

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 June 2005 (02.06.2005)

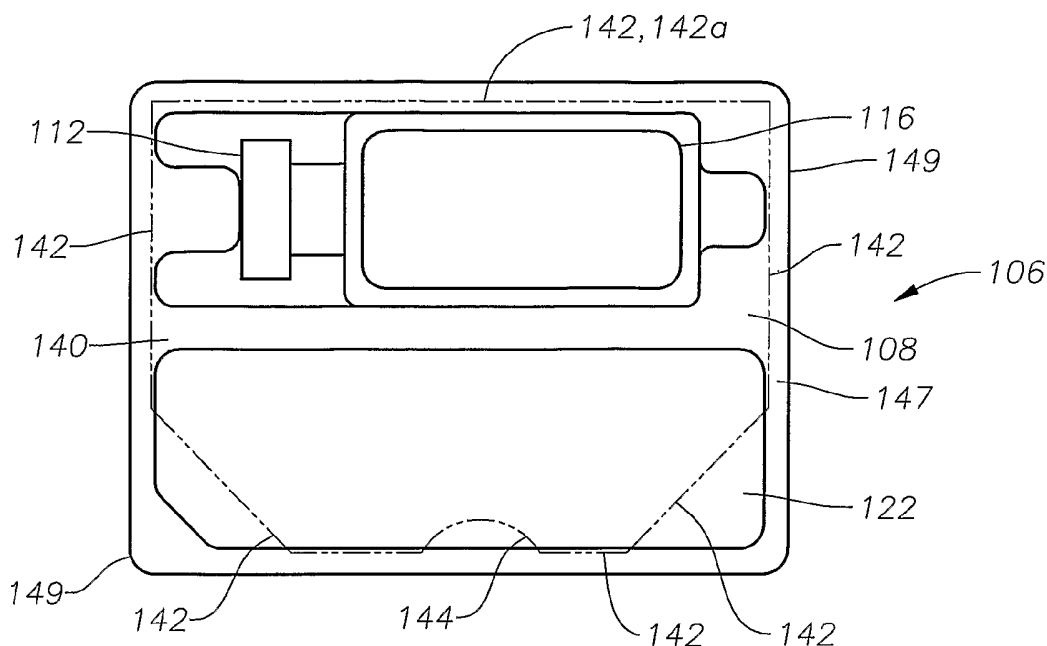
PCT

(10) International Publication Number
WO 2005/048873 A2

- (51) International Patent Classification⁷: **A61F** (74) Agents: LEE, W. David, et al.; Alcon Research, Ltd., Mail Code Q-148, 6201 South Freeway, Fort Worth, Texas 76132 (US).
- (21) International Application Number: PCT/US2004/036519
- (22) International Filing Date: 2 November 2004 (02.11.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/519,133 12 November 2003 (12.11.2003) US
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: KIT FOR ADMINISTRATION OF A DRUG



(57) Abstract: A kit for the administration of a drug, especially to the posterior segment of the eye, is disclosed. The kit may include a plastic tray having a specially designed plastic window that functions as a tamper-evident seal. The kit may also minimize potential damage to components of the kit that are specially designed for posterior segment ophthalmic administration.



Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

KIT FOR ADMINISTRATION OF A DRUG

This application claims the priority of U.S. Provisional Application No. 60/519,133 filed November 12, 2003.

5 Field of the Invention

The present invention generally pertains to a kit for the administration of a drug, especially an ophthalmic drug. More particularly, but not by way of limitation, the present invention pertains to a kit for the administration of a drug to the posterior segment of the eye.

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Description of the Related Art

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Several diseases and conditions of the posterior segment of the eye threaten vision. Age related macular degeneration (ARMD), choroidal neovascularization (CNV), retinopathies (e.g., diabetic retinopathy, vitreoretinopathy), retinitis (e.g., cytomegalovirus (CMV) retinitis), uveitis, macular edema, glaucoma, and neuropathies are several examples.

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ARMD is the leading cause of blindness in the elderly of developed countries. ARMD attacks the center of vision and blurs it, making reading, driving, and other detailed tasks difficult or impossible. About 200,000 new cases of ARMD occur each year in the United States alone. Current estimates reveal that approximately forty percent of the population over age 75, and approximately twenty percent of the population over age 60, suffer from some degree of macular degeneration. “Wet” ARMD is the type of ARMD that most often causes blindness. In wet ARMD, newly

formed choroidal blood vessels (CNV) leak fluid and cause progressive damage to the retina.

In the particular case of CNV in ARMD, three main methods of treatment are currently being developed, (a) photocoagulation, (b) photodynamic therapy, and (c) the use of angiogenesis inhibitors. Photocoagulation is the most common treatment modality for CNV. However, photocoagulation can be harmful to the retina and is impractical when the CNV is near the fovea. Furthermore, over time, photocoagulation often results in recurrent CNV. Photodynamic therapy is a relatively new technology. The long-term efficacy of photodynamic therapy to treat ARMD is still largely unknown. Oral or parenteral (non-ocular) administration of anti-angiogenic compounds is also being tested as a systemic treatment for ARMD. However, due to drug-specific metabolic restrictions, systemic administration usually provides sub-therapeutic drug levels to the eye. Therefore, to achieve effective intraocular drug concentrations, either an unacceptably high dose or repetitive conventional doses are required.

Various needles and cannulae have been used to deliver drugs to the back of the eye, external to the globe. Examples of such needles and cannulae are disclosed in U.S. Patent No. 6,413,245 and the references cited therein.

Various implants have also been developed for delivery of anti-angiogenic (and other) compounds locally to the eye. Examples of such implants are disclosed in U.S. Patent Nos. 5,824,072, U.S. Patent No. 5,476,511, and U.S. Patent No. 5,773,019.

Kits for the administration of ophthalmic drugs have been reported in the literature. An example of such a kit is disclosed in International Publication No. WO 01/49226.

However, a need exists in the field of ophthalmology for an improved kit for the administration of an ophthalmic drug, especially to the posterior segment of the eye. The improved kit should be safe for the patient, easy for the physician to use, capable of supporting the administration of a wide spectrum of drugs, and capable of supporting administration of drug in an outpatient setting.

Summary of the Invention

The present invention is a kit for the administration of a drug, especially to the posterior segment of the eye. In one aspect of the present invention, the kit may include a plastic tray having a specially designed plastic window that functions as a tamper-evident seal. In another aspect of the invention, the kit may minimize potential damage to components of the kit that are specially designed for posterior segment ophthalmic administration.

Brief Description of the Drawings

For a more complete understanding of the present invention, and for further objects and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective, schematic view of a kit for the administration of a drug according to a preferred embodiment of the present invention;

FIG. 2 is a top, schematic view of an internal support structure of the kit of FIG. 1;

FIG. 3 is a top, schematic view of a plastic tray for holding the components of the kit of FIG. 1;

FIG. 4 is a front, schematic view of a vial holding the drug to be administered using the kit of FIG. 1;

FIG. 5 is a side, partially sectional, schematic view of a preferred embodiment of a cannula of the kit of FIG. 1;

5 FIG. 6 is a top, schematic view of primary packaging of the cannula of FIG. 5;

FIG. 7 is a top, schematic view of a syringe of the kit of FIG. 1 and its primary packaging; and

FIG. 8 is a top, schematic view of a needle and needle guard of the kit of FIG. 1 and its primary packaging.

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Detailed Description of the Preferred Embodiments

The preferred embodiments of the present invention and their advantages are best understood by referring to FIGS. 1 through 8 of the drawings, like numerals being used for like and corresponding parts of the various drawings.

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FIGS. 1-3 schematically illustrate a kit 100 for the administration of a drug according to a preferred embodiment of the present invention. Kit 100 generally includes a setup structure 102, a support structure 104 for disposing within setup structure 102, and a plastic tray 106 for disposing within both support structure 104 and setup structure 102. Kit 100 is preferred for administration of an ophthalmic drug, and kit 100 is most preferred for administration of a drug to the posterior segment of the eye. However, kit 100 may also be used for the administration of non-ophthalmic drugs.

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Referring to FIGS. 3-8, tray 106 includes a top surface 108. Top surface 108 includes an area 112 for receiving a bottle or vial 114 of drug or pharmaceutical preparation 115 to be administered; an area 116 for receiving the primary packaging

118 of a cannula 50 for administering drug; and an area 122 for receiving the primary packaging 124 of a syringe 126 and the primary packaging 128 of needle 130 and needle guard or shield 132, all of which are used for administering drug. Areas 112, 116, and 122 are preferably recessed from top surface 108 and are preferably
5 integrally molded into tray 106.

Bottle 114 is preferably a conventional glass vial 134 having a rubber stopper 136 retained by a sealing structure 138. Drug 115 to be held in bottle 114 includes a pharmaceutically active agent. The pharmaceutically active agent may be any
10 any pharmaceutically active agent suitable for use in humans or animals, and is preferably any pharmaceutically active agent suitable for ophthalmic use. A preferred ophthalmic pharmaceutically active agent is an angiostatic steroid for the prevention or treatment of age related macular degeneration. Preferred angiostatic steroids include the angiostatic steroids disclosed in U.S. Patent Nos. 5,679,666 and 5,770,592, which are incorporated herein in their entirety by this reference. Preferred
15 ones of such angiostatic steroids are cortisenes including 4,9(11)-Pregnadien-17 α ,21-diol-3,20-dione and 4,9(11)-Pregnadien-17 α ,21-diol-3,20-dione-21-acetate.

Primary packaging 118, 124, and 128 are preferably conventional soft or hard plastic packaging having a removable, sterile paper cover. A preferred cannula 50 is shown in Fig. 5 and is more fully disclosed in U.S. Patent No. 6,413,245, which is
20 incorporated herein in its entirety by this reference. Cannula 50 has a curved distal portion 52 and a straight proximal portion 54 separated by a bend 57. Cannula 50 also has a hub 56, a hollow bore 58, blunt tip 62, and an orifice 64. As is more fully described in U.S. Patent No. 6,413,245, the arc length A of distal portion 52, the radius of curvature B of distal portion 52, the angle C between a tangent 72 of distal
25 portion 52 at bend 57 and proximal portion 54, and the length D of proximal portion

54 are specially designed to facilitate drug delivery to the posterior segment of the eye.

Syringe 126 is a conventional syringe such as the syringe available from Becton, Dickinson, and Company of Franklin Lakes, New Jersey under part number 309628 W12811. Needle 130 is a conventional, straight needle, and needle guard 132 is a
5 conventional needle guard. A preferred needle and needle guard is available from Becton, Dickinson, and Company under part number 305165.

Tray 106 preferably also includes a clear plastic window or cover 140 that is adhered to top surface 108. Window 140 preferably covers all of top surface 108, including areas 112, 116, and 122. Window 140 preferably includes a perforation line
10 142 (shown in dashed lines) having a pre-cut section 144. Window 140 is preferably made from polystyrene. Window 140 is preferably heat sealed to top surface 108 in a region 147 generally between perforation line 142 and the outer periphery 149 of top surface 108.

Referring to FIG. 2, support structure 104 is preferably made of a foldable,
15 corrugated material of sufficient strength to protect tray 106 and its contents during shipping. Structure 104 has a top surface 146 with an opening 148 leading to an internal volume 150 designed to receive tray 106. The outer periphery 149 of top surface 108 of tray 106 is supported by top surface 146.

Referring to FIG. 1, setup structure 102 is preferably made of foldable
20 paperboard that is suitable for receiving high quality graphics via conventional printing methods. Structure 102 generally includes a body 152 having a top surface 154 with an opening 156 leading to an internal volume 158, a cover 160 rotationally coupled to body 152 along an edge 162 of top surface 154, and opposing ends 164a and 164b. Ends 164a and 164b may be unfolded in the conventional manner of a
25 carton to provide access to internal volume 158. In addition, cover 160 may be

removably secured to a front surface 161 of body 152 using a pressure sensitive tape or other conventional sealing material (not shown). Tray 106 is sized to fit within internal volume 150 of support structure 104, and the resulting combination of tray 106 and structure 104 is sized to fit within internal volume 158 of setup structure 102.

5 Setup structures similar to structure 102 of the present invention having a body 152, top surface 154, an internal volume 158, cover 160, and opposing ends 164a and 164b, but without opening 156, are conventional. Such conventional structures may have a perforation line in the cardboard material of top surface 154 that can be broken to provide access to internal volume 158. In addition, such conventional structures
10 may have a clear plastic window disposed in the cardboard material of top surface 154 and within the perforation line to provide visibility to internal volume 158.

Kit 100 may be used by a physician and his or her staff in the following preferred manner. Kit 100 is shipped to a user as shown in FIG. 1, with the exception that cover 160 is secured to front surface 161 of structure 102 via pressure sensitive
15 tape. When kit 100 is ready for use, the seal created by the pressure sensitive tape is broken and cover 160 is lifted as shown in FIG. 1. Clear plastic window 140 of tray 106 allows the user to visualize all the components required for drug delivery. In addition, if upon opening cover 160 perforation line 142 is unbroken, the user knows that the contents of kit 100 have not been tampered with subsequent to manufacture
20 and that the contents of kit 100 are safe to use. The use of a perforated, clear plastic window 140, versus a conventional Tyvek™ cover, also immediately signifies to a user that tray 106 and the exteriors of bottle 114 and primary packaging 118, 124, and 128 are not sterile.

Next, the user's thumb is placed within pre-cut section 144, and window 140
25 is opened and preferably removed by pulling toward cover 160, breaking perforation

segment of the eye. The improved kit is safe for the patient, easy for the physician to use, capable of supporting the administration of a wide spectrum of drugs, and capable of supporting administration of drug in an outpatient setting.

5 It is believed that the operation and construction of the present invention will be apparent from the foregoing description. While the apparatus and methods shown or described above have been characterized as being preferred, various changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the following claims.

What is claimed is:

1. A kit for the administration of a drug, comprising:

a plastic tray having a top surface, an area recessed from said top surface and holding a component of said kit, and a plastic window sealed to said top surface and covering said area; and

a perforation line formed in said window and enclosing said area;

wherein said perforation line may be broken to provide access to said area and said component.

2. The kit of claim 1 wherein said perforation line comprises a pre-cut

section.

3. The kit of claim 1 wherein said plastic window is made from a clear plastic allowing visibility to said area.

4. The kit of claim 1 wherein said drug is an ophthalmic drug.

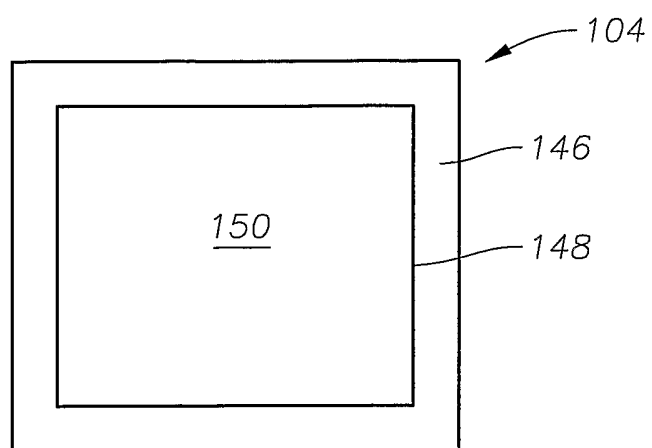
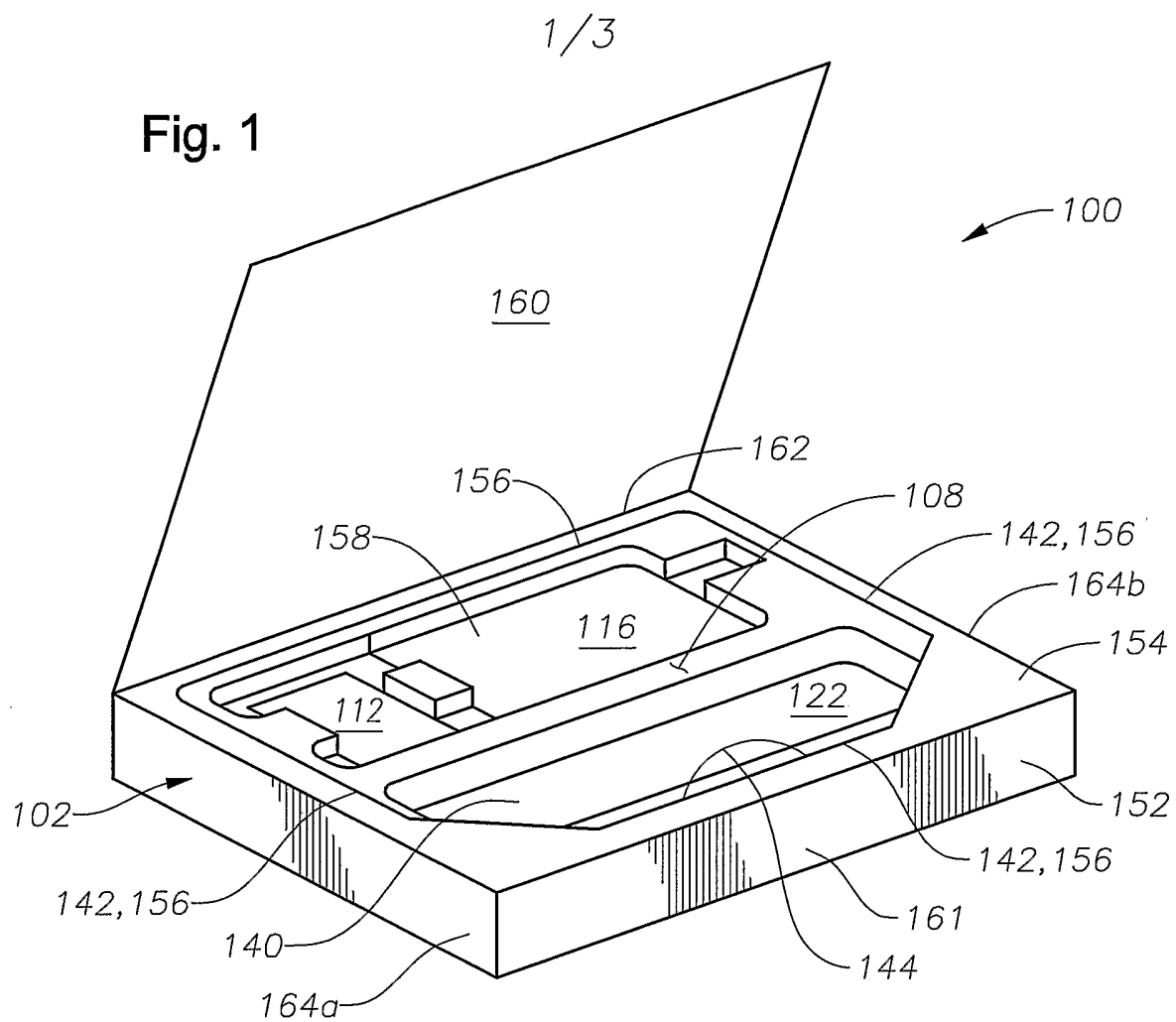


Fig. 2

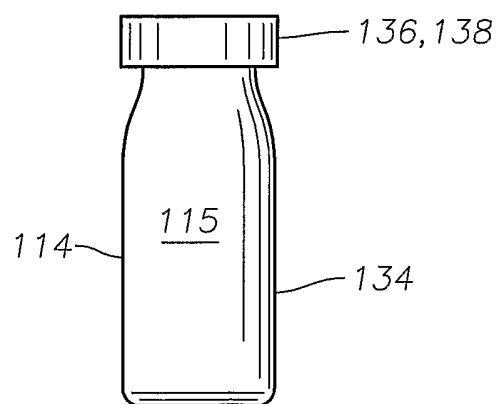


Fig. 4

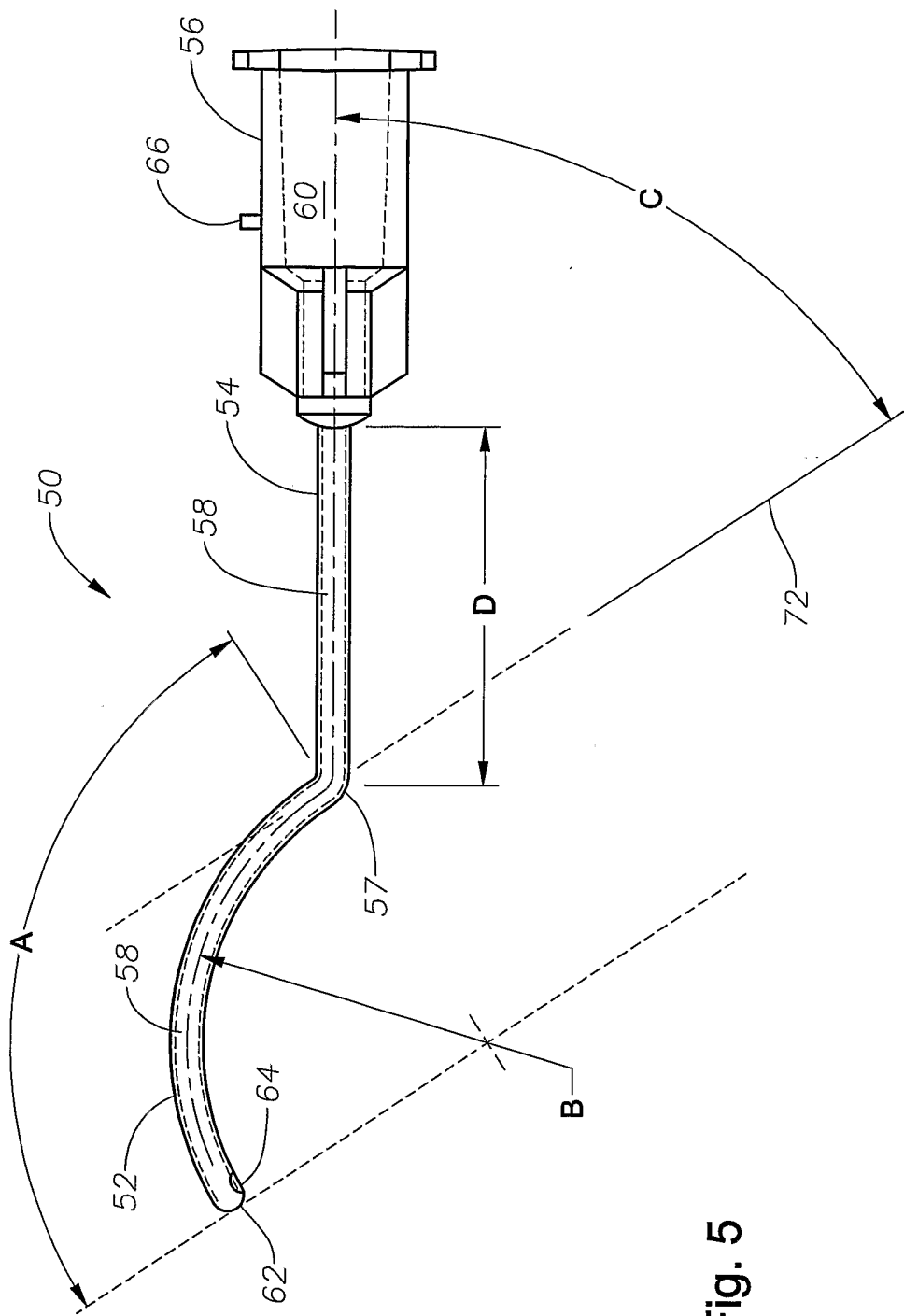


Fig. 5

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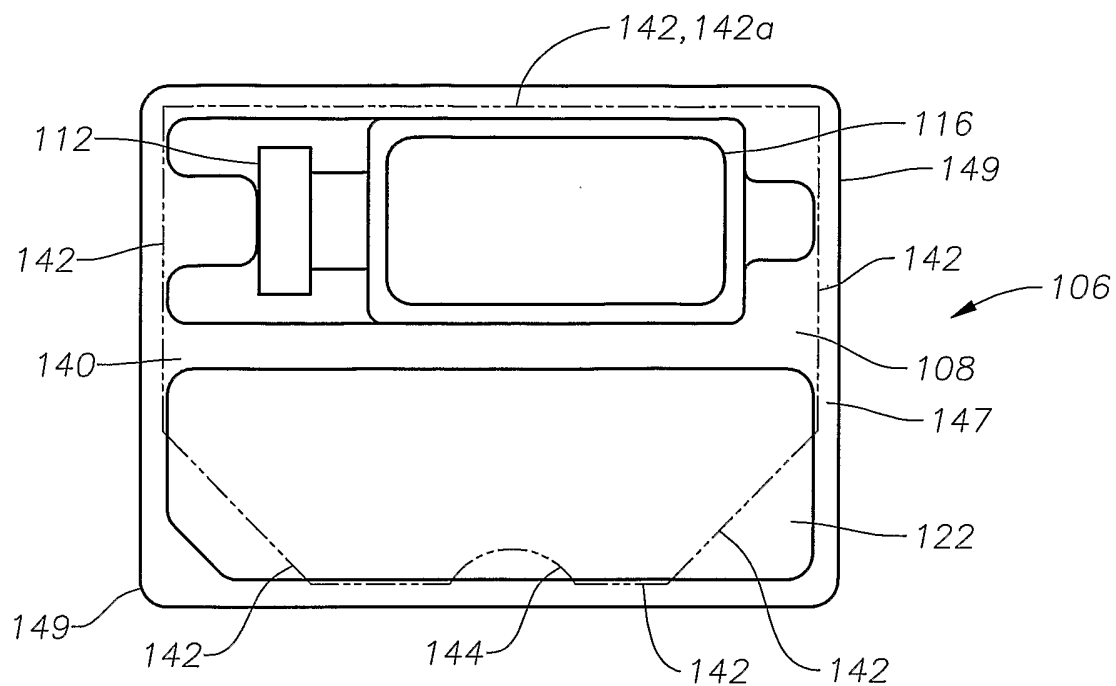


Fig. 3

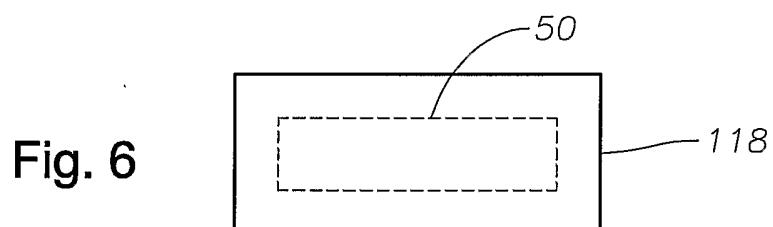


Fig. 6

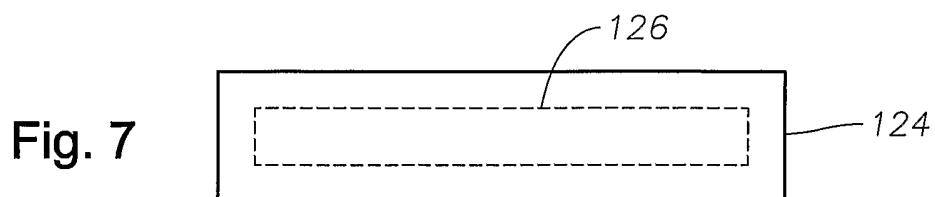


Fig. 7

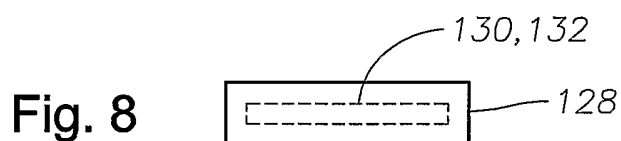


Fig. 8