, arranging the outer lumen ports 448 and the inner lumen ports 464 in a plurality of outer rings 449 and a plurality of inner rings 465, respectively, that are in the stacked arrangement may provide a number of advantages over other configurations (e.g., linear, spiral, etc.). For example, by stacking the plurality of outer rings 449 and the plurality of inner rings 465, it may be possible to increase the number of ports provided on the distal end 436 of the elongate stylet 432 without increasing the diameter of the elongate stylet 432. Accordingly, the disclosed stacked configuration may allow for increased opportunities to provide precise component delivery to the target site.

[0046] Furthermore, arranging the plurality of inner rings 465 and the plurality of outer rings 449 as described herein may further act to reduce the risk that the needle assembly 400 becomes clogged during a procedure. Notably, the proposed configuration allows for more even distribution of components, such as fluid, across the target site (e.g., compared to traditional port configurations including spiral, linear, etc.) which may effectively reduce the risk of clogging or blockages forming within the needle assembly 400.

[0047] In some embodiments, the stacked arrangement of the plurality of inner rings 465 and the plurality of outer rings 449 may also allow for increased control and precision in the delivery of components to the target site. For example, by providing ports around the circumference of each of the elongate cannula 440 and the inner cannula 450, it may be possible to evenly distribute components, such as fluid, from each side of the needle assembly 400 simultaneously or substantially simultaneously and at even intervals along the length of the needle assembly 400. This may be particularly advantageous during procedures which involve precise placement of components within the target site.

[0048] Further still, the arrangement of the plurality of inner rings 465 and the plurality of outer rings 449 described herein may also provide improved visibility of the needle assembly 400 during placement. For example, the inner rings and outer rings may be more easy to identify during placement of the delivery system 100, which may allow for more accurate placement of the needle assembly 400 within the target site.

[0049] Referring again to FIGS. 1 and 2A-2B, it should be appreciated that, in some embodiments, the needle assembly 400 may be used in conjunction with the introducer cannula 560 (also sometimes referred to in the art as a coaxial introducer needle) to allow elongate stylet 432 to be removed from the introducer cannula 560, while maintaining access to the target site with the elongate stylet 432. That is, a portion of the delivery system 100 may be removed from the introducer cannula 560 and replaced with a variety of other instruments, such as a biopsy device or another stylet. In some aspects, the introducer cannula 560 has a coaxial hub 562, a coaxial cannula 564, a cannula lumen 566 and a distal annular rim 568. The cannula lumen 566, for example, is configured (e.g., having a cylindrical shape) to receive the elongate stylet 432 of the needle assembly 400. When the elongate stylet 432 of the needle assembly 400 is fully inserted into the cannula lumen 566 of the introducer cannula 560 (e.g., distal movement of the elongate stylet 432 is stopped by contact of the hub 430 of the needle assembly 400 with the coaxial hub 562 of the introducer cannula 560, the plurality ports of the elongate stylet 432 are located distal to the distal annular rim 568 of the introducer cannula 560. That is, the distal end 436 of the elongate stylet 432 extends beyond the distal annular rim 568 such that the introducer cannula 560 does not block the plurality of ports.

[0050] Turning now to FIG. 3, an illustrative method 600 of operating a delivery system is depicted. In these embodiments, the method may begin at block 610, which may involve coupling a dual chamber applicator to a needle assembly. In these embodiments, the dual chamber applicator may include a first component chamber and a second component chamber, and the dual chamber applicator may be coupled to the needle assembly such that the first component chamber is fluidly coupled to a first channel of the needle assembly and the second component chamber is fluidly coupled to a second channel of the needle assembly.

[0051] With the dual chamber applicator coupled to the needle assembly, the dual chamber applicator may be depressed to supply a first component to the first channel and a second component to the second channel, as depicted at blocks 620 and 630. In these embodiments, the first component may be contained within the first component chamber, while the second

component may be contained within the second component chamber. The dual chamber applicator may further include a piston, or other similar mechanism, that may be depressed to deploy the first component from the first component chamber and the second component from the second component chamber, respectively. In some embodiments, the piston may be coupled to both the first component chamber and the second component chamber, such that the first component and the second component are deployed simultaneously into the first channel and the second channel, respectively, as is depicted in FIG. 3

[0052] In these embodiments, once the first component and the second component have entered the first and second channels, respectively, the first component and the second component may traverse the needle assembly to reach a distal portion of the needle assembly. Once the first component and the second component reach the distal end of the needle assembly, the method may move to block 640, which may involve mixing the first component with the second component within the needle assembly. In these embodiments, the second component may flow out of a plurality of ports positioned within a distal end of the second channel, such that the second component may pass into the first channel and mix with the first component. Once the first component and the second component have mixed, the method may move to block 640, which may involve deploying the first component and the second component mixture to the target site.

[0053] As should be appreciated in view of the foregoing a delivery system is disclosed. The delivery system may include a dual chamber applicator and a needle assembly, with the dual chamber applicator being fluidly coupled to the needle assembly. The dual chamber applicator may include a first component chamber and a second component chamber, with the first component chamber being fluidly coupled to a first channel of the needle assembly and the second component chamber being fluidly coupled to a second channel of the needle assembly. In operation, the dual chamber applicator may be engaged to deploy a first component to the first channel (e.g., via the first component chamber) and a second component to the second channel (e.g., via the second component chamber). In these embodiments, the needle assembly may further include a plurality inner lumen ports positioned circumferentially about the second channel and a plurality of outer lumen ports positioned about the first channel, with the plurality of inner points fluidly coupling the first channel to the second channel and the plurality of outer lumen ports fluidly coupling the first channel to a target site. Accordingly, as the second component flows through the second channel, the second component may pass through the plurality of inner points such that the second component enters the first channel and mixes with the first component. In

these embodiments, the mixture of the first component and the second component may be deployed to the target site. The plurality of inner lumen ports may be arranged in a plurality of inner rings, while the plurality of outer lumen ports may be arranged in a plurality of outer rings, such that each of the plurality of inner lumen ports is adjacent at least one of the plurality of outer lumen ports in a longitudinal direction. By stacking the plurality of outer rings and the plurality of inner rings in this manner, it may be possible to increase the number of ports provided on the needle assembly without increasing the diameter of the needle assembly. Additionally, the stacked port arrangement allows for more even distribution of components, such as fluid, across the target site, which may effectively reduce the risk of clogging or blockages forming within the needle assembly as compared to other commonly use port configuration (e.g, spiral, linear, etc.).

[0054] Embodiments may be further described with references to the following numbered clauses:

[0055] Clause 1. A needle assembly, comprising: an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction; and an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, and each of the plurality of inner rings being spaced from one another in the longitudinal direction, wherein the plurality of outer rings and the plurality of inner rings are aligned in the longitudinal direction.

[0056] Clause 2. The needle assembly of clause 1, wherein the first channel is configured to receive a first component and the second channel is configured to receive a second component, the first component being different from the second component.

[0057] Clause 3. The needle assembly of clause 1 or 2, wherein the first component and the second component are hydrogels.

[0058] Clause 4. The needle assembly of any of clauses 1-3, wherein the second component enters the first channel via the plurality of inner lumen ports, and a distal end of the elongate cannula receives the second component and the first component and causes the first

component and the second component to mix.

[0059] Clause 5. The needle assembly of any of clauses 1-4, wherein a resultant mixture of the first component and the second component is deployed to a target site via the plurality of outer lumen ports.

[0060] Clause 6. The needle assembly of any of clauses 1-5, wherein at least one of the plurality of inner rings is positioned proximally to each of the plurality of outer rings.

[0061] Clause 7. The needle assembly of any of clauses 1-6, wherein the elongate cannula further includes a distal end having a distal port.

[0062] Clause 8. The needle assembly of any of clauses 1-7, wherein the plurality of inner lumen ports fluidly couple the second channel to the first channel.

[0063] Clause 9. The needle assembly of any of clauses 1-8, wherein the plurality of outer lumen ports provide an exterior opening into the first channel. component are hydrogels.

[0064] Clause 10. A delivery system, comprising: a dual chamber applicator comprising: a first component chamber containing a first component and a second component chamber containing a second component; a needle assembly coupled to the dual chamber applicator, the needle assembly comprising: an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction; and an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, each of the plurality of inner rings being spaced from one another in the longitudinal direction, and each of the plurality of inner rings being in alignment with each of the plurality of outer rings in the longitudinal direction; wherein the first component chamber is fluidly coupled to the first channel and the second component chamber is fluidly coupled to the second channel, such that the first component chamber provides the first component to the first channel and the second component chamber provides the second component to the second channel.

[0065] Clause 11. The delivery system of clause 10, wherein at least one of the plurality of inner rings is positioned proximally to each of the plurality of outer rings.

[0066] Clause 12. The delivery system of clauses 10 or 11, wherein the first component and the second component are hydrogels.

[0067] Clause 13. The delivery system of any of clauses 10-12, wherein the second component enters the first channel via the plurality of inner lumen ports, and a distal end of the elongate cannula receives the second component and the first component and causes the first component and the second component to mix.

[0068] Clause 14. The delivery system of any of clauses 10-13, wherein a resultant mixture of the first component and the second component is deployed to a target site via the plurality of outer lumen ports.

[0069] Clause 15. The delivery system of any of clauses 10-14, wherein the elongate cannula further includes a distal end having a distal port.

[0070] Clause 16. The delivery system of any of clauses 10-15, wherein the plurality of inner lumen ports fluidly coupled the second channel to the first channel.

[0071] Clause 17. The delivery system of any of clauses 10-16, wherein the plurality of outer lumen ports provide an exterior opening into the first channel.

[0072] Clause 18. The delivery system of any of clauses 10-17, further comprising an auxiliary applicator coupled to the needle assembly.

[0073] Clause 19. The delivery system of any of clauses 10-18, w herein the auxiliary applicator comprises a saline chamber.

[0074] Clause 20. The delivery system of any of clauses 10-19, wherein the saline chamber of the auxiliary applicator is fluidly coupled to the first channel and/or the second channel.

[0075] Clause 21. A method of operating a delivery system, comprising: coupling a dual chamber applicator to a needle assembly such that a first component chamber containing a first component of the dual chamber applicator is fluidly coupled to a first channel defined by an outer lumen of the needle assembly and a second component chamber containing a second

component of the dual chamber applicator is fluidly coupled to a second channel defined by an inner lumen of the needle assembly, wherein the outer lumen of the needle assembly includes a plurality of outer lumen ports arranged in a plurality of outer rings and the inner lumen of the needle assembly includes a plurality of inner lumen ports arranged in a plurality of inner rings; deploying the first component to the first channel and the second component to the second channel; and deploying a resultant mixture of the first component and the second component to a target site via the plurality of outer lumen ports; wherein the first component and the second component mix at a distal end of the needle assembly.

[0076] Clause 22. The method of clause 21, wherein the resultant mixture of the first component and the second component is a hydrogel.

[0077] Clause 23. The method of clause 22 or 23, further comprising coupling an auxiliary applicator having a saline chamber to the needle assembly such that the saline chamber is fluidly coupled to the first channel and/or the second channel.

[0078] Clause 24. The method of any of clauses 21-23, further comprising deploying saline from the auxiliary applicator to the first channel and/or the second channel of the needle assembly.

[0079] The terminology used herein is for the purpose of describing particular aspects only and is not intended to be limiting. As used herein, the singular forms "a," "an," and "the" are intended to include the plural forms, including "at least one," unless the content clearly indicates otherwise. "Or" means "and/or." As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items. It will be further understood that the terms "comprises" and/or "comprising," or "includes" and/or "including" when used in this specification, specify the presence of stated features, regions, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, regions, integers, steps, operations, elements, components, and/or groups thereof. The term "or a combination thereof" means a combination including at least one of the foregoing elements.

[0080] It is noted that the terms "substantially" and "about" may be utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. These terms are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting

in a change in the basic function of the subject matter at issue.

[0081] While particular embodiments have been illustrated and described herein, it should be understood that various other changes and modifications may be made without departing from the spirit and scope of the claimed subject matter. Moreover, although various aspects of the claimed subject matter have been described herein, such aspects need not be utilized in combination. It is therefore intended that the appended claims cover all such changes and modifications that are within the scope of the claimed subject matter.

CLAIMS

1. A needle assembly, comprising:

an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction; and

an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, and each of the plurality of inner rings being spaced from one another in the longitudinal direction,

wherein the plurality of outer rings and the plurality of inner rings are aligned in the longitudinal direction.

2. The needle assembly of claim 1, wherein the first channel is configured to receive a first component and the second channel is configured to receive a second component, the first component being different from the second component.

3. The needle assembly of claim 2, wherein the first component and the second component are hydrogels.

4. The needle assembly of claim 2, wherein the second component enters the first channel via the plurality of inner lumen ports, and a distal end of the elongate cannula receives the second component and the first component and causes the first component and the second component to mix.

5. The needle assembly of claim 4, wherein a resultant mixture of the first component and the second component is deployed to a target site via the plurality of outer lumen ports.

6. The needle assembly of claim 1, wherein at least one of the plurality of inner rings is positioned proximally to each of the plurality of outer rings.

7. The needle assembly of claim 1, wherein the elongate cannula further includes a distal end having a distal port.

8. The needle assembly of claim 1, wherein the plurality of inner lumen ports fluidly couple the second channel to the first channel.

9. The needle assembly of claim 1, wherein the plurality of outer lumen ports provide an exterior opening into the first channel.

10. A delivery system, comprising:

a dual chamber applicator comprising:

a first component chamber containing a first component and a second component chamber containing a second component;

a needle assembly coupled to the dual chamber applicator, the needle assembly comprising:

an elongate cannula including an outer lumen defining a first channel and having a plurality of outer lumen ports, the plurality of outer lumen ports being arranged in a plurality of outer rings about the outer lumen in a circumferential direction, and each of the plurality of outer rings being spaced from one another in a longitudinal direction; and

an inner cannula disposed within the outer lumen, the inner cannula including an inner lumen defining a second channel and having a plurality of inner lumen ports, the plurality of inner lumen ports being arranged in a plurality of inner rings about the inner lumen in the circumferential direction, each of the plurality of inner rings being spaced from one another in the longitudinal direction, and each of the plurality of inner rings being in alignment with each of the plurality of outer rings in the longitudinal direction;

wherein the first component chamber is fluidly coupled to the first channel and the second component chamber is fluidly coupled to the second channel, such that the first component chamber provides the first component to the first channel and the second component chamber provides the second component to the second channel.

11. The delivery system of claim 10, wherein at least one of the plurality of inner rings is positioned proximally to each of the plurality of outer rings.

12. The delivery system of claim 11, wherein the first component and the second component are hydrogels.

13. The delivery system of claim 10, wherein the second component enters the first channel via the plurality of inner lumen ports, and a distal end of the elongate cannula receives the second component and the first component and causes the first component and the second component to mix.

14. The delivery system of claim 13, wherein a resultant mixture of the first component and the second component is deployed to a target site via the plurality of outer lumen ports.

15. The delivery system of claim 10, wherein the elongate cannula further includes a distal end having a distal port.

16. The delivery system of claim 10, wherein the plurality of inner lumen ports fluidly coupled the second channel to the first channel.

17. The delivery system of claim 10, wherein the plurality of outer lumen ports provide an exterior opening into the first channel.

18. The delivery system of claim 10, further comprising an auxiliary applicator coupled to the needle assembly.

19. The delivery system of claim 18, wherein the auxiliary applicator comprises a saline chamber.

20. The delivery system of claim 19, wherein the saline chamber of the auxiliary applicator is fluidly coupled to the first channel and/or the second channel.

21. A method of operating a delivery system, comprising:

coupling a dual chamber applicator to a needle assembly such that a first component chamber containing a first component of the dual chamber applicator is fluidly coupled to a first channel defined by an outer lumen of the needle assembly and a second component chamber containing a second component of the dual chamber applicator is fluidly coupled to a second channel defined by an inner lumen of the needle assembly, wherein the outer lumen of the needle assembly includes a plurality of outer lumen ports arranged in a plurality of outer rings and the inner lumen of the needle assembly includes a plurality of inner lumen ports arranged in a plurality of inner rings;

deploying the first component to the first channel and the second component to the second channel; and

deploying a resultant mixture of the first component and the second component to a target site via the plurality of outer lumen ports;

wherein the first component and the second component mix at a distal end of the needle assembly.

22. The method of claim 21, wherein the resultant mixture of the first component and the second component is a hydrogel.

23. The method of claim 22, further comprising coupling an auxiliary applicator having a saline chamber to the needle assembly such that the saline chamber is fluidly coupled to the first channel and/or the second channel.

24. The method of claim 23, further comprising deploying saline from the auxiliary applicator to the first channel and/or the second channel of the needle assembly.

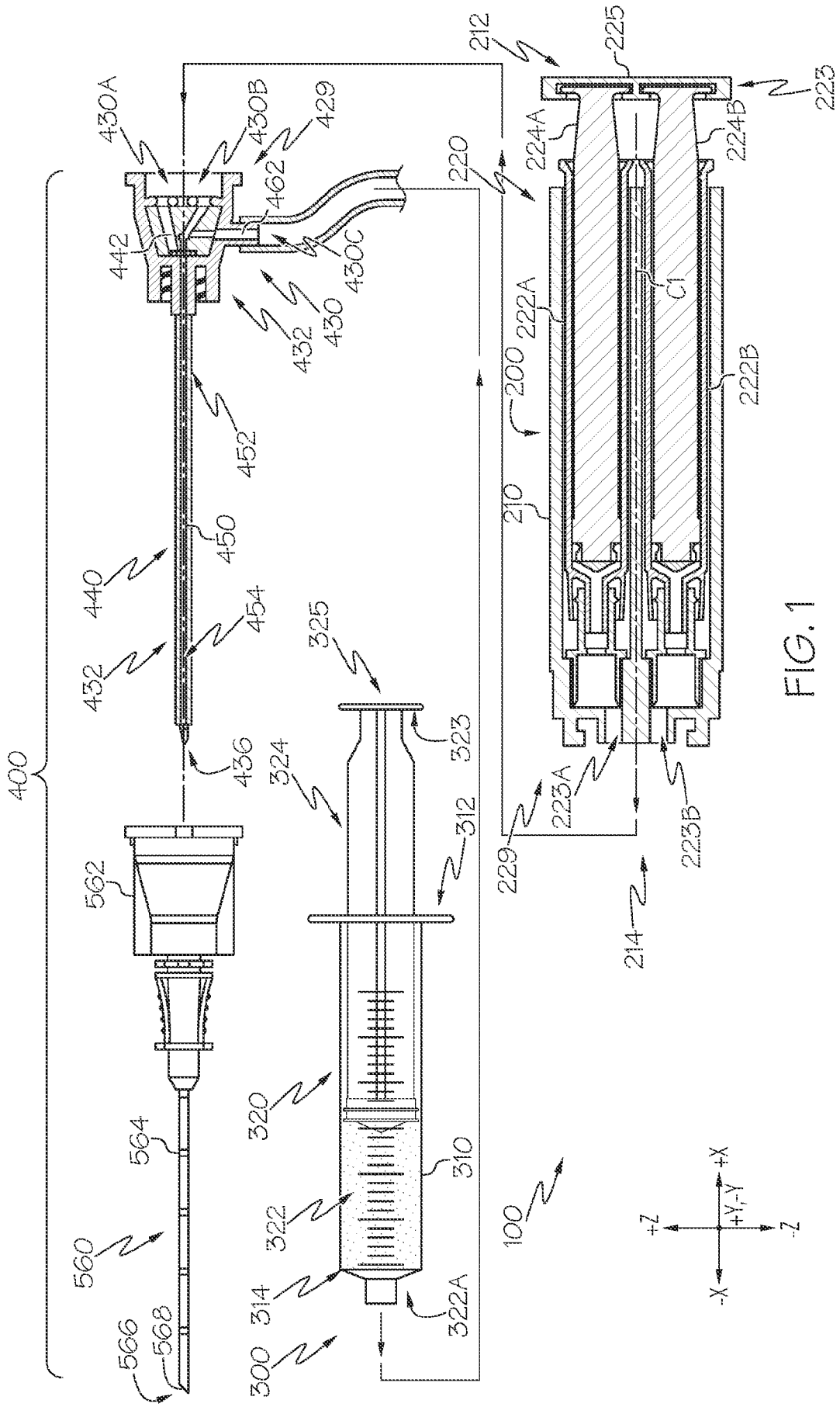

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225
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430A
430B
429
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224B
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462
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430C
222A
C1
222B
430
432
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210
450
440
454
325
432
323
436
324
223A
223B
312
229
562
214
320
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FIG. 1

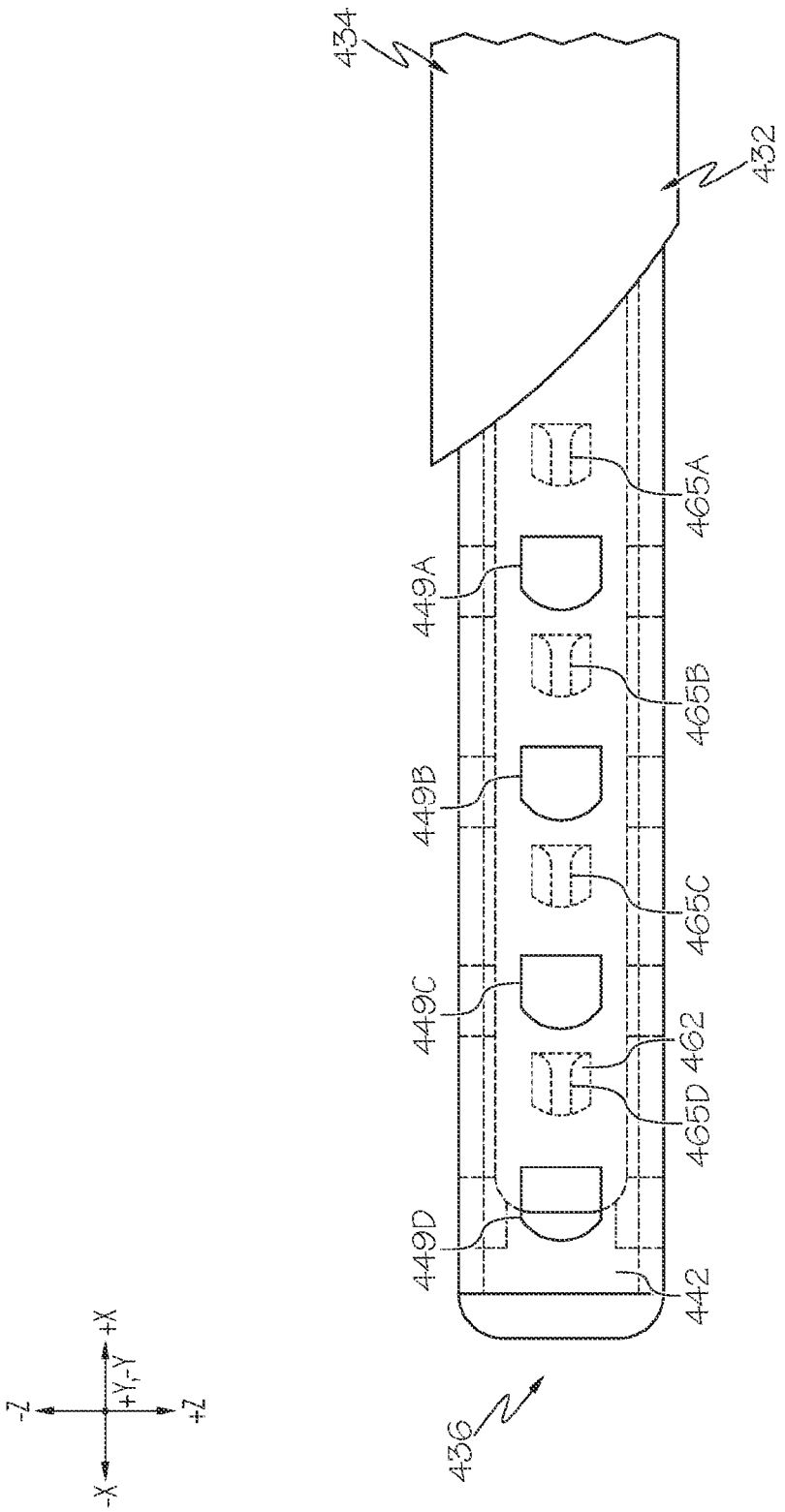

434
432
465A
449A
465B
449B
465C
449C
462
465D
449D
442
436
+X
-Z
+Y,-Y
+Z
-X

FIG. 2B

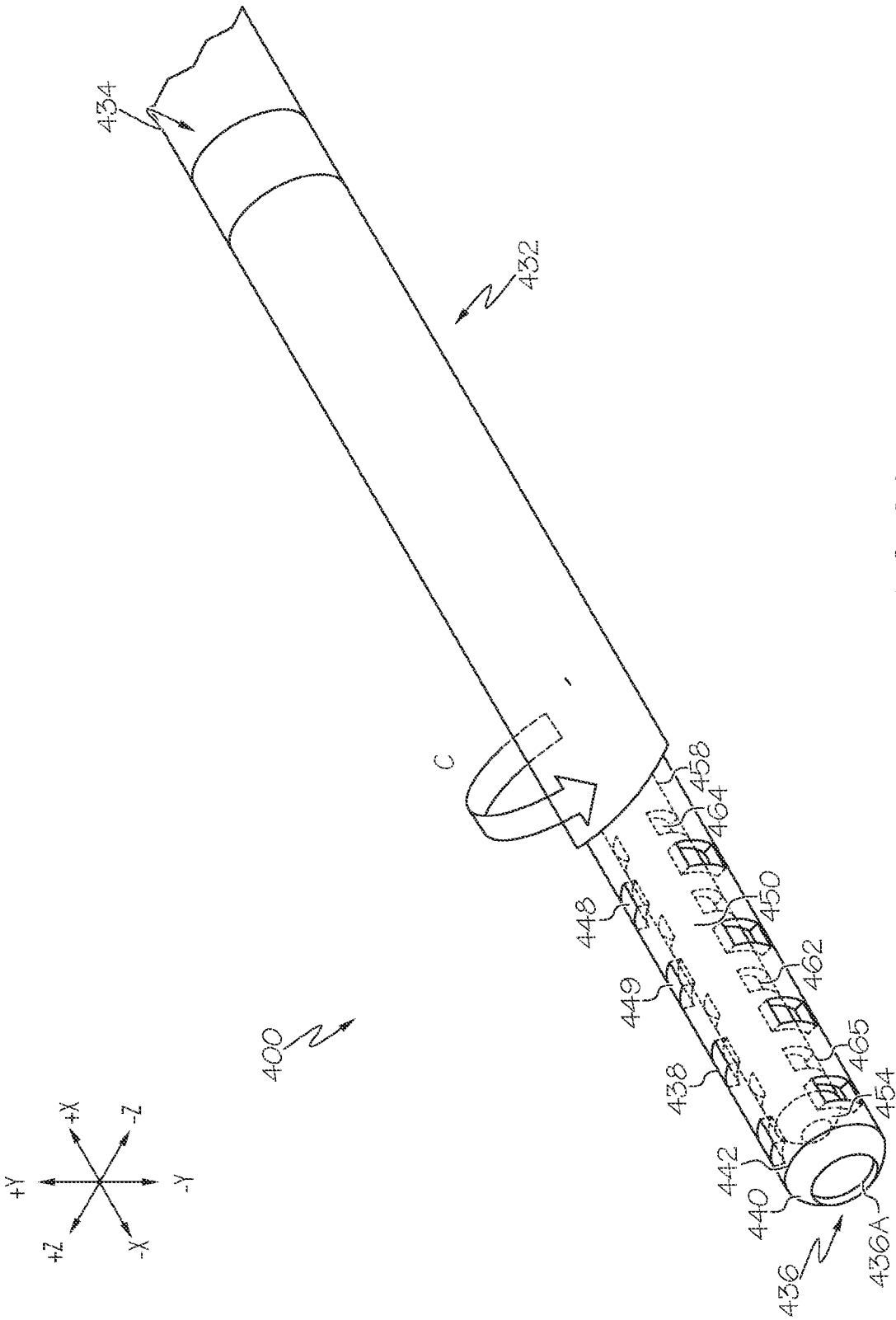

434
432
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458
464
448
450
449
462
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442
440
436
436A
400
+Y
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-Y
+Z
-X

FIG. 2A

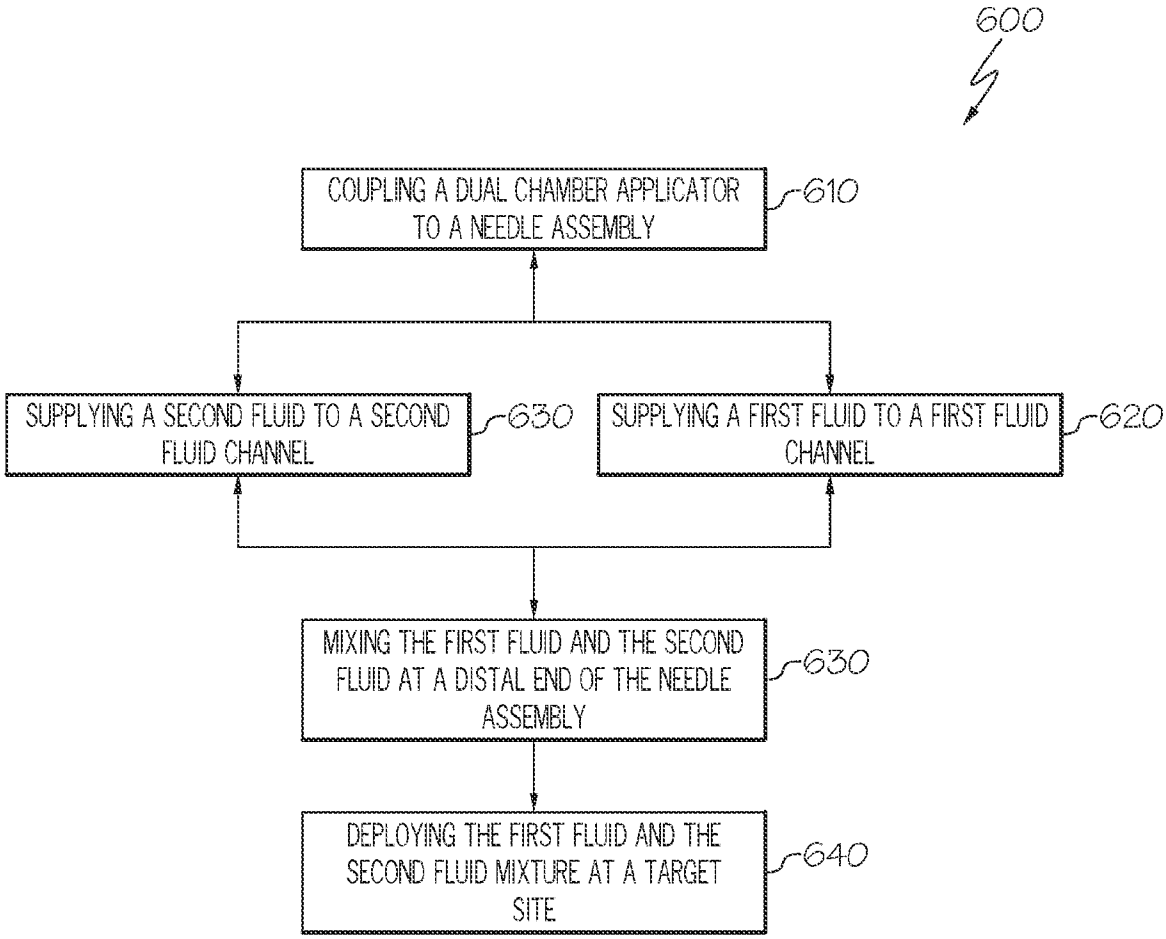

600
COUPLING A DUAL CHAMBER APPLICATOR TO A NEEDLE ASSEMBLY
610
SUPPLYING A SECOND FLUID TO A SECOND FLUID CHANNEL
630
SUPPLYING A FIRST FLUID TO A FIRST FLUID CHANNEL
620
MIXING THE FIRST FLUID AND THE SECOND FLUID AT A DISTAL END OF THE NEEDLE ASSEMBLY
630
DEPLOYING THE FIRST FLUID AND THE SECOND FLUID MIXTURE AT A TARGET SITE
640

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2023/027002

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/19 A61M5/32
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

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 2011/077644 A1 (PHAM FRANCIS [US] ET AL) 31 March 2011 (2011-03-31) the whole document	1,2,6-9
X	WO 99/22683 A1 (TING WINDSOR [US]; TSITLIK JOSHUA E [US]) 14 May 1999 (1999-05-14) the whole document	1,6,8,9
X	US 2023/028989 A1 (D'LIMA DARRYL D [US] ET AL) 26 January 2023 (2023-01-26) the whole document	1-20

☐ 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
23 January 2024	07/02/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Delmotte, Pierre

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2023/027002

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-24
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 21-24

The method defined in claims 21-24 is a method of treatment of the human or animal body by therapy because it claims "deploying a resultant mixture of the first component and the second component to a target site". The first and second components being understood from the description as having a therapeutic effect and the target site being understood as being a patient. No international search and no preliminary examination are required for such methods (Art. 17(2)(a)i, Rule 39.1(iv); Art. 34(4)(a)i, Rule 67.1(iv), PCT GL 9.08-9.10). See also Rule 43 bis PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2023/027002

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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