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[Continued on next page]

(54) Title: CANNULA WITH CONTROLLED DEPTH OF INSERTION

FIG. 5

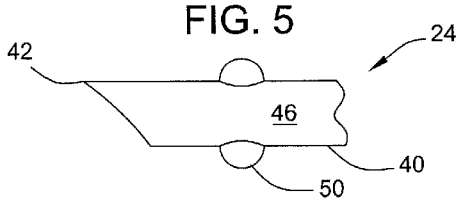


FIG. 6

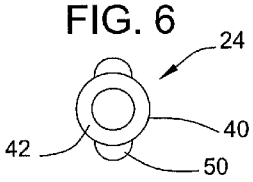


FIG. 7

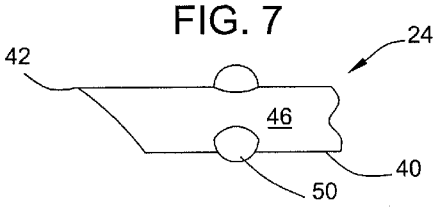
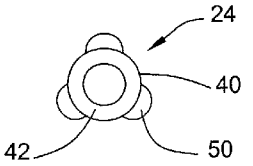


FIG. 8



(57) Abstract: A cannula (24) for administration of a medicine to a target location (26) includes a tube 40 ()with at least one nodule (50) disposed along the circumferential surface (46) and spaced at a defined distance (54) from the distal end (42) of the tube (40). An arrangement (20) for delivery of a medicine to a target location (26) includes the cannula (24) and a pump (22) fluidly coupled to the cannula (24). The distal end (42) of the cannula (24) may be inserted into a target location (26) until the nodule (50) reaches a surface (46) that limits a depth of penetration before delivery of the medication.

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DESCRIPTION

CANNULA WITH CONTROLLED DEPTH OF INSERTION

Cross-Reference To Related Applications

[0001] This application claims priority to U.S. Provisional Patent Application 61/515,547, which was filed on August 5, 2011, which is included herein by reference in its entirety for all purposes.

Technical Field

[0002] This patent disclosure relates generally to systems for the delivery of medicine, and, more particularly to structures for controlling the depth of penetration of a delivery cannula relative to a point of delivery.

Background

[0003] The delivery of medications by injection may be in the form of a single administration(s), or a series of administrations that occur at predetermined intervals over a set time period. Medication can be delivered using a pump to a cannula that is placed into the target bone or tissue. Pumps for delivering the medication may be, for example, in the form of a syringe or a primary drug container, that is actuated to deliver a predetermined volume of medicine at set times or time intervals, or in response to a delivery trigger.

[0004] A number of injectable medication delivery applications require the placement of the delivery cannula remotely from the pump. In such applications, the delivery cannula may be fluidly coupled to the pump by flexible tubing, which allows for required placement of the cannula, convenient placement of the pump, and provides flexibility to the clinician to manipulating the medication delivery setup. For example, the pump may be supported on the surface of a table or in a bag, or on the patient's body itself.

[0005] Accurate placement of the cannula requires not only accurate placement for insertion, but also precise depth insertion. In this regard, it is desirable that there be minimum interference with the line of sight to the patient end of the cannula so the medical personnel may clearly visualize the penetrating end of the cannula along with the target tissue or bone. Ensuring delivery of medication at the correct depth is critical to maximizing

efficacy of many medications and compliance with indicated route of administration. For example, too deep of penetration of a cannula may result in intramuscular delivery as opposed to an intended subcutaneous delivery, while too shallow penetration may result in subcutaneous delivery, as opposed to an intended intramuscular delivery.

Summary

[0006] The disclosure describes, in one aspect, a cannula for use in the administration of a medicine to a target location. The cannula includes a tube having a proximal end and a distal end, a lumen extending between the proximal and distal ends, and an outer circumferential surface defining a circumference. At least one nodule is disposed along the outer circumferential surface and spaced at a defined distance from the distal end of the tube. The at least one nodule may be utilized as depth limiters to control the depth of cannula insertion at a target location.

[0007] In one embodiment, the cannula may be utilized for administration of a medicine to a targeted location into the inner ear. The cannula may be inserted through an ear canal of an ear such that the distal end of the cannula and the at least one nodule are caused to pass through a tympanic membrane. The distal end of the cannula may be placed adjacent to or in contact with a target location at the membrane wall of the inner ear such that the at least one nodules limit the insertion depth of the cannula into the wall. The medicine may then be administered to the target location. The at least one nodule may be sized, shaped, arranged and/or otherwise configured to permit passage through one or more membranes, such as the tympanic membrane, while not permitting passage through other membranes, such as the temporal bone lining the inner ear.

[0008] The disclosure describes, in another aspect, an arrangement for delivery of a medicine to a target location. The arrangement includes a cannula and a pump fluidly coupled to the cannula. The cannula includes a tube having a proximal end and a distal end, a lumen extending between the proximal and distal ends, and an outer circumferential surface defining a circumference. The at least one nodule is disposed along the circumferential surface and spaced at a defined distance from the distal end of the tube.

[0009] The disclosure describes, in yet another aspect, a method of delivering a medicine to a target location. The method includes the steps of positioning the distal end of a cannula for insertion into the target location, inserting the distal end of the cannula into the target location until a nodule disposed on the outer surface of the cannula reaches a surface that

limits a depth of penetration into the target location, and delivering the medicine through the cannula to the target location.

[0010] The disclosure describes, in a further aspect, a method of fabricating the cannula comprising the steps of providing a tube, and forming the at least one nodule on the outer surface of the tube by at least one of metal stamping, precision welding, injection molding, needle overmold, adhesion, interference fit, and electrochemical deposition, and combinations thereof.

Brief Description of the Drawing(s)

[0011] FIG. 1 is a schematic view of a medicine delivery system according to aspects the disclosure.

[0012] FIG. 2 is an enlarged fragmentary isometric view of an end of a cannula of FIG. 1 according to aspects of the disclosure.

[0013] FIG. 3 is an enlarged fragmentary side elevational view of the end of the cannula of FIG. 2.

[0014] FIG. 4 is an end view of the cannula of FIG. 2.

[0015] FIG. 5 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0016] FIG. 6 is an end view of the cannula of FIG. 5.

[0017] FIG. 7 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0018] FIG. 8 is an end view of the cannula of FIG. 7.

[0019] FIG. 9 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0020] FIG. 10 is an end view of the cannula of FIG. 9.

[0021] FIG. 11 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0022] FIG. 12 is an end view of the cannula of FIG. 11.

[0023] FIG. 13 is an enlarged end view of another embodiment of a cannula according to aspects of the disclosure.

[0024] FIG. 14 is an end view of the cannula of FIG. 13.

[0025] FIG. 15 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0026] FIG. 16 is an end view of the cannula of FIG. 15.

[0027] FIG. 17 is an enlarged fragmentary side elevational view of an end of another embodiment of a cannula according to aspects of the disclosure.

[0028] FIG. 18 is an end view of the cannula of FIG. 17.

Detailed Description

[0029] The invention relates to a device and method for controlling the position of a medicine delivery cannula, and related methods of manufacturing and methods of use. Accurate positioning of a delivery cannula and dispensing of medication to a target location is critical to the efficacy, compliance, and success of many medical treatments. The present invention provides a device and methodology for targeting the delivery cannula and the appropriate depth in a target membrane to improve the administration of such treatments. Utilizing the present inventions for drug delivery to targeted location may greatly improve the efficacy of the treatment, ease or simplify the surgical operation of the physician, and decrease the amount of pain or discomfort felt by the patient. For example, certain treatments must be delivered to the inner ear. Too shallow penetration of a cannula in this sensitive location may result in inaccurate or incomplete delivery of the medication while too deep penetration may cause substantial pain and/or harm to the patient. The embodiments of the present invention function to ensure that the accurate depth for drug delivery is reached, thereby maximizing drug efficacy while maintaining or improving patient comfort.

[0030] Turning to FIG. 1, there is illustrated an arrangement 20 for administration of a medicine. For purposes of this disclosure, the term "medicine" is intended to include a substance or preparation used in treating disease or a health condition, maintaining health, or treating, preventing, alleviating, or curing of disease or a health condition. The term "medicine" may include, for example, gaseous, liquid, and powder form pharmaceutical treatments. The device may be used in a number of locations for drug delivery such as, for example, the inner ear of a patient, as illustrated in FIG. 1.

[0031] The arrangement 20 includes a pump 22 that is fluidly connected to a cannula 24 for administration of the medicine to a target location 26, such as within a tissue or within a bone. The pump 22 may include any appropriate administration device, such as, by way of example only, a syringe, or some other container the holds the medicine for delivery, and may be manually or automatically actuated. The pump 22 provides one or more of a single

administration of medicine, administration of medicine over period of time, administration of medicine at controlled intervals, or administration of medication upon manual activation.

[0032] The pump 22 may be fluidly coupled directly to the cannula 24, or, as shown in FIG. 1, the pump 22 may be fluidly coupled to the cannula 24 by a secondary cannula or tubing 28, which serves as a medicine pathway to the delivery cannula 24. The tubing 28 may be of any appropriate design and material. By way of example, the tubing 28 may be formed of polyurethane tubing or another suitable material. The proximal end 30 of the tubing 28 is securely coupled to the pump 22, while the distal end 31 of the tubing 28 is coupled to a proximal end 32 of the cannula 24 by any appropriate method, such as an interference fit or partial, controlled dissolution of the material of the tubing 28. A control clamp 34, such as the illustrated hemostat, may be provided to further control flow of medicine through the arrangement and may, optionally, be used to control flow. It will be appreciated that the flexibility and length of the tubing 28 allow the pump 22 to be disposed at a location that is a distance from the cannula 24. In this way, the pump 22 may be disposed on a support surface, such as a table (not illustrated), carried in a pouch or pocket (not illustrated), or disposed directly on or in body tissue (not illustrated). Alternatively, as stated above, a syringe or other primary drug container may be utilized to initially store the treatment and dispense it for delivery to the targeted location.

[0033] The delivery cannula 24 includes a tube 40 with a proximal end 32, where a drug treatment may be introduced, and a distal end 42, where a drug treatment may be dispensed, and a lumen 44 (see FIG. 2) extending between the proximal and distal ends 32, 42 along a longitudinal axis. The distal end 42 may be blunt, as illustrated in FIGS. 1-4, or beveled to a sharp tip, as illustrated in FIGS. 5-18, for example. The outer surface 46 of the cannula 24 is generally circumferential, and defines a circumference 48. In use, the distal end 42 of the cannula 24 is inserted into the target location 26 such that medicine from the pump 22 may be delivered through the tubing 28 (if included) and the lumen 44 of the cannula 24 to the target location 26.

[0034] The cannula 24 may be made of a number of materials, such as, for example, plastic or metal. The cannula 24 may be a rigid cannula or a soft cannula. In at least one embodiment, the cannula 24 is a rigid steel cannula with no bevel.

[0035] According to a feature of this disclosure, the cannula 24 includes an injection depth regulating arrangement in the form of at least one nodule 50 that is disposed along the circumferential outer surface 46 and spaced from the distal end 42 of the tube 40. When the

distal end 42 of the cannula 24 is inserted into the target location 26, the nodule 50 will contact a surface 52 to control the penetration depth of the cannula 24. It will be appreciated that surface 52 may be a surface of the target location 26 for medicine delivery, or the surface 52 may be an alternate surface. By way of example only, if the target location 26 is bone, the surface 52 may be the surface of a tissue covering the bone. Thus, the nodule 50 provides a positive stop for the clinician / end user / patient to press against the surface 52 for administration of the medicine, with the distance 54 of the nodule 50 from the distal end 42 of the cannula 24 and the at least one nodule 50 functioning to limit the penetration into the target location 26.

[0036] The one or more nodules 50 may be located on the outer surface of the cannula 24 at any desirable location along its longitudinal axis. For example, the one or more nodules 50 may be located at or near the distal end 42 of the cannula 50 in one or more embodiments, while one or more nodules 50 may be located at or near the proximal end 32 of the cannula 50 in one or more alternate embodiments. By way of example only, in various embodiments, the distance 54 of the nodule 50 from the distal end 42 of the cannula 24 may be on the order of 0.1 mm, 0.2 mm, or 0.5 mm in a blunt tipped cannula 24, or any other appropriate distance. It will be appreciated that the distance 54 may be adjusted in a cannula 24 having a sharpened tip.

[0037] The cannula 24 may include one nodule 50, or a plurality of nodules 50. The cannula 24 may include two nodules 50 as shown, for example in FIGS. 5-6, or three nodules 50 as shown, for example in FIGS. 7-8, or four nodules 50 as shown, for example in FIGS. 9-10, or any number of nodules 50. It will be appreciated that the nodules 50 may be substantially evenly spaced about the circumference, as shown in FIGS. 5-10, or they may be unevenly spaced (not shown). Alternately, the nodules 50 may be disposed substantially adjacent one another about the circumference, as shown, for example, in FIGS. 11-12. Furthermore, the nodules may be disposed substantially adjacent one another about the circumference such that they effectively form an outer ring. Moreover, the nodules 50 may be disposed about the circumference in a plane disposed at a right angle to the axis of the cannula 24, as illustrated, or, for example, in a plane disposed at an angle to the axis of the cannula 24 (not shown). Nodules 50 disposed in an angled plane may be particularly useful, for example, when the cannula 24 is to rest against the target location 26 at an angle. Angular positioning of the distal end 42 of the cannula 24 at a target location 26 may alternatively be achieved by positioning one or more nodules distal or proximal to the location of one or more

other nodules, such that they are located at different distances from the same reference point on the cannula. When two or more of these unevenly spaced nodules come in contact with the target location, they cannula 24 will be caused to rest at an angle to the target location.

[0038] The height 56 and outer shape of the nodules 50 may have the same or different cross-sectional profiles in embodiments of the cannula 24. The nodules 50 illustrated in FIGS 1-12 are substantially hemispherically shaped, although they may be alternately shaped. For example, the nodules 50 may have the shape of a cone, triangle, pyramid, or a sphere having a segment removed, or the shape of a segment of a sphere, or the shape of an ellipse. The nodules 50 may be oval, square, rectangular, or trapezoidal. Those of skill in the art will appreciate, however, that smooth structures may minimize opportunities for the nodules 50 to catch on tissue as the distal end 42 of the cannula 24 is moved toward or away from the target location 26, and may minimize opportunities for any possible damage to such tissue or the target location 26.

[0039] By way of further example, the nodules 50 may have a ramped shape, that is, they may include a base end 60 that increases to a peak end 62 at which the nodule 50 displays the greatest height 56, as shown, for example, in FIGS. 13-18. In this regard, the nodules 50 may be disposed with the base end 60 of one nodule 50 substantially adjacent the peak end 62 of another nodule 51, as shown, for example, in FIGS. 13-14. Alternately, ramp-shaped nodules 50 may be disposed substantially parallel to the axis of the cannula 50, as shown in FIGS. 15-18. It will be appreciated that such a ramped structure may facilitate insertion of the cannula 50 during placement or retraction of the cannula 50 during removal of the cannula 50 following the administration of medicine. For example, a cannula 24 having the ramp-shaped nodules 50 placed as illustrated in FIGS. 15 and 16 may facilitate movement of the distal end 42 of the cannula 24 completely through a tissue before reaching a target location 26, or removal following administration if the ramp-shaped nodules 50 are placed as illustrated in FIGS. 17 and 18. For example, in the administration location as illustrated in FIG. 1, the distal end 42 of the cannula 24 may be moved through the tympanic membrane 64 before reaching the ultimate target location 26. The utilization of ramp-shaped nodules 50 may assist in this placement or removal.

[0040] It will be appreciated by those of skill in the art that the extent to which the cannula 24 penetrates into the target location 26 is determined by distance 54 of the nodule 50 from the distal end 42 of the cannula 24, the height 56 of the nodule 50 (measured perpendicularly to the axis of the cannula 24), and the shape of the nodule 50, as well as the

compressibility of the target location 26. Thus, the design of the cannula 24 may be tailored to the application and target location 26 for which it will be utilized.

[0041] The cannula 24 may be fabricated by any appropriate method. The nodules 50 may be pre-formed as part of the cannula 24 or may be added to the cannula 24 by a number of manufacturing methodologies. For example, the one or more nodules 50 may be welded, such as by micro-welding, to the tube 40. In such configurations, the material of the welded nodules 50 may be a similar/identical material from that of the cannula 24. In at least one embodiment, the one or more nodules 50 are steel nodules welded to a rigid steel tube 40. Alternatively, the nodules 50 may be mounted, attached, formed, or otherwise fixed to the tube 40 by methods known in the art including metal stamping, precision welding, injection molding, needle overmold, adhesion, interference fit, and electrochemical deposition, among others. Some fabrication methods, for example, precision welding, may be done in the absence of oxygen or in an inert atmosphere to prevent oxidation of the cannula 24. The choice of fabrication method may be contingent on application and the material of the cannula 24 and of the nodules 50.

[0042] According to one method, multiple nodules 50 are laser welded to the outer surface 46 of the tube 40 in an atmosphere of inert gas. The laser is utilized to smooth the intersection of the nodules 50 at the outer surface 46 after forming each nodule 50 or on completion of all nodules. The cannula 24 may then be abrasive bead blasted or deburred by any appropriate method. Preferably, each cannula 24 is inspected to ensure both weld strength and integrity of the lumen 44.

[0043] In summary, the cannula 24 containing the one or more depth limiting nodules 50 may be used in a number of different applications. Generally, the cannula 24 may be used to deliver drug treatments to a target location 26 at a particular depth. For example, the cannula 24 may be utilized for drug delivery into bone, such as the temporal bone for inner ear delivery of drug. Similarly, the cannula 24 may be utilized for intramuscular delivery, intradermal delivery, subcutaneous delivery, or any other indicated route of administration, where the delivery is to be targeted at a particular depth. Inasmuch as the cannula 24 includes discrete nodules 50, the nodules 50 do not obstruct or only minimally obstruct the distal end 42 of cannula 24 during placement, providing medical personnel with a line of sight and hence enhanced opportunity for accurate placement.

[0044] It will be appreciated that the foregoing description provides examples of the disclosed system and technique. However, it is contemplated that other implementations of

the disclosure may differ in detail from the foregoing examples. All references to the disclosure or examples thereof are intended to reference the particular example being discussed at that point and are not intended to imply any limitation as to the scope of the disclosure more generally. All language of distinction and disparagement with respect to certain features is intended to indicate a lack of preference for those features, but not to exclude such from the scope of the disclosure entirely unless otherwise indicated.

[0045] Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context.

[0046] Accordingly, this disclosure includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the disclosure unless otherwise indicated herein or otherwise clearly contradicted by context.

CLAIM(S):

We claim:

1. A cannula 24 for use in the administration of a medicine to a target location 26, the cannula 24 comprising:

a tube 40 including a proximal end 32 and a distal end 42, a lumen extending between the proximal and distal ends 32, 42, and an outer circumferential surface 46 defining a circumference 48,

at least one nodule 50 disposed along the circumferential surface 46 and spaced from the distal end 42 of the tube 40.

2. The cannula 24 of claim 1 comprising a single nodule 50.

3. The cannula 24 of claim 1 comprising a plurality of nodules 50.

4. The cannula 24 of claim 3 wherein the nodules 50 are substantially evenly spaced about the circumference 48.

5. The cannula 24 of claim 3 wherein the nodules 50 are unevenly spaced about the circumference 48.

6. The cannula 24 of claim 1 wherein the nodule 50 is substantially the shape of a cone formed at the circumferential surface 46 of the tube 40.

7. The cannula 24 of claim 1 wherein the nodule 50 is of a substantially hemispherical shape.

8. The cannula 24 of claim 3 wherein the nodules 50 are positioned at substantially the same distance 54 from a distal end 42 of the cannula 24.

9. The cannula 24 of claim 3 wherein the nodules 50 are positioned at two or more distances 54 from a distal end 42 of the cannula 24.

10. The cannula 24 of claim 1 wherein the nodule 50 has a ramped shape.

11. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, and the base and peak ends 60, 62 alternate about the circumference 48.

12. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, the base end 60 being disposed toward the distal end 42 of the tube 40, and the peak end 62 being disposed away from the distal end 42 of the tube 40.

13. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, the base end 60 being disposed away from the distal end 42 of the tube 40, and the peak end 62 being disposed toward the distal end 42 of the tube 40.

14. The cannula 24 of claim 1 wherein the tube 40 is rigid.

15. The cannula 24 of claim 1 wherein the tube 40 is flexible.

16. The cannula 24 of claim 1 wherein the distal end 42 of the tube 40 is angled to a point.

17. The cannula 24 of claim 1 wherein the distal end 42 of the tube 40 is not angled.

18. An arrangement 20 for delivery of a medicine to a target location 26, the arrangement comprising

the cannula 24 of any of claims 1-17, and

a pump 22 fluidly coupled to the cannula 24.

19. A method of delivering a medicine to a target location 26, the method comprising the steps of:

positioning the distal end 42 of the tube 40 of any of claims 1-17 for insertion into the target location 26,

inserting the distal end 42 of the tube 40 into the target location 26 until the nodule 50 reaches a surface 46 that limits a depth of penetration into the target location 26, and

delivering the medicine to the target location 26.

20. A method of fabricating the cannula 24 of any of claims 1-17, the steps comprising

providing a tube 40

forming the at least one nodule 50 on the outer surface 46 of the tube 40 by at least one of metal stamping, precision welding, injection molding, needle overmold, adhesion, interference fit, and electrochemical deposition.

AMENDED CLAIMS
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1. A cannula 24 for use in the administration of a medicine to a target location 26, the cannula 24 comprising:

a tube 40 including a proximal end 32 and a distal end 42, a lumen extending between the proximal and distal ends 32, 42, and an outer circumferential surface 46 defining a circumference 48,

at least one nodule 50 disposed along the circumferential surface 46 and spaced from the distal end 42 of the tube 40, said nodule 50 being disposed to limit penetration of the distal end 42 of the tube 40 into a target location.

2. The cannula 24 of claim 1 comprising a single nodule 50.

3. The cannula 24 of claim 1 comprising a plurality of nodules 50.

4. The cannula 24 of claim 3 wherein the nodules 50 are substantially evenly spaced about the circumference 48.

5. The cannula 24 of claim 3 wherein the nodules 50 are unevenly spaced about the circumference 48.

6. The cannula 24 of claim 1 wherein the nodule 50 is substantially the shape of a cone formed at the circumferential surface 46 of the tube 40.

7. The cannula 24 of claim 1 wherein the nodule 50 is of a substantially hemispherical shape.

8. The cannula 24 of claim 3 wherein the nodules 50 are positioned at substantially the same distance 54 from a distal end 42 of the cannula 24.

9. The cannula 24 of claim 3 wherein the nodules 50 are positioned at two or more distances 54 from a distal end 42 of the cannula 24.

10. The cannula 24 of claim 1 wherein the nodule 50 has a ramped shape.

11. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, and the base and peak ends 60, 62 alternate about the circumference 48.

12. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, the base end 60 being disposed toward the distal end 42 of the tube 40, and the peak end 62 being disposed away from the distal end 42 of the tube 40.

13. The cannula 24 of claim 10 wherein the nodule 50 includes a base end 60 and a peak end 62, the base end 60 being disposed away from the distal end 42 of the tube 40, and the peak end 62 being disposed toward the distal end 42 of the tube 40.

14. The cannula 24 of claim 1 wherein the tube 40 is rigid.

15. The cannula 24 of claim 1 wherein the tube 40 is flexible.

16. The cannula 24 of claim 1 wherein the distal end 42 of the tube 40 is angled to a point.

17. The cannula 24 of claim 1 wherein the distal end 42 of the tube 40 is not angled.

18. The cannula 24 of claim 1 wherein said nodule 50 is adapted to permit penetration of the nodule 50 through a first tissue.

19. A method of delivering a medicine to a target location 26, the method comprising the steps of:

positioning the distal end 42 of the tube 40 of any of claims 1-18 for insertion into the target location 26,

inserting the distal end 42 of the tube 40 into the target location 26 until the nodule 50 reaches a surface 46 that limits a depth of penetration into the target location 26, and

delivering the medicine to the target location 26.

20. A method of fabricating the cannula 24 of any of claims 1-18, the steps comprising

providing a tube 40

forming the at least one nodule 50 on the outer surface 46 of the tube 40 by at least one of metal stamping, precision welding, injection molding, needle overmold, adhesion, interference fit, and electrochemical deposition.

21. An arrangement 20 for delivery of a medicine to a target location 26, the arrangement comprising

the cannula 24 of any of claims 1-18, and

a pump 22 fluidly coupled to the cannula 24.

STATEMENT UNDER ARTICLE 19

Independent claim 1 has been amended to further define and describe the structure of the at least one nodule. Dependent claim 18 has been added to further define and describe the structure of the at least one nodule. Original dependent claim 18 has be renumbered as claim 19. Original dependent claim 19 has been renumbered as claim 21. Original dependent claims 18, 19, and 20, now claims 19, 21, and 20, respectively, have been amended to depend from claims 1-18 instead of 1-17.

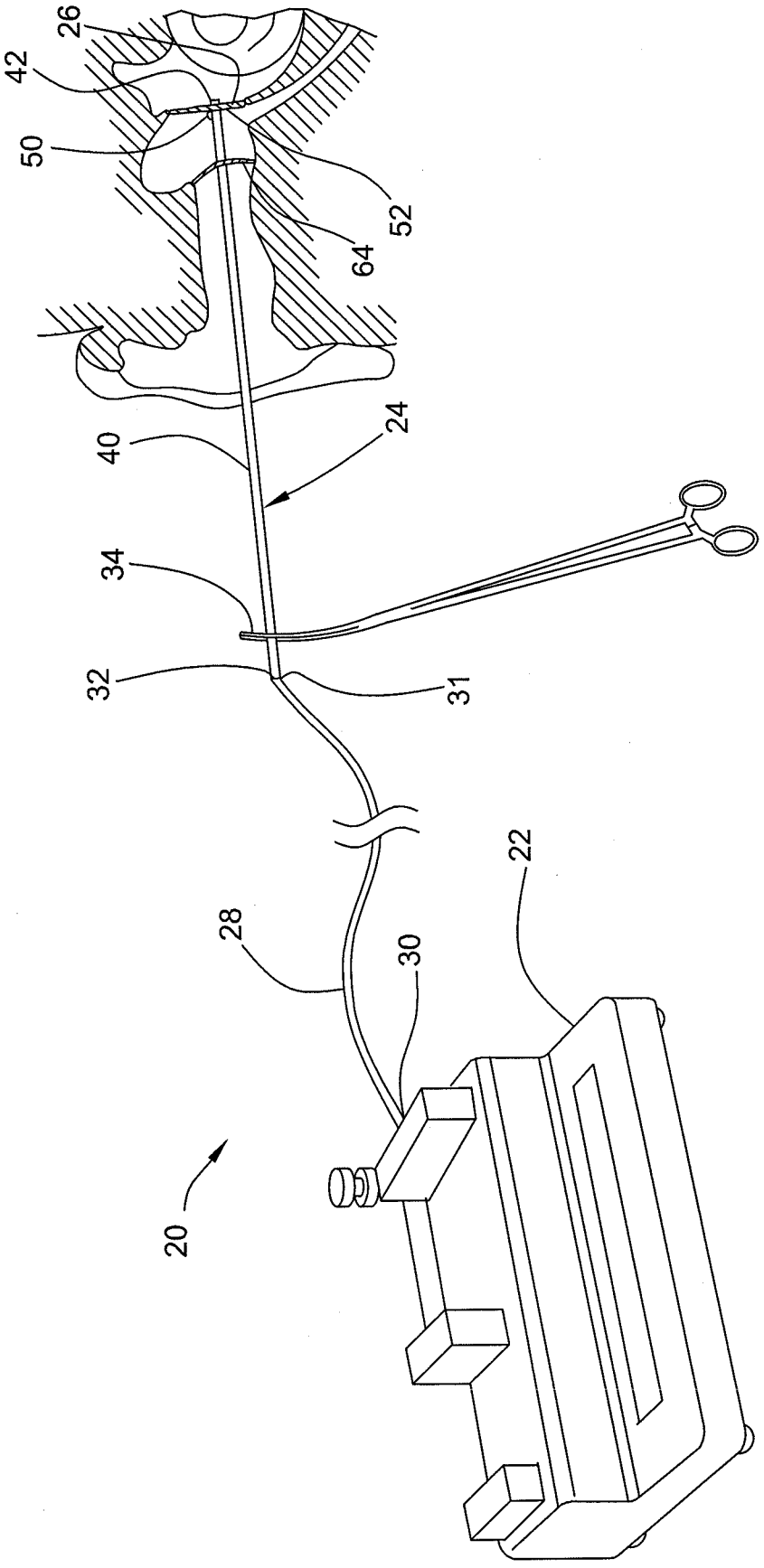


FIG. 1

FIG. 2

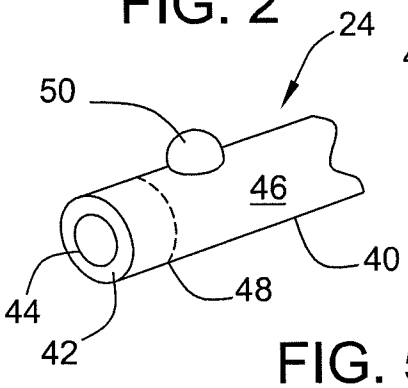


FIG. 3

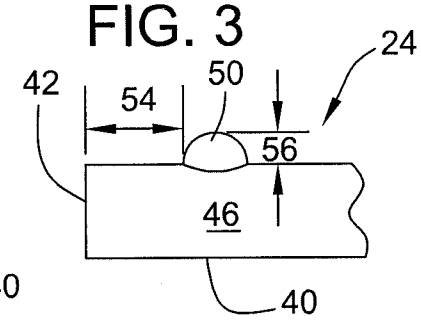


FIG. 4

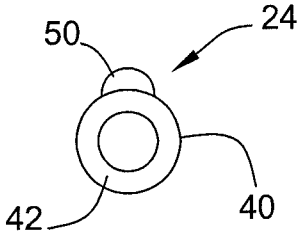


FIG. 5

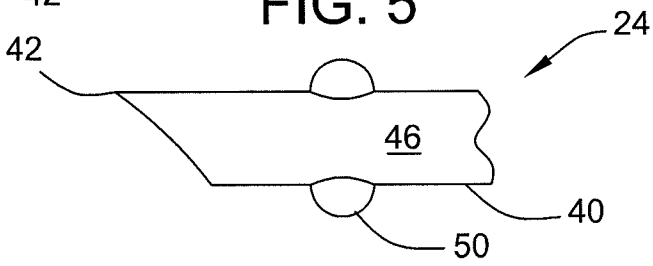


FIG. 6

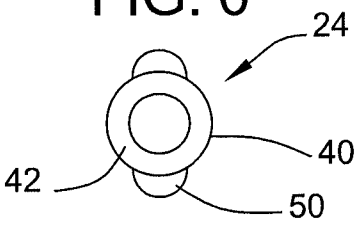


FIG. 7

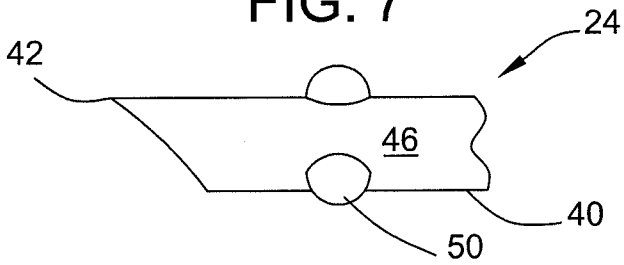


FIG. 8

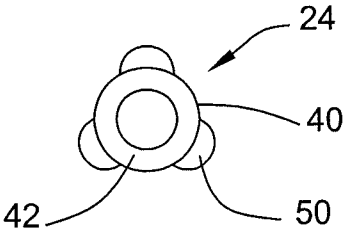


FIG. 9

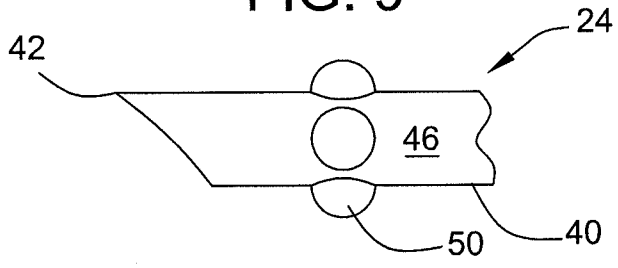


FIG. 10

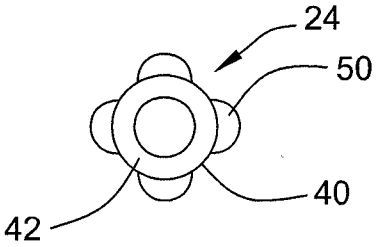


FIG. 11

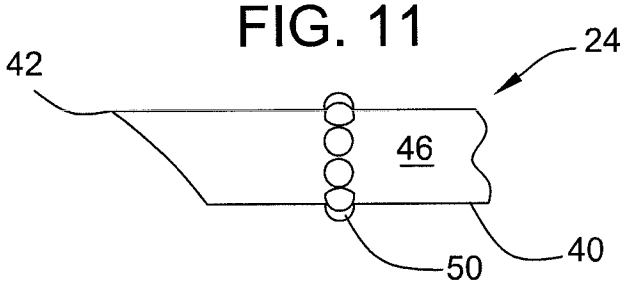


FIG. 12

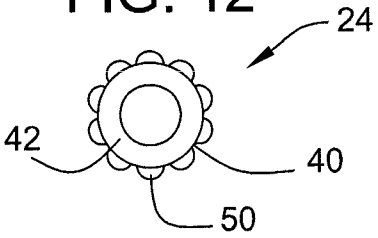


FIG. 13

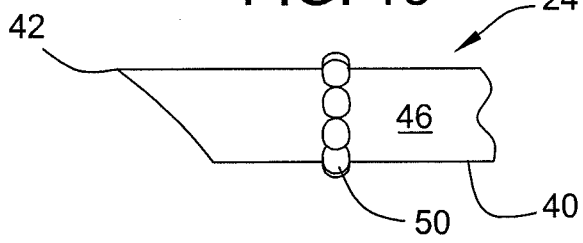


FIG. 14

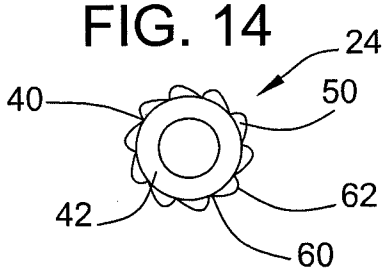


FIG. 15

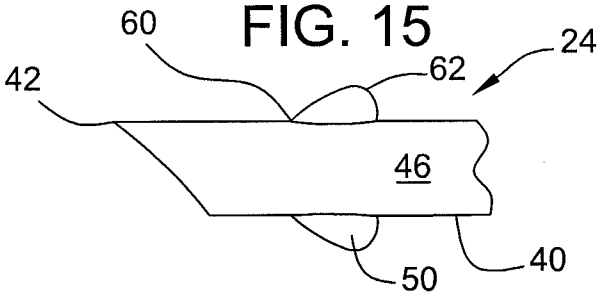


FIG. 16

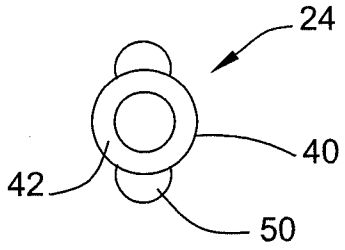


FIG. 17

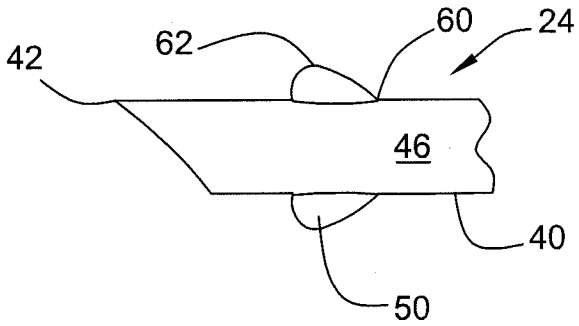
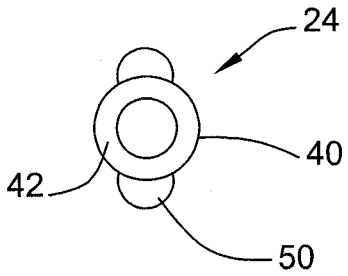


FIG. 18



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/049575

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32 A61M5/46
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 2008/071246 A1 (NAZZARO MARTIN [US] ET AL) 20 March 2008 (2008-03-20) paragraph [0029]; figures 5A,5C	1-18,20
X	EP 2 016 963 A1 (POLY MEDICURE LTD [IN]) 21 January 2009 (2009-01-21) paragraphs [0054] - [0060]; figures 7-9	1-18,20
X	WO 2010/100241 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; LANIN IRINA [DE]; FORYS BERNHARD [DE]) 10 September 2010 (2010-09-10) page 1, line 28 - page 4, line 6; figures 1A-2	1-18,20

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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
25 October 2012	31/10/2012

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	Krassow, Heiko

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/049575

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/131345 A1 (MILLER LARRY [US] MILLER LARRY J [US]) 16 June 2005 (2005-06-16) paragraph [0069]; figure 14A --- US 2009/124973 A1 (D AGOSTINO EDUARDO [US] ET AL) 14 May 2009 (2009-05-14) paragraph [0076]; figure 9 ---	1-18,20
A		1-18,20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/049575

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.: 19
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 19 defines subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, and no search report has been drawn up on said claims.The subject-matter defined comprises methods for treatment of the human body by surgery, i.e. methods for infusing or injecting fluid.

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/049575

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008071246 A1	20-03-2008	US 2008071246 A1	20-03-2008
		WO 2008033426 A1	20-03-2008
EP 2016963 A1	21-01-2009	AR 067547 A1	14-10-2009
		AT 484305 T	15-10-2010
		CN 101743028 A	16-06-2010
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		CO 6260088 A2	22-03-2011
		EA 201070156 A1	29-10-2010
		EP 2016963 A1	21-01-2009
		EP 2241346 A2	20-10-2010
		EP 2279770 A2	02-02-2011
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		JP 2010533533 A	28-10-2010
		KR 20100059803 A	04-06-2010
		PE 04562009 A1	15-05-2009
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		WO 2010100241 A1	10-09-2010
US 2005131345 A1	16-06-2005	NONE	
US 2009124973 A1	14-05-2009	US 2009124973 A1	14-05-2009
		WO 2009061339 A1	14-05-2009

摘要: 一種用於將藥物給藥至目標位置(26)的套管(24)，該套管(24)包括具有至少一個結節(50)的管(40)，所述至少一個結節(50)沿圓周表面(46)設置並且從管(40)的遠端(42)以限定的距離(54)間隔開。一種用於將藥物遞送至目標位置(26)的排列(20)包括套管(24)和與套管(24)以流體相连接的泵(22)。在藥物遞送之前，套管(24)的遠端(42)可以插入至目標位置(26)中，直到結節(50)到達對穿透深度進行限制的表面(46)為止。