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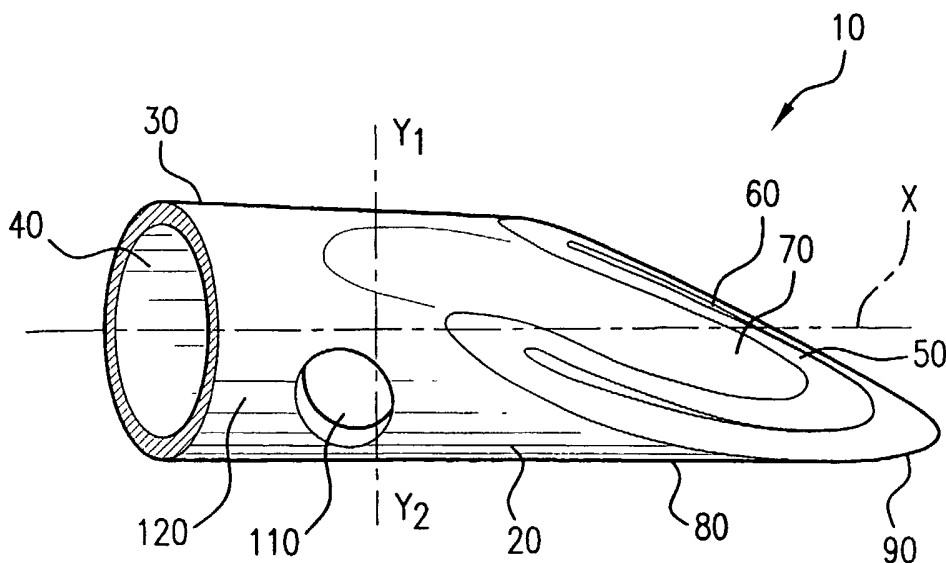
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(54) Title: NEEDLES



(57) Abstract: A needle (10) having a shaft (20) with a distal end (40) defining a distal opening (60). The shaft has a longitudinal axis (X) that extends through the distal opening and the distal opening has a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.

NEEDLES

FIELD OF THE INVENTION

[0001] The present invention relates to needles that minimize or prevent damage to the site in which the needles are inserted. The present invention also relates to methods of using needles for therapeutic purposes.

BACKGROUND

[0002] Needles have a wide variety of applications in the medical field. For instance, needles are used to delivery therapeutic agents, collect bodily fluids, and fill intravascular drug access devices. In many such applications, there is a desire to avoid or reduce damage to the site in which the needle is inserted. For example, intravascular drug access devices often include a chamber for holding a therapeutic agent and a pierceable rubber septum for receipt of a needle to either fill or empty the chamber. Repeated piercing of the septum with the needle can damage the septum leading to infusion of the septum fragments into the patient's vascular system or into any catheter or other device having access to the port, thereby occluding the port.

[0003] With respect to delivering a therapeutic agent to a target site in the body, particularly directly delivering a therapeutic agent to a target site, current injection needles have beveled open ends with Lancet point tips. Such open-ended needles have the potential to core tissue as the needles penetrate the tissue. In the case of directly delivering a therapeutic agent to a myocardial wall of the heart, since most myocardial direct injection procedures involve injecting a therapeutic agent into the left ventricle walls, the risk of tissue embolism into the left ventricular cavity exists.

[0004] Accordingly, there is a need for a needle that will prevent or minimize damage to the site in which the needle is inserted.

SUMMARY OF THE INVENTION

[0005] In one aspect, the present invention provides a needle comprising a shaft having a distal end defining a distal opening and having a longitudinal axis extending

through the distal opening. The distal opening has a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.

[0006] In another aspect, the present invention provides a method of directly delivering a therapeutic agent to a target site of a body other than the spinal cord by providing a drug delivery device comprising a Huber needle or pencil-point needle at the distal portion thereof and positioning the needle adjacent to the target site. The therapeutic agent is then directly delivered to the target site through the needle.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only and wherein:

[0008] FIG. 1 is a side view of an embodiment of a needle according to the present invention.

[0009] FIG. 2 illustrates the projection area of the distal opening of the embodiment of the needle depicted in FIG. 1.

[0010] FIG. 3 is a perspective view of an alternative embodiment of a needle according to the present invention.

[0011] FIG. 4 illustrates the projection area of the distal opening of the embodiment of the needle depicted in FIG. 3.

[0012] FIG. 5 is a perspective view of another embodiment of a needle according to the present invention.

[0013] FIG. 6 is an end view of the embodiment of the needle illustrated in FIG. 5.

[0014] FIG. 7 is a perspective view of an alternative embodiment of a needle according to the present invention.

[0015] FIG. 8 is a top view of a needle according to the present invention depicting an alternative embodiment of the distal opening of the needle.

[0016] FIG. 9 is a perspective view of a Huber needle.

[0017] FIGs. 10-14 are side views of different types of "pencil-point" needles.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Referring to **FIG. 1**, an embodiment of an aspect of the present invention provides a needle 10 comprising a shaft 20 having a proximal end 30 defining a proximal opening 40 and a distal end 50 defining a distal opening 60. A longitudinal axis X of shaft 20 extends through distal opening 60. The projected area A₁ of distal opening 60, according to this aspect of the present invention, is smaller than a cross-sectional area of a section of shaft 20 proximal to distal end 50. As indicated in **FIG. 2**, projected area A₁ of distal opening 60 is the area of distal opening 60 projected onto a plane perpendicular to longitudinal axis of shaft 20. To measure the cross-sectional area of a section of shaft 20, a cross-section of shaft 20 may be taken of any section of shaft 20 between proximal opening 40 and distal end 50. For example, as indicated in **FIG. 1**, a cross-section may be taken along lines Y₁ and Y₂.

[0019] Referring further to **FIG. 1**, in this embodiment, distal end 50 may comprise opposing first surface 70 and second surface 80 with first surface 70 being indented towards second surface 80. Distal end 50 may also terminate in a curvilinear tip 90, such as a rounded tip, as illustrated in **FIG. 1**. The degree of the curve of tip 90 is sufficiently blunt to avoid coring or excessive damage to the target site in which needle 10 is inserted but sufficiently pointed to pierce the target site.

[0020] Referring to **FIG. 3**, in another embodiment of needle 10, distal end 50 comprises opposing first extension 130 and second extension 140 that are angled towards each other and whose tips 135 and 136 partially define distal opening 60. **FIG. 4** depicts the projected area A₁ of distal opening 60, which is smaller than a cross-sectional area of a section of shaft 20 proximal to distal end 50 according to this aspect of the present invention. Referring to **FIG. 5**, in an alternative embodiment, second extension 140 is longer than first extension 130 in a direction parallel to longitudinal axis X of shaft 20. Preferably tips 135 and 136 of first and second extensions 130 and 140 are beveled, as illustrated in **FIGs. 5** and **6**. Further, as illustrated in **FIGs. 5** and **6**, first and second extensions 130 and 140 may mutually define at least one opening 150, which is offset from the longitudinal axis of shaft 20. Referring to **FIG. 6**, which is an end view of needle 10 illustrated in **FIG. 5**, preferably, first and second extensions 130 and 140 mutually define a pair of openings 150a and 150b that are each offset from longitudinal

axis **X**. Although openings **150a** and **150b** are illustrated as being tear-drop shaped, such openings may have any shape. Referring to **FIG. 7**, in an alternative embodiment, distal end **50** does not include first and second extensions defining openings offset from axis **X**, but rather simply tapers towards distal opening **60**. The degree in which distal end tapers can be any degree such that the projection area of distal opening **60** is smaller than a cross-sectional area of a section of shaft **20** proximal to distal end **50**. For example, angle **a** and/or angle **b**, as indicated in **FIGs. 5** and **7**, may be from about 14° to about 30°.

[0021] In any of the embodiments of this aspect of the present invention, shaft **20** may comprise at least one port **110** on a side surface **120** thereof as depicted in **FIG. 1**. For example, shaft **20** may include a pair of ports **110** on opposing side surfaces of shaft **20**. Whether shaft **20** has ports **110** may depend, for example, on the characteristics of the therapeutic agent that is delivered through shaft **20**. For example, shaft **20** may comprise ports **110** if a high volume of a therapeutic agent and/or a therapeutic agent having a high viscosity is delivered through shaft **20** and shaft **20** may comprise no ports **110** if a low volume of a therapeutic agent and/or a therapeutic agent having a low viscosity is delivered through shaft **20**. In embodiments where shaft **20** does comprise ports **110**, such ports may be of any number, size, and shape.

[0022] Furthermore, distal opening **60**, according to this aspect of the present invention, may be a continuous opening or a discontinuous opening. For example, **FIG. 8** illustrates a discontinuous distal opening **60** as section **60a** of opening **60** is open, section **60b** of opening **60** is closed near tip **90** and, section **60c** is open. Of course, as will be understood by one in the art, distal opening **60** may have patterns of discontinuity other than the pattern illustrated in **FIG. 8**.

[0023] It should be emphasized that the above-described embodiments are merely exemplary and the present invention contemplates any design of needle **10** having a distal opening **60** through which longitudinal axis **X** extends and where distal opening **60** has a projected area **A1** that is smaller than a cross-sectional area of a section of shaft **20** proximal to distal end **50**.

[0024] The present invention also contemplates drug delivery devices, such as syringes or catheters, which have attached to the distal portions thereof, a needle according to any embodiment of this aspect of the present invention. Such drug delivery

devices can be used to deliver any therapeutic agent to a target site of a body. To perform such delivery, a needle of this aspect of the present invention is attached to the distal portion of the drug delivery device and a therapeutic agent is loaded in the drug delivery device. The drug delivery device is placed in proximity to the target site and the needle is inserted in the target site. The therapeutic agent is then delivered through the needle to the target site of the body. Although a needle according to any embodiment of this aspect of the present invention has many applications and the needle is not in any way limited to a specific application, it is particularly useful for reducing or preventing coring or other damage to tissue. Accordingly, a needle according to any embodiment of this aspect of the present invention is particularly suited for direct delivery of a therapeutic agent to an organ or tissue, such as the myocardial wall of the heart, that is accessed from a blood vessel or from the blood stream and that when accessed by a needle, could result is a tissue core entering the blood stream.

[0025] A needle according to any embodiment of this aspect of the present invention can also be used to access a drug delivery port, such as an intravascular drug access device (IVAD). Such drug delivery ports are used for the delivery of therapeutic agents and are typically implanted in a subcutaneous pocket, such as the anterior upper chest wall below the clavicle. As mentioned previously, the drug delivery ports also usually include a chamber for the therapeutic agent and a pierceable septum for receipt of a needle to either fill or empty the chamber. According to the present invention, in order to access the drug delivery port, to delivery a therapeutic agent to the port for example, a drug delivery device, such as a syringe, is filled with a therapeutic agent and a needle according any embodiment of this aspect of the present invention is attached to the drug delivery device. The needle is inserted into the drug delivery port and the therapeutic agent is introduced into the drug delivery port through the needle. In instances where the drug delivery port includes a chamber covered with a septum, the needle pierces the septum to access the chamber to introduce the therapeutic agent to the chamber. Because of the particular configuration of the needle, damage to the septum is minimized even after repeated piercing of the septum. Of course, it will be understood to one of skill in the art that the needle can also be used to remove a therapeutic agent from the drug delivery port or to flush the drug delivery port with a saline solution, for example.

[0026] In another exemplary application, a needle according to any embodiment of this aspect of the present invention, is used to delivery a therapeutic agent to a spinal column of a body. For example, the needle can be used to delivery anesthesia, such as an epidural or spinal anesthesia, to the spinal column or to delivery any other drug intrathecally. Once again, because of the configuration of the needle, excessive damage to the affected area of the spinal column may be minimized or eliminated.

[0027] In addition to delivery of therapeutic agents to a target site of a body or an IVAD, a needle according to any embodiment of this aspect of the present invention, can be used to collect a fluid sample from a fluid containment site of a body. In such an application, the needle is attached to the distal portion of a drug delivery device and the needle is inserted into the fluid containment site of the body. A vacuum is created in the drug delivery device to collect the fluid sample from the fluid containment site. The fluid containment site can be any cavity, sac, or region in general of a body that stores or contains a fluid. Such fluids include, for example, blood, amniotic fluid, serous fluid, and cerebrospinal fluid. Accordingly, non-limiting examples of fluid containment sites include arteries and veins; the amniotic sac; serous cavities such as the peritoneal cavity, the pleural cavity, and the pericardial cavity; and the subarachnoid space.

[0028] It should be emphasized that the above mentioned methods of using a needle of any embodiment of this aspect of the present invention are merely illustrative and such needle can be used for any other appropriate purpose or application.

[0029] In another aspect, the present invention provides a method of directly delivering (as opposed to systemically delivering) a therapeutic agent to a target site of a body using a Huber needle, depicted in **FIG. 9**, or a "pencil point" needle, depicted in **FIG. 10**. In general, a Huber needle **200** has a distal portion **210** with a lateral bend and a laterally facing opening **220**. The needle terminates in a sharpened tip **230**. In general, a pencil-point needle **300** has a lateral opening **310** and a closed tip **320** at the distal end **340**. According to this aspect of the present invention, a Huber needle **200** or a pencil point needle **300** is attached to the distal portion of a drug delivery device, such as a syringe or catheter. The needle **200** or **300** is then positioned adjacent to the target site and the therapeutic agent is delivered to the target site through needle **200** or **300**.

[0030] Both the Huber needle and the pencil point needle are well-known in the art and further description of Huber needles are described, for example, in U.S. Patent Nos. 2,409,979, 2,717,599, and 2,748,769, all of which are incorporated herein by reference. The Huber needle to be used for direct delivery of a therapeutic agent includes safety Huber needles, straight Huber needles, and right-angled Huber needles. With respect to the pencil-point needle, this aspect of the present invention contemplates any type of pencil-point needle for direct delivery, including, for example, the designs illustrated in **FIGs. 10-14**.

[0031] The target site to which the therapeutic agent is delivered via the Huber needle or pencil-point needle according to this aspect of the present invention includes any target site other than the spinal cord. In a preferred embodiment, the target site is the heart and in an even more preferred embodiment, the target site is the myocardium.

[0032] In any of the aspects and embodiments of the present invention, the exact nature or identity of the therapeutic agent to be delivered will, of course, depend on the nature of the application of the needle and will be readily known to one in the art. For example, for direct delivery to the heart, the therapeutic agent may include anti-thrombogenic agents, anti-restenosis agents, angiogenic and anti-angiogenic agents, anti-inflammatory agents, anti-neoplastic/anti-proliferative/anti-mitotic agents, calcium entry blockers, anti-microbials, nitric oxide donors, anti-coagulants, vascular cell growth promoters, vascular cell growth inhibitors, vasodilating agents, agents which interfere with endogeneous vascoactive mechanisms, survival genes which protect against cell death, cells, and combinations thereof. Non-limiting examples of therapeutic agents for drug delivery into the spinal column, including intrathecal delivery, include anesthetics, analgesics, and chemotherapeutic agents.

[0033] In general, the therapeutic agent may be any pharmaceutically acceptable agent such as a non-genetic therapeutic agent, a biomolecule, a small molecule, or cells.

[0034] Exemplary non-genetic therapeutic agents include anti-thrombogenic agents such heparin, heparin derivatives, prostaglandin (including micellar prostaglandin E1), urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, sirolimus (rapamycin), tacrolimus, everolimus, monoclonal antibodies capable of blocking smooth muscle cell proliferation,

hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, rosiglitazone, prednisolone, corticosterone, budesonide, estrogen, estradiol, sulfasalazine, acetylsalicylic acid, mycophenolic acid, and mesalamine; anti-neoplastic/anti-proliferative/anti-mitotic agents such as paclitaxel, cladribine, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, epothilones, endostatin, trapidil, and angiostatin; anti-cancer agents such as antisense inhibitors of c-myc oncogene; anti-microbial agents such as triclosan, cephalosporins, aminoglycosides, nitrofurantoin, silver ions, compounds, or salts; biofilm synthesis inhibitors such as non-steroidal anti-inflammatory agents and chelating agents such as ethylenediaminetetraacetic acid, O,O'-bis (2-aminoethyl)ethyleneglycol-N,N,N',N'-tetraacetic acid and mixtures thereof; antibiotics such as gentamycin, rifampin, minocyclin, and ciprofloxacin; antibodies including chimeric antibodies and antibody fragments; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide; nitric oxide (NO) donors such as lisidomine, molsidomine, L-arginine; NO-carbohydrate adducts, polymeric or oligomeric NO adducts; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warafin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; vascular cell growth promoters such as growth factors, transcriptional activators, and translational promoters; vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; agents which interfere with endogenous vasoactive mechanisms; and any combinations and prodrugs of the above.

[0035] Exemplary biomolecules include peptides, polypeptides and proteins; oligonucleotides; nucleic acids such as double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), and ribozymes; genes; carbohydrates; angiogenic factors including growth factors; cell cycle inhibitors; and anti-restenosis agents. Nucleic acids

may be incorporated into delivery systems such as, for example, vectors (including viral vectors), plasmids or liposomes.

[0036] Non-limiting examples of proteins include monocyte chemoattractant proteins ("MCP-1) and bone morphogenic proteins ("BMP's"), such as, for example, BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15. Preferred BMPS are any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6, and BMP-7. These BMPs can be provided as homodimers, heterodimers, or combinations thereof, alone or together with other molecules. Alternatively, or in addition, molecules capable of inducing an upstream or downstream effect of a BMP can be provided. Such molecules include any of the "hedghog" proteins, or the DNA's encoding them. Non-limiting examples of genes include survival genes that protect against cell death, such as anti-apoptotic Bcl-2 family factors and Akt kinase and combinations thereof. Non-limiting examples of angiogenic factors include acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, and insulin like growth factor. A non-limiting example of a cell cycle inhibitor is a cathepsin D (CD) inhibitor. Non-limiting examples of anti-restenosis agents include p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation.

[0037] Exemplary small molecules include hormones, nucleotides, amino acids, sugars, and lipids and compounds have a molecular weight of less than 100kD.

[0038] Exemplary cells include stem cells, progenitor cells, endothelial cells, adult cardiomyocytes, and smooth muscle cells. Cells can be of human origin (autologous or allogenic) or from an animal source (xenogenic), or genetically engineered.

[0039] Any of the therapeutic agents may be combined to the extent such combination is biologically compatible.

[0040] To provide controlled release of the therapeutic agents in embodiments where such a property is desired, the therapeutic agents may be microencapsulated with polymers to form a polymeric material/therapeutic agent matrix. When delivered into the

target site, the therapeutic agent may be released from the polymer as it slowly dissolves into the aqueous bodily fluids and diffuses out of the polymer.

[0041] As mentioned previously, certain aspects and embodiments of the present invention relate to delivering a therapeutic agent to a target site in a body. Unless described otherwise, non-limiting examples of such target sites include any body lumina and organ such as the coronary vasculature, esophagus, trachea, colon, biliary tract, urinary tract, prostate, brain, lung, liver, heart, skeletal muscle, kidney, bladder, intestines, stomach, pancreas, ovary, cartilage, eye, bone, and the like.

[0042] Aspects and embodiments of the present invention can be used, for example, in any application for treating, preventing, or otherwise affecting the course of a disease or tissue or organ dysfunction. Such applications include inducing or inhibiting angiogenesis, preventing or treating restenosis, treating a cardiomyopathy or other dysfunction of the heart, treating Parkinson's disease, stroke or other dysfunction of the brain, treating cystic fibrosis or other dysfunction of the lung, treating or inhibiting malignant cell proliferation, treating any malignancy, and inducing nerve, blood vessel or tissue regeneration in a particular tissue or organ.

[0043] The foregoing description has been set forth merely to illustrate the invention and is not intended as being limiting. Each of the disclosed aspects and embodiments of the present invention may be considered individually or in combination with other aspects, embodiments, and variations of the invention. In addition, unless otherwise specified, none of the steps of the methods of the present invention are confined to any particular order of performance. Modifications of the disclosed embodiments incorporating the spirit and substance of the invention may occur to persons skilled in the art and such modifications are within the scope of the present invention. Furthermore, all references cited herein are incorporated by reference in their entirety.

1. A needle comprising:
a shaft having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.
2. The needle of claim 1, wherein the distal end comprises opposing first and second surfaces and the second surface is indented towards the second surface.
3. The needle of claim 1, wherein the distal end of the shaft comprises at least one port on a side surface thereof.
4. The needle of claim 2, wherein the distal end terminates in a curvilinear distal tip.
5. The needle of claim 1, wherein the distal end of the shaft is tapered.
6. The needle of claim 1, wherein the distal end comprises opposing first and second extensions, the first and the second extensions being angled towards each other.
7. The needle of claim 6, wherein the second extension is longer than the first extension in a direction parallel to the longitudinal axis of the shaft.
8. The needle of claim 6, wherein the first and second extensions mutually define at least one opening offset from the longitudinal axis of the shaft.
9. The needle of claim 8, wherein the at least one opening is a pair of openings, each opening being offset from the longitudinal axis of the shaft.
10. The needle of claim 6, wherein the first and the second extensions each terminate in beveled distal tips.

11. A catheter having the needle of claim 1 at a distal portion thereof.
12. A syringe having the needle of claim 1 at a distal portion thereof.
13. A method of delivering a therapeutic agent to a target site of a body comprising:
providing a drug delivery device containing a therapeutic agent and comprising the needle of claim 1 at a distal portion thereof; and
delivering the therapeutic agent through the needle to a target site of a body.
14. The method of claim 13, wherein the drug delivery device is a catheter or a syringe.
15. The method of claim 13, wherein the target site is selected from a group consisting of the heart, lung, brain, liver, skeletal muscle, smooth muscle, kidney, bladder, intestines, stomach, pancreas, ovary, prostate and cartilage.
16. The method of claim 13, wherein delivering the therapeutic agent comprises directly delivering the therapeutic agent to the target site.
17. A method of accessing a drug delivery port comprising:
providing a drug delivery device comprising the needle of claim 1 at a distal portion thereof; and
inserting the needle of the drug delivery device into a drug delivery port to access the drug delivery port.
18. The method of claim 17, wherein accessing the drug delivery port comprising introducing a therapeutic agent through the needle into the drug delivery port.
19. The method of claim 17, wherein the drug delivery device is a syringe or catheter.

20. The method of claim 17, wherein the drug delivery port comprises a septum, the needle of the drug delivery device piercing the septum to access the drug delivery port.
21. A method of delivering a therapeutic agent to a spinal column comprising:
providing a drug delivery device containing a therapeutic agent and comprising the needle of claim 1 at a distal portion thereof; and
introducing the therapeutic agent through the needle into a spinal column.
22. A method of collecting a fluid sample from a body comprising:
providing a drug delivery device comprising the needle of claim 1 at a distal portion thereof;
inserting the needle into a fluid containment site of a body; and
creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body.
23. The method of claim 22, wherein the fluid sample comprises blood, amniotic fluid, serous fluid, or cerebrospinal fluid.
24. A method of directly delivering a therapeutic agent to a target site of a body comprising:
providing a drug delivery device comprising a Huber needle at a distal portion thereof;
positioning the needle adjacent to the target site; and
directly delivering the therapeutic agent through the Huber needle to the target site, wherein the target site is not a spinal cord.
25. The method of claim 24, wherein the target site is an organ selected from a group consisting of the heart, lung, brain, liver, skeletal muscle, smooth muscle, kidney, bladder, intestines, stomach, pancreas, ovary, prostate and cartilage.

26. The method of claim 25, wherein the target site is the heart.

27. The method of claim 26, wherein the target site is the myocardium.

28. A method of directly delivering a therapeutic agent to a target site of a body comprising:

providing a drug delivery device comprising a pencil-point needle at a distal portion thereof;

positioning the needle adjacent to the target site; and

directly delivering the therapeutic agent through the pencil-point needle to the target site, wherein the target site is not a spinal cord.

29. The method of claim 28, wherein the target site is an organ selected from a group consisting of the heart, lung, brain, liver, skeletal muscle, smooth muscle, kidney, bladder, intestines, stomach, pancreas, ovary, prostate and cartilage.

30. The method of claim 29, wherein the target site is the heart.

31. The method of claim 30, wherein the target site is the myocardium.

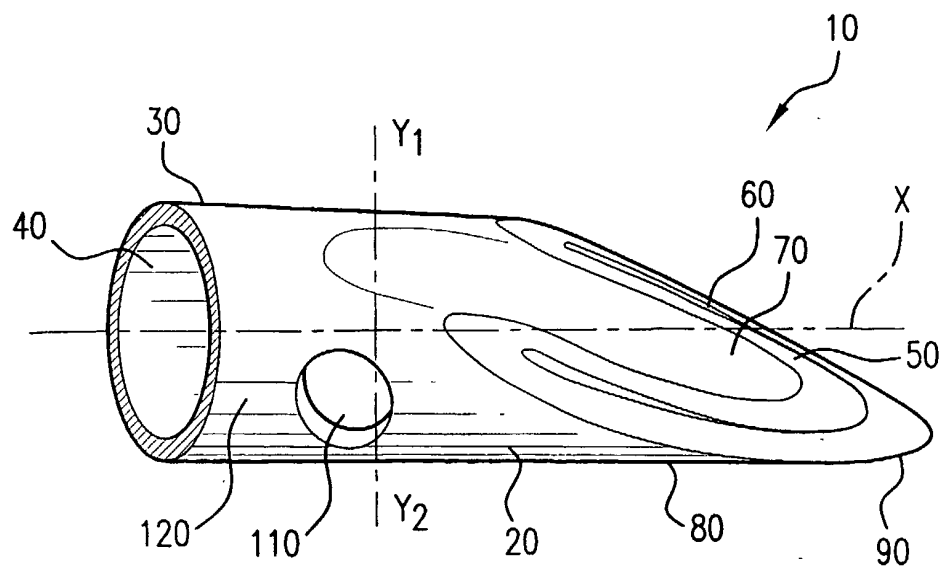


FIG. 1

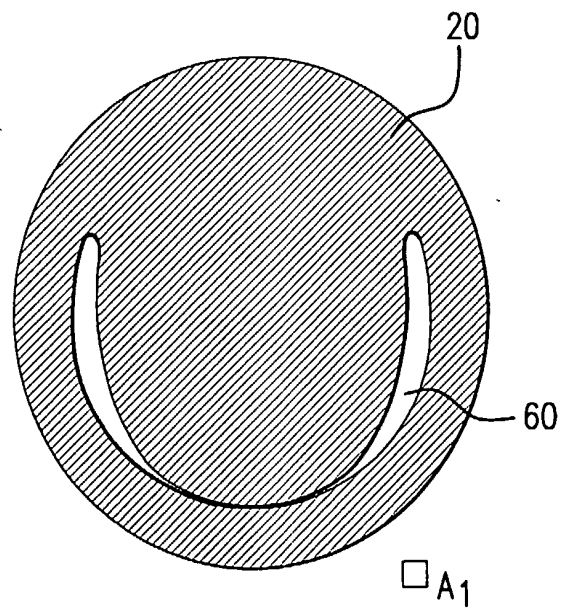


FIG. 2

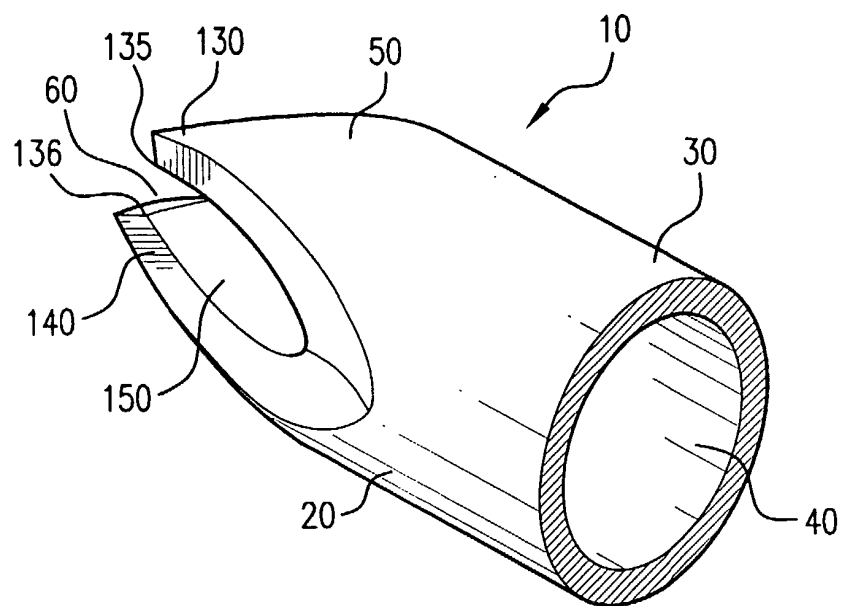


FIG. 3

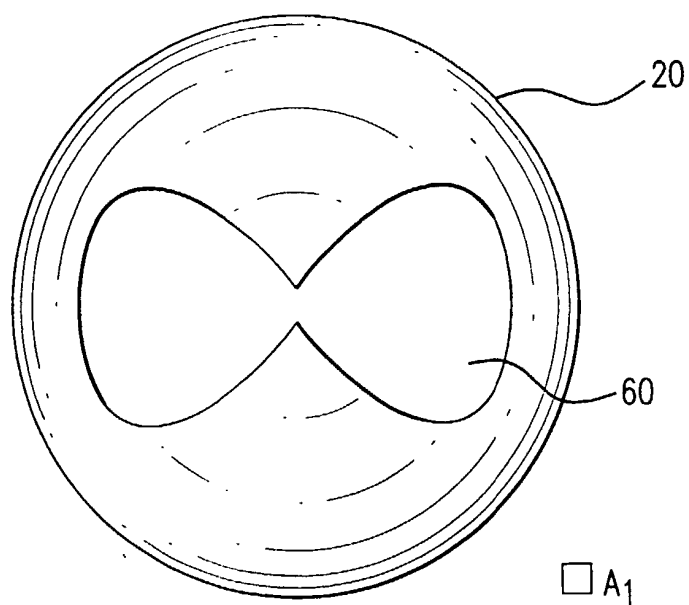


FIG. 4

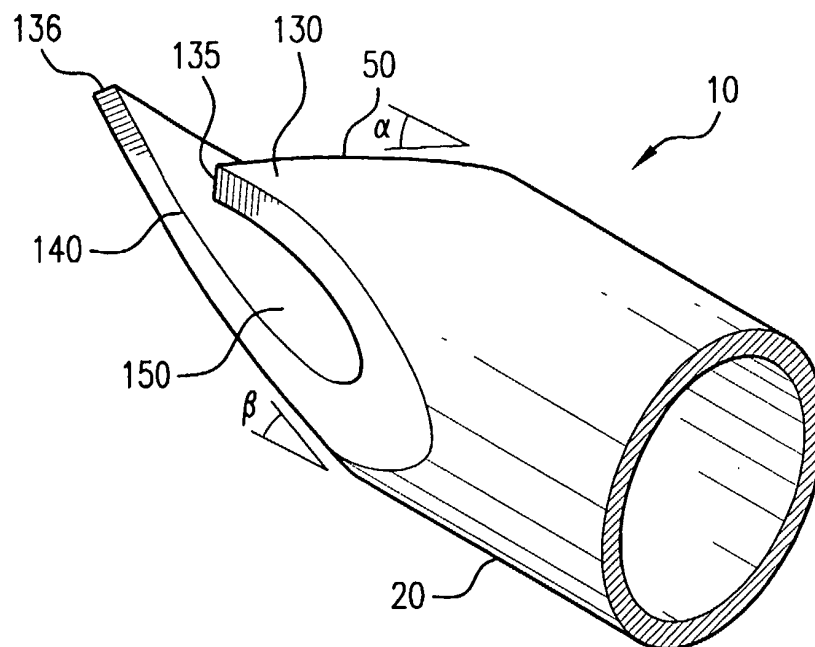


FIG. 5

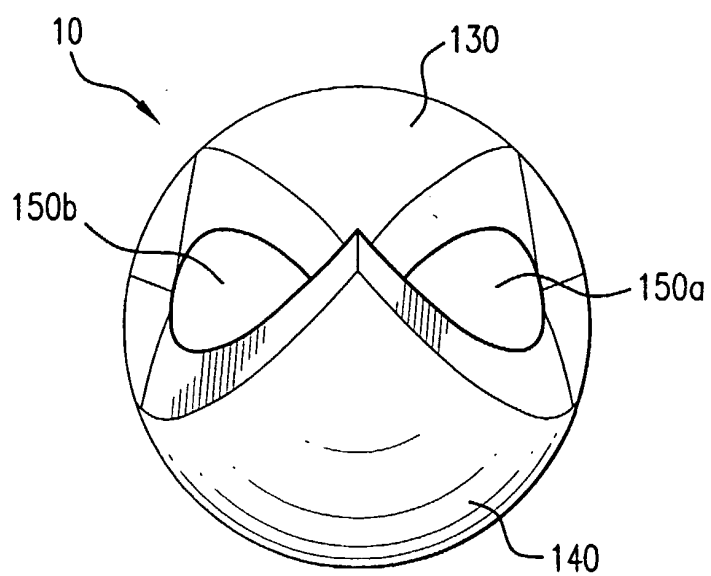


FIG. 6

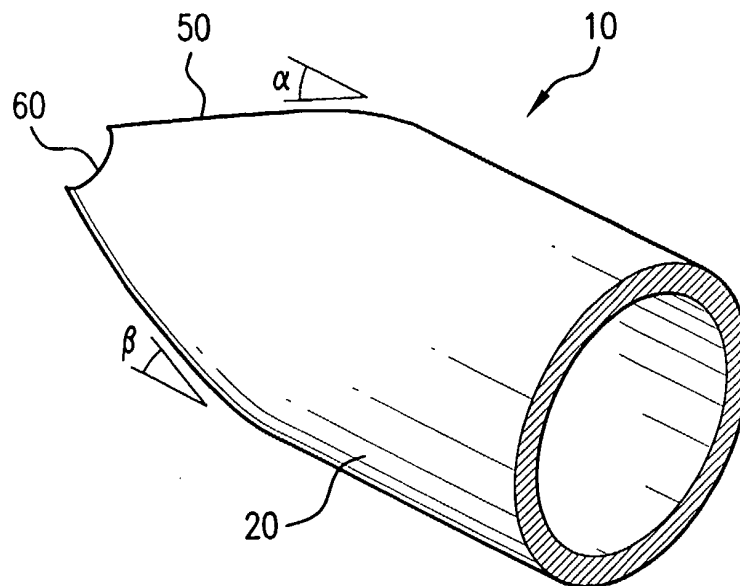


FIG. 7

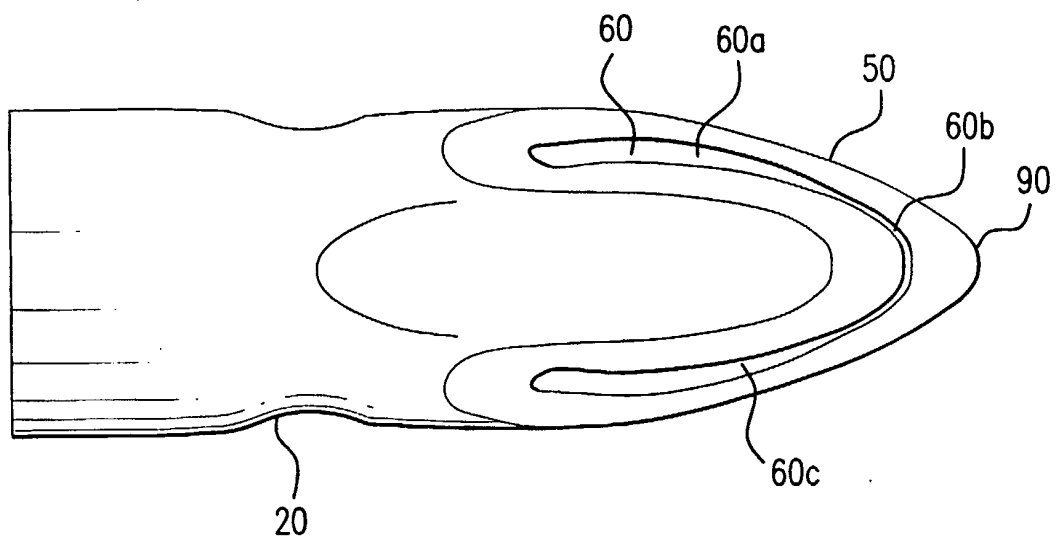


FIG. 8

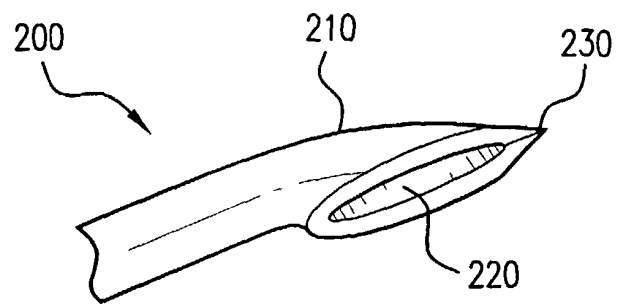


FIG. 9

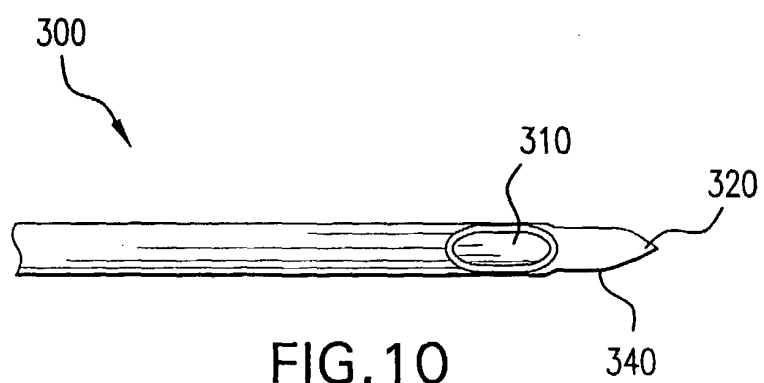


FIG. 10

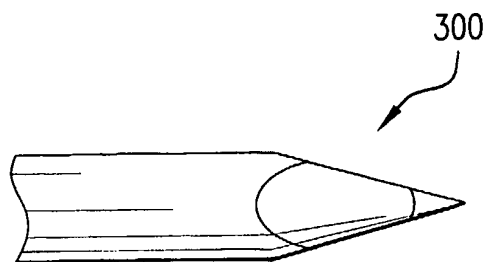


FIG. 11

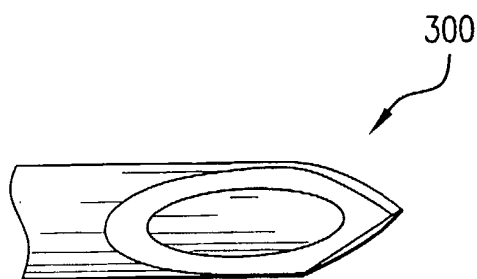


FIG. 12

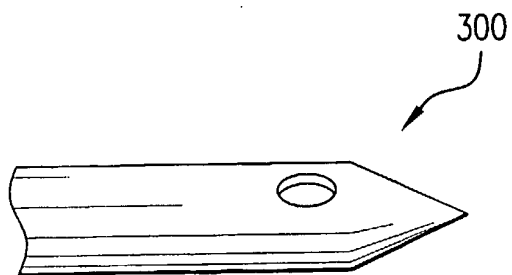


FIG. 13

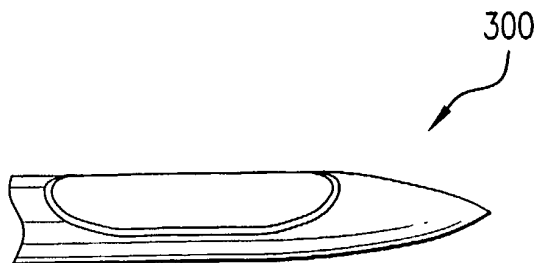


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2005/007707

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A needle (10) having a shaft (20) with a distal end (40) defining a distal opening (60). The shaft has a longitudinal axis (X) that extends through the distal opening and the distal opening has a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/007707

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

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)

IPC 7 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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 826 492 A (MAGASI ET AL) 2 May 1989 (1989-05-02) column 7, line 8 - line 22; figures 6,7 -----	1-12
X	US 3 906 932 A (AYRES ET AL) 23 September 1975 (1975-09-23) the whole document -----	1
X	US 4 753 641 A (VASLOW ET AL) 28 June 1988 (1988-06-28) abstract; figures -----	1
X	BE 631 225 A (BAXTER LABORATOIRE, INC.) 16 August 1963 (1963-08-16) the whole document -----	1
X	FR 2 057 353 A (ESCOFFIER FRERES SA) 21 May 1971 (1971-05-21) abstract; figures -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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 document 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.

8 document member of the same patent family

Date of the actual completion of the international search

24 June 2005

Date of mailing of the international search report

05/07/2005

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Authorized officer

Ehram, F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/007707

Box 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. ☒ Claims Nos.: 13-31
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery and Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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 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 fee, this Authority did not invite payment of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/007707

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