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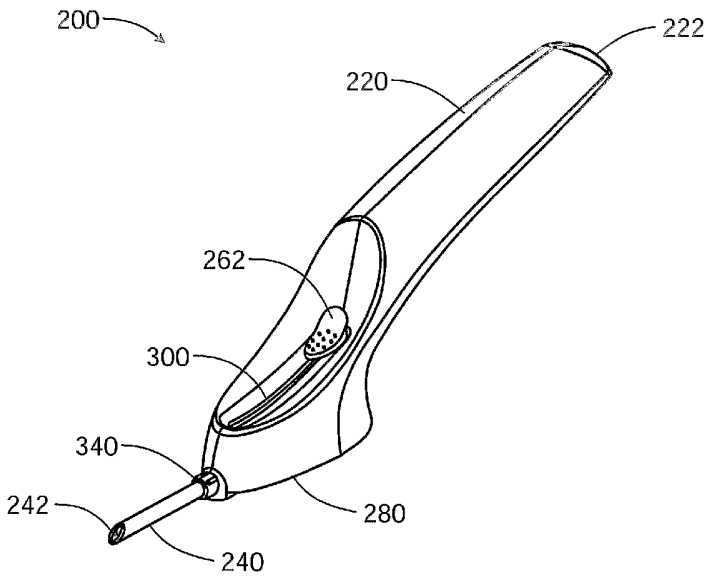
(54) Title: IMPLANTING DEVICE AND METHOD OF USING SAME



(57) Abstract: A device for inserting implantable objects beneath the skin of a patient includes a handle for grasping the device and a base connected to the handle. The base comprises a post, a cannula, and a flexible actuator positioned in an angled track. The cannula is positioned coaxially around and is longitudinally slidable over the post from an extended position, where an implantable object is retained in the cannula, to a retracted position, where the implantable object is released from the cannula. A flexible actuator positioned on an angled track in the base is slidably engaged with a boss on the cannula and is used to move the cannula from an extended position to a retracted position to release the implantable object from the cannula; the actuator flexes between a locked and an unlocked position. The angled track provides for control of the release of the implantable object.

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IMPLANTING DEVICE AND METHOD OF USING SAME

FIELD OF THE INVENTION

[0001] The present invention relates generally to an implanting device and a method for inserting implantable objects beneath the skin of a patient. More particularly, the present invention relates to an implanting device which provides improved control of implantable object release due to an angled track located on the base of the implanting device.

BACKGROUND

[0002] Drugs may be delivered to patients by a variety of methods including oral intravenous administration, inhalation of aerosols, an epidermal patch, and subcutaneous implants. The method chosen depends, among other things, upon the desired therapeutic concentration of the drug or pharmaceutical to be achieved in the patient and the duration the concentration must be maintained.

[0003] Recently released materials and pharmaceuticals have been developed which allow a drug to be subcutaneously introduced or administered beneath the skin of a patient so that the drug is slowly released over a long period of time. Such implants allow a drug to be dispensed in a relatively uniform dose over many months or years. This method of administering drugs is becoming especially important and popular as a method of administering contraceptives.

[0004] Previously, subcutaneous implants and other types of implants have been inserted beneath the skin by use of a trocar system, which is a two piece system including a cannula and an obdurator. First, an incision is made through the skin and the cannula and obdurator are inserted together through the skin. Next, the obdurator is withdrawn, leaving the cannula in place as a guide for inserting the implant. The implant is inserted through the

cannula, and the obduratoris used to push the implant to the end of the cannula. The obdurator is then used to force the implant out of the cannula while the cannula is withdrawn, such that the implant is deposited in the channel previously occupied by the cannula. The cannula and obdurator are then withdrawn completely, leaving the implant in place beneath the skin.

[0005] This trocar insertion process requires substantial expertise in coordinating the pressing of the obdurator and the withdrawing of the cannula to deposit the implant in the channel. If these two processes are not properly coordinated, the implant may be forced into the tissue so that the implant has to make its own channel as it is inserted. Forcing the implant into the tissue causes additional trauma to the tissue and may cause the implant to become damaged by the force exerted by the obdurator. This is especially true for a hydrogel implant. While subcutaneous implantation may be done surgically using a scalpel to make the incision and a trocar system to place the implant, such methods require a physician or other highly trained person. Recently improved instruments for inserting subcutaneous implants have been developed which typically require far less skill to operate, and thus may be better suited for non-surgical physicians and other less skilled individuals, and require less time to perform the implantation procedure.

[0006] U.S. Pat. No. 4,105,030 discloses an implanting apparatus for use in subcutaneously implanting multiple pellets in animals. The apparatus provides a one-handed implanting system that reduces the risk of trauma from forcing the implant into the tissue, and it also reduces contamination. The animal implant apparatus includes a handle, a needle containing the pellets to be implanted, and a rod positioned within the needle for pushing the pellets out of the needle. Once the needle containing the pellets has been inserted subcutaneously, a spring loaded trigger on the handle is activated which causes the needle to be automatically withdrawn by a spring leaving the implanted pellets in place. However, the

handle configuration of this implanting device is designed for use in animals, such as cattle, and due to it's size and shape, it would be difficult to use for inserting implants subcutaneously in humans. Further, it is not possible to control the motion of the needle in this device because the needle will automatically retract upon activation of the trigger. The complex spring loaded propelling system and trigger of this implant apparatus increase the chances that the device will jam and fail to eject the pellets when required.

[0007] Contraceptive steroids that are implanted subcutaneously are normally imbedded in biologically inert polymers, some of which are biodegradable. The pellets made from such materials are typically long and cylindrical in cross section, and the size of these materials is on the order of the size of a pencil lead. The materials are generally flexible, ranging from somewhat flexible to very flexible nature. See, for example, U.S. Pat. No. 4,451,253, which describes some exemplary contraceptive pellets and an apparatus for individually implanting such pellets subcutaneously.

[0008] The size and shape of an implant pellet are important in determining the rate of delivery of a particular drug from a subcutaneous implant. Practical considerations put constraints on the dimensions of a subcutaneous implant. In particular, the length of an implant is generally limited. A typical implant is on the order of 1 1/2 to 2 inches long. Longer implants are much more difficult to accurately locate. They are also more susceptible to breakage, which may affect the drug delivery rate and, in general, are simply more cumbersome and cosmetically apparent. Because of this, it is frequently necessary to implant a desired amount of a drug as a plurality of individual, shorter implant pellets rather than as a single longer pellet. Thus, an instrument which can quickly allow a physician or nurse to implant a plurality of pellets with minimal physical and psychological trauma to a patient would be desirable. When implanting several implants, care must be taken to accurately place the implants in a manner such that one does not interfere with the dissolution of the others.

SUMMARY

[0009] Embodiments of the present invention include a device which may be used for implanting various pharmaceuticals and therapeutic drug delivery devices. Such implantable objects may include those such as silicone rubber capsules or tubes that contain a synthetic progestin birth control hormone. The flexible tubes may steadily release a low dose of hormone into the bloodstream.

[0010] One embodiment of the present invention is an implant device for inserting implantable objects subcutaneously into a patient, comprising a handle for grasping the device during insertion of an implantable object and a base connected to the handle. The base comprises a post, a cannula, and a flexible actuator positioned in an angled track. The cannula is positioned coaxially around and is longitudinally slidable over the post from an extended position, where an implantable object is retained in the cannula, to a retracted position, where the implantable object is released from the cannula. A flexible actuator positioned on an angled track in the base is slidably engaged with a boss on the cannula and is used to move the cannula from an extended position to a retracted position to release the implantable object from the cannula; the actuator flexes between a locked and an unlocked position.

[0011] The flexible actuator of the implant device may be locked to prevent movement of the cannula and thereby prevents any undesired dispensing or insertion of implantable objects. By pressing the flexible actuator into a second position (when the actuator is in the track in a distal position with respect to the handle) a locking portion of the actuator is engaged to prevent retraction of the cannula. The lock may be released by alternately pressing the flexible actuator to a first position.

[0012] The implanting device may further include one or more implantable objects within the cannula. The implanting device may also include a cartridge for holding multiple implantable objects that are sequentially fed into the cannula after an implantable object is dispensed by movement of the actuator and cannula. The cartridge may be removably mounted and have a channel containing an implantable object that is parallel to a central bore of the cannula.

[0013] According to a further aspect of the present invention, a method of inserting a subcutaneous implantable object with an implanting device of the present invention includes inserting a cannula of the implanting device beneath the skin of a patient with an implantable object positioned within the cannula and manually retracting the cannula along the angled track using the flexible actuator to release the implantable object beneath the skin. The implanting device may then be withdrawn from the patient or another implantable object from a cartridge positioned within the cannula may be subsequently inserted. The implanting device used in the method includes a handle, a base, and a cannula slidably engaged with a flexible actuator located in an angled track.

[0014] According to another further aspect of the present invention, a kit for inserting an implantable object and maintaining sterile conditions includes an implanting device including a handle and a base connected to the handle, the base comprising a post, a cannula, and a flexible actuator positioned in an angled track, where the cannula is positioned coaxially around and is longitudinally slidable over the post from an extended position, where an implantable object is retained in the cannula, to a retracted position, where the implantable object is released from the cannula, and where the actuator is positioned on an angled track in the base is slidably engaged with a boss on the cannula and is used to move the cannula from an extended position to a retracted position to release the implantable object from the

cannula; a cutting device for making an implanting incision in a patient's tissue; supplies for maintaining sterility of the implant insertion process; and wound dressings.

[0015] The implantable object and implanting device of the present invention may be useful for insertion of implants coated with a sol-gel coatings or with hydrogel implants. The active agent may be slowly released by the implant or the coating on the implant when placed in watery environments such as blood or tissue. The device may be used to implant any such implant.

[0016] The present invention provides embodiments of an implanting device for inserting implantable objects which provides improved control of implantable object release due to the angled track located on the base of the implanting device. The flexible actuator is positioned on the angled track, which helps to prevent the forcing of the implantable object into the tissue, as such uncontrollable forcing can cause trauma to the tissue and may cause the implant to become damaged.

DESCRIPTION OF THE DRAWINGS

[0017] In part, other aspects, features, benefits and advantages of the embodiments of the present invention will be apparent with regard to the following description, appended claims and accompanying drawings where:

[0018] FIG. 1 is an isometric view of an implanting device according to the present invention with the cannula retracted and the flexible actuator is in an unlocked position;

[0019] FIG. 2 is an isometric view of the implanting device with the cannula in a fully extended position with the flexible actuator in a locked position;

[0020] FIG. 3 is an exploded view of an implanting device according to an embodiment of the present invention.

[0021] FIG. 4 is a side view of an implanting device according to the present invention with the cannula in a fully extended position with the flexible actuator in a locked position;

[0022] FIG. 5 is a top view of an implanting device according to the present invention with the cannula in a fully extended position with the flexible actuator in a locked position.

DETAILED DESCRIPTION

[0023] Before the present compositions and methods are described, it is to be understood that this invention is not limited to the particular molecules, compositions, methodologies or protocols described, as these may vary. It is also to be understood that the terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope of the present invention which will be limited only by the appended claims.

[0024] It must also be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural reference unless the context clearly dictates otherwise. Thus, for example, reference to a "cell" is a reference to one or more cells and equivalents thereof known to those skilled in the art, and so forth. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the present invention, the preferred methods, devices, and materials are now described. All publications mentioned herein are incorporated by reference. Nothing herein is to be construed as an admission that the invention is not entitled to antedate such disclosure by virtue of prior invention.

[0025] The present invention provides an implanting device for subcutaneously inserting implantable objects containing beneficial agents, such as pharmaceuticals for the prevention, treatment, and diagnosis of disease. The implanting device **200** according to one embodiment of the present invention is illustrated in the perspective view in Figure 1. The implanting device **200** includes a handle **220**, a movable elongated cannula **240** (shown in a retracted position), a flexible actuator button **262** connected to a flexible actuator **260** (shown in FIG. 3) for moving the cannula **240** along a post rod **244** (shown in FIG. 3), and a base **280**. The base **280** is distal to the handle end **222**. In the retracted position, the cannula **240** is drawn into the interior of the handle base **280** by the flexible actuator button **262** as it is moved or slid toward the handle end. The flexible actuator button **262** is guided by an angled track **300** which is non-parallel with respect to the axis of motion of the cannula **240** or the axis of the post rod **244** (shown in FIG. 3). The cannula **240** may be slid or moved with respect to the post rod **244** (shown in FIG. 3) and housing base **280** with cannula guide **340**. Movement of the flexible actuator **260** in a direction toward the cannula guide **340** and along the track **300** away from the handle **220** results in extension of the cannula **240** through the cannula guide **340**.

[0026] In Figure 2 the implanting device **200** is shown with the cannula **240** in an extended position. In FIG. 2 the flexible actuator button **262** is shown distal to the handle end **222**. In this position the flexible actuator may be locked to prevent withdrawal of the cannula **240** and unintended insertion of implantable objects. Movement of the flexible actuator button **262** in a direction away from the cannula guide **340** and along the angled track **300** towards the handle **220** causes retraction of the cannula **240** and release of an implantable object (not shown) positioned within the bore **242** of the cannula.

[0027] Motion of the flexible actuator is along an angled ramp which provides increased precision in control of the movement of the cannula along the post rod axis. This provides the user with the advantage of greater control of insertion of implantable objects.

[0028] With respect to Figure 3 there is shown an exploded isometric view of the embodiment shown in Figures 1 and 2. In this Figure, the implanting device **200** is shown in two portions **200a** and **200b**, which includes a handle **220** having first and second portions **220a** and **220b**, a base **280** having first and second portions **280a** and **280b**; a cannula guide **340** having first and second cannula guide portions **340a** and **340b**; and a handle end **222** including handle end portions **222a** and **222b**. The angled track **300** is formed from two opposing recessed track walls **300a** and **300b** which, when the portions **200a** and **200b** of the implanting device are assembled, form the angled track **300**. Within the implanter handle **220** are portions of a flexible actuator channel **248a**, (and **248b** in handle **220b** not shown in FIG. 3), which, when assembled, form a flexible actuator channel **248** for guiding the tab **268** of the flexible actuator within the assembled implanter handle **220**.

[0029] The flexible actuator **260** in Figure 3 includes a button **262**, a boss channel **272**, a lower guide post **264** (not shown in FIG. 3), lower guide post **266**, thin profile guide **270**, and tab **268**. The button **260** is seated in the scoop **310**. The boss channel **272** receives the guide posts **362** and **364** from the cannula boss **360**. Movement of the flexible actuator **260** along the angled track **300**, in the direction away from the cannula guide **340** and toward the post boss retainer **248**, allows cannula boss guide posts **362** and **364** within the boss channel **272** to remain at a constant position relative to the post **244**, while the boss channel **272** moves relative to them and at the same time pulls the cannula **240** toward the post retainer **248**. The boss channel **272** engages the cannula boss guide posts **362** and **364** and permits a pulling or pushing force to be exerted on the cannula **240**, for extension and retraction, as the flexible actuator **260** is moved along the angled track **300**.

[0030] Flexible actuator guide post **266** and flexible actuator guide post **264** (not shown in Figure 3) are attached to flexible actuator **260** and rest on top of angled guide ramp **350b** (not shown in Figure 1C) and angled guide ramp **350a** respectively. An angled guide ramp **350** is formed by joining guide ramp portion **350a** shown in Figure 3 and guide ramp portion **350b** (not shown in Figure 3) together. The flexible actuator guide posts **264** (not shown in Figure 3) and **266** shown in Figure 3 move parallel to the angled guide ramp **350b** (not shown in Figure 3) and angled guide ramp **350b** respectively translating movement of the flexible actuator **260** along the angled track **300** into movement of the boss channel **272** perpendicular to the axis of the cannula **240** as the flexible actuator **260** is moved toward or away from the post retainer **248**. Cannula boss guide posts **366** (not shown in Figure 3) and **368** lie below linear guide **352a** and **352b** (not shown in Figure 1C) and on top of base step **354a** and **354b** (not shown in Figure 3) maintains the cannula in a substantially fixed orientation with respect to the base **280**.

[0031] The degree to which movement of the flexible actuator **260** between any two points along the guide ramp **350** is translated into linear motion of the cannula **242** along the post **244** depends upon the angle of the base guide ramp **350**. The greater the angle that the base guide **350** makes with respect to the post **244**, the more control that may be exerted over lateral movement of the cannula **240**. The shape of the base guide ramp portions **350a** in Figure 3 and **350b** (not shown in Figure 3) may be a linear or curvilinear.

[0032] Post **244** is coaxially located within cannula bore **242** and is secured to the housing base **280** by post retainer **248** through post boss **246**. The post **244** is inserted into the end of the cannula **242** where the cannula boss **360** is located and protrudes through cannula guide **340** which provides support and alignment for the post **244**. The diameter of the cannula guide **340** is made so that movement of the cannula **260** into and out of the base **280** along the post **244** occurs without binding or restriction of the cannula **240** with the inner

diameter of the cannula guide **340**. The diameter of the cannula guide **340** may also be sized so that it prevents entrainment of fluids, particles, and other debris adhering to the cannula **240** from being drawn into the implanter base **280**.

[0033] Figure 4 shows a side view of the implanting device of the present invention with the cannula in an extended position. In Figure 4, the flexible actuator button **262** is shown distal to the handle end **222**. In this position, the flexible actuator may be locked to prevent withdrawal of the cannula **240** and unintended insertion of implantable objects. Movement of the flexible actuator button **262** in a direction away from the cannula guide **340** and along the angled track **300** towards the handle **220** causes retraction of the cannula **240** and release of an implantable object (not shown) positioned within the bore **242** of the cannula **240**.

[0034] Figure 5 shows a top view of the implanting device of the present invention with the cannula **240** in an extended position. In FIG. 5, the flexible actuator button **262** is shown distal to the handle end **222**. In this position, the flexible actuator may be locked to prevent the withdrawal of the cannula **240** and unintended insertion of implantable objects. Movement of the flexible actuator button **262** in a direction away from the cannula guide **340** and along the angled track **300** towards the handle **220** causes retraction of the cannula **240** and release of an implantable object (not shown) position within the bore **242** of the cannula **240**.

[0035] The implanting device may be made from molded, cast, machined components or combinations of these. For example the implanter portions **200a** and **200b** may be molded from chemically and mechanically suitable plastics such a polyvinylidine fluoride (PVDF) or ultrahigh molecular weight polyethylene (UPE). The cannula **240** may be made from a variety of surgically acceptable stainless steels or titanium alloys, and the post may be made using similar materials or plastics like PVDF.

[0036] The implanter handle **220** includes a grasping portion and may fit into the palm of the users hand. The handle is substantially symmetrical so that the implanting device can be used by either right or left handed users. Extending from the handle is a base portion 280 which includes a track 300 in which a flexible actuator 260 slides to extend or retract the cannula 240. The track is formed by two opposed track side walls 300a and 300b angled with respect to the device post **244**, and that form a slot extending through the track **300**along a length of the track to receive the actuator 260 and thin profile guide 272.

[0037] The cannula **240** includes a boss fitting at an end proximal to the handle **220** of the device. The cannula boss **360** is secured around the proximal end of the cannula **240** and provides guide posts **264** and **266** that fit into a channel on the flexible actuator **260**. The cannula boss **360** may be attached to the cannula **240** in any known manner such as by insert molding, press fitting, adhesive bonding, threading, ultrasonic staking, and the like.

[0038] The flexible actuator **260** includes a channel which receives the cannula boss guide posts **362** and **364** and allows them to slide and move within the channel. The flexible actuator **260** has a thin profile guide **270** which extends through the slot in the track **300** and guides the flexible actuator **260** in the track **300** as it slides longitudinally along the track. The thin profile guide **270** of the flexible actuator is connected to an actuator button **262** for engagement by a user's finger to move the actuator along the angled track **300**. The actuator button **262** may have a ridged, grooved, or knurled slip surface which may be engaged by the user's thumb.

[0039] A longitudinal axis passes through a center of the cannula **240** and the post **244** in the base of the implanting device. The track along which the flexible actuator**260** moves is not parallel to this axis along one or more portions of the track; the track may be linear or curvilinear. The track has a distal portion which provides a stop for the flexible actuator and also permits securing of the flexible actuator which locks the cannula in the

initial loaded position and prevents unintended release of the implantable object from the device. The flexible actuator **260** is released from the locked position by pressing the flexible actuator button **262**. When the flexible actuator **260** is in the locked position a substantial force may be applied longitudinally on the distal end of the cannula **240** without causing the cannula to retract.

[0040] Once the flexible actuator **260** has been unlocked, further manual pressure on the actuator button **262** in the direction toward the handle **220** causes the flexible actuator to slide along the track. As the actuator slides in the direction of the handle, the cannula **240** is withdrawn over the post **244** and one or more implantable objects held stationary by the post **244** may be released from the cannula **240**. The flexible actuator **260** allows the user to manually control the motion of the cannula **260** throughout the implant insertion process. The angle or slope of the track with respect to the axis of the post permits the user to exert greater control over the motion of the cannula than could be achieved using a linear track to guide the withdrawal of the cannula.

[0041] Although the implanting device is preferably a single use device, the implanting device according to the present invention may also be made for reuse. The reusable embodiment of the implanting device will preferably be formed of an autoclavable material known to those skilled in the art for sterilization and reuse.

[0042] The post **244** is positioned within the base **280** and is fixed within the proximal end of the base by a post retainer **248**. The post has a protrusion or boss at one of its ends which engages and secures the post **244** to the post retainer **248**. The post retainer **248** is secured to an interior surface of the implanter base. The distal end of the post **244** is configured to engage the implantable object as the cannula **240** is retracted over the post **244**. This distal end of the post **244** may have a flat leading edge for engaging the implantable object or may also take on other configurations depending on the particular implantable

object to be inserted. Some other distal end configurations include but are not limited to blunt, beveled, concave, and convex end surfaces.

[0043] The post **244** preferably has an outer diameter which is somewhat smaller than an inner diameter of the cannula **240** to provide clearance through the cannula tube and limit binding or restriction of the post within the cannula. The post diameter with respect to the cannula should limit the amount of material that can bypass the cannula and become entrapped within the base.

[0044] The handle of the present invention is designed for one handed operation with the handle grasped by the hand while the thumb is used to slide the flexible actuator in the angled track. The handle preferably has a size and shape that can be easily manipulated during implant insertion. The orientation of the handle relative to the cannula allows the user to firmly grip the handle, yet easily keep the handle parallel to the skin surface to prevent the cannula from diving into other tissue or piercing out through the skin during insertion. The implanting device includes a bottom surface of the base which is substantially planar and parallel to the cannula.

[0045] A distal tip of the cannula **240** may be formed at various beveled angles, such as between about 30 degrees and about 45 degrees, or at a sharp point, such as 27 degrees which can cut skin. The preferred design of the cannula tip is a design with a beveled tip which does not cut unbroken skin and does not require special sharps disposal. The cannula of the implanting device is preferably inserted into the patient through a small incision made in the patient's skin to minimize scaring.

[0046] In operation the implanting device may be loaded with an implantable object either manually or with a cartridge. An incision is made at an implantation site and the cannula is inserted through the incision to a desired depth. Preferably, a depth indicating marker, such as a ring, is provided on the cannula to assist in locating the implantable object

at a particular depth. Once the cannula is placed under the skin at a desired location for the implantable object, the flexible actuator is drawn back manually causing the cannula to be withdrawn over the implantable object and the post. When the cannula has been fully withdrawn, the implanting device is withdrawn from the patient leaving the implantable object in place.

[0047] The two handle portions and base portions may be assembled in any known manner such as by ultrasonic welding, adhesive bonding, press-fit bosses, or a snap fit. A rear surface of the handle rests against the palm of the user to steady the implanting device as the thumb moves the flexible actuator along the angled track. Pressure may also applied to the base by the index finger of the user during insertion of the cannula.

[0048] The assembly of the implanting device will be described with reference to the exploded view, which illustrates the implanting device prior to assembly. A cannula **240** with boss **360** secured to it is slid over a post **244** and the flexible actuator **260** is slid onto the upper cannula boss guide posts. This subassembly is oriented in one portion of an implanting device so that the proximal end of the post **244** is secured to a post boss retainer **248**. Next, the flexible actuator **260** may be received within the actuator channel, the lower cannula boss guide post is positioned below the linear guide within the base, and the cannula **240** with the post **244** inside of it is received into a cannula guide portion. Placement of the second implanter portion over the first implanter portion with the previously described subassembly positioned inside of it, traps the cannula, its guide posts, and the flexible actuator and its guide posts between cutouts in the second portion of the implanter.

[0049] When the implanting device is assembled, the flexible actuator **260** is slidably connected to the upper cannula boss guide posts mounted to the cannula **240**. The flexible actuator **260** slides along the angled or curvilinear track **300** from a distal portion of the track which serves as a locking position to the proximal end of the track.

[0050] One embodiment of the present invention is a kit which may include additional parts along with an implanting device which may be combined together to implant therapeutics, pharmaceuticals, or microencapsulated sensors into a patient . The kit may include the implanter in a first compartment. A second compartment may includes a syringe, needles, scalpel, and any other instruments needed. A third compartment may includes gloves, drapes, wound dressings and other procedural supplies for maintaining sterility of the implanting process, as well as an instruction booklet. A fourth compartment may include additional cannula and posts. A cover of the kit may include illustrations of the implanting procedure and a clear plastic cover may be placed over the compartments to maintain sterility.

[0051] Embodiments of the present invention include a device which may be used for implanting various pharmaceuticals, therapeutic drug delivery devices such as silicone rubber capsules that contain a synthetic progestin birth control hormone, or encapsulated microsensors. The angled guide track of the device permits finer control of the cannula motion during implantation which aids in the proper positioning of implants within the patient. Embodiments of the present invention contain fewer parts than other implant devices.

[0052] Although the present invention has been described in considerable detail with reference to certain preferred embodiments thereof, other versions are possible. Therefore the spirit and scope of the appended claims should not be limited to the description and the preferred versions contained within this specification.

CLAIMS

What is claimed:

1. A device for implanting at least one object beneath the skin of a patient comprising:

a handle for grasping the device during insertion of an object, the handle having a distal end, a proximal end, and an angled track formed on the handle;

a base connected to the handle, the base comprising:

a post longitudinally fixed to the handle, the post extending from the distal end of the handle;

a hollow cannula positioned coaxially around and longitudinally slidable over the post from an extended position, in which at least one object is retained in the cannula, to a retracted position, in which at least one object is released from the cannula;

and a flexible actuator slidably engaged to the cannula to move the cannula from the extended position to the retracted position to release the object from the cannula, wherein the actuator flexes between a locked and an unlocked position.

2. The device of claim 1 further comprising one or more implantable objects.

3. The device of claim 1, wherein the implantable objects comprise one or more of either therapeutics, pharmaceuticals, or microencapsulated sensors.

4. The device of claim 1 further comprising a cartridge removably mounted and parallel to a central bore of said cannula and a means for moving objects into the cannula for delivery upon retraction of said cannula.

5. The device of claim 1 wherein the angled track is formed from two opposing recessed track walls angled with respect to the post.

6. The device of claim 1 wherein the angled track is either linear or curvilinear.

7. The device of claim 1 wherein the angled track has a stop at the distal portion that permits securing of the actuator and locks the cannula in a loaded position.

8. The device of claim 1 wherein the flexible actuator comprises a button, a boss channel, at least two guide posts, a guide, and a tab extending upwardly and non-parallel from the guide posts attached to the cannula, wherein the boss channel engages the guide posts and permits a pulling or pushing force to be exerted on the cannula, for extension or retraction, as the flexible actuator tab is moved by moving the button along the angled track.

9. The device of claim 1 wherein pressing the flexible actuator in the distal position of the angled track engages a locking portion of the actuator to prevent retraction of the cannula.

10. The device of claim 9 wherein the flexible actuator is released from the locked position by pressing the actuator.

11. The device of claim 1 wherein the base includes a bottom surface that is substantially planar and parallel to the cannula.

12. The device of claim 1, wherein the cannula includes a tip at the distal end that is

formed from at least one beveled angle of between 30 and 45 degrees.

13. The device of claim 1 wherein the cannula includes a tip at the distal end that is formed at a sharp point of 27 degrees.

14. The device of claim 1, wherein the cannula includes a depth indicating marker.

15. A method of inserting an object beneath the skin of a patient, comprising the steps of:

inserting a hollow cannula of an implanting device beneath the skin of a patient, where at least one implantable object is positioned within the cannula;

using a flexible actuator that is attached to the implanting device along an angled track that is slidably engaged to the cannula to manually retract the cannula over the implantable object and leave the implantable object beneath the skin;

withdrawing the implanting device from the patient.

16. The method of claim 15, further comprising the step of pressing the flexible actuator in the distal position of the angled track to engages a locking portion of the actuator to prevent retraction of the cannula;

17. The method of claim 15, further comprising the step of pressing the flexible actuator to release the actuator from the locked position.

18. A system for implanting an object beneath the skin of a patient, comprising:

means for creating an incision into the skin of the patient;

means for maintaining a sterile environment;

means for placing the implantable object beneath the skin of the patient, comprising an angled means for insertion beneath the skin and a means for withdrawing the angled means for insertion while leaving the implantable object beneath the skin;

angled means for manually controlling the insertion of the implantable object to prevent unnecessary damage to patient tissue from force.

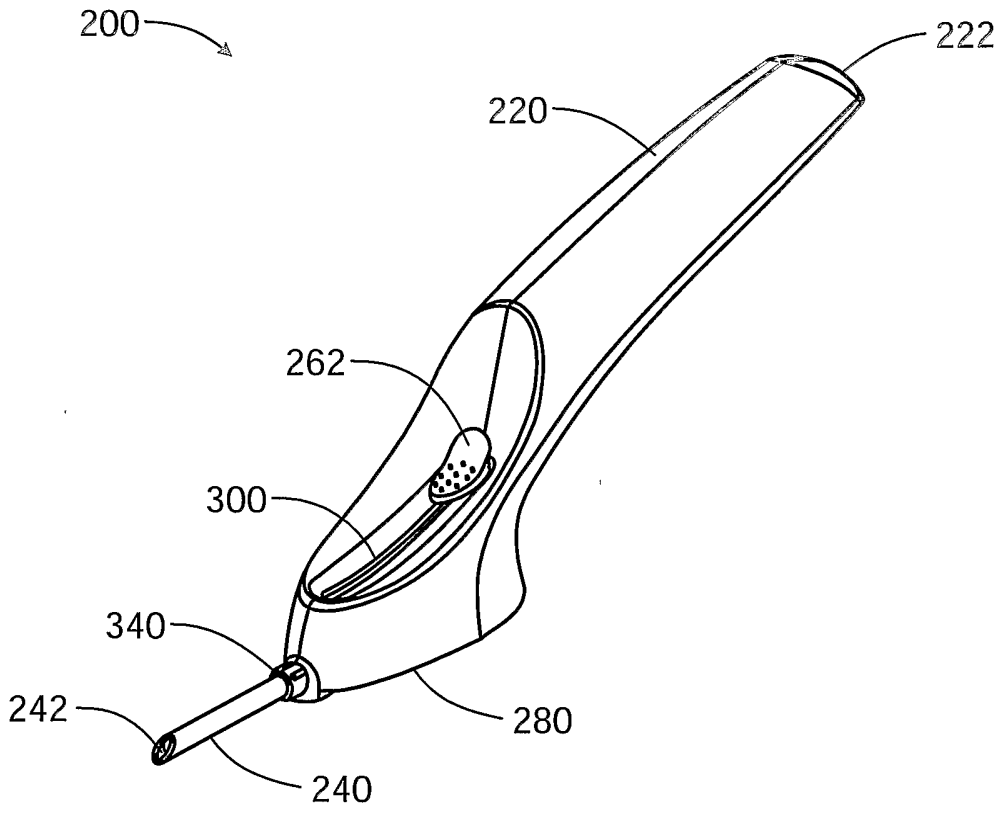


FIG. 1

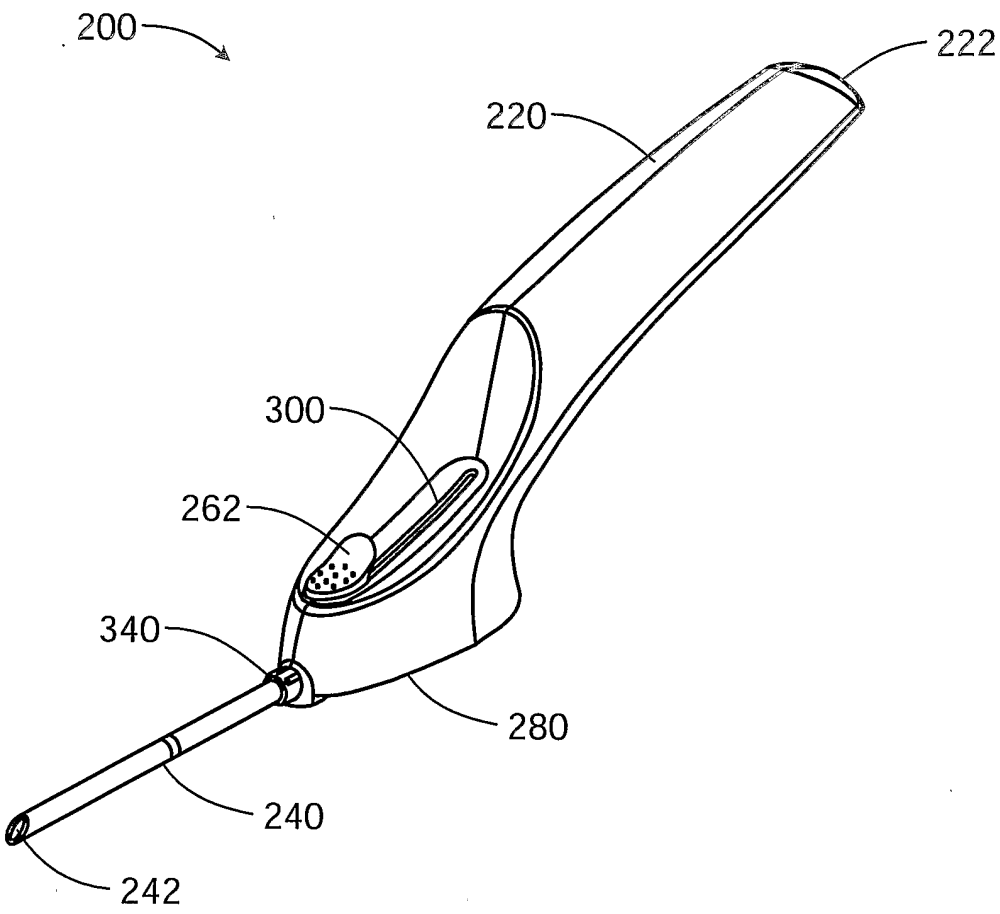
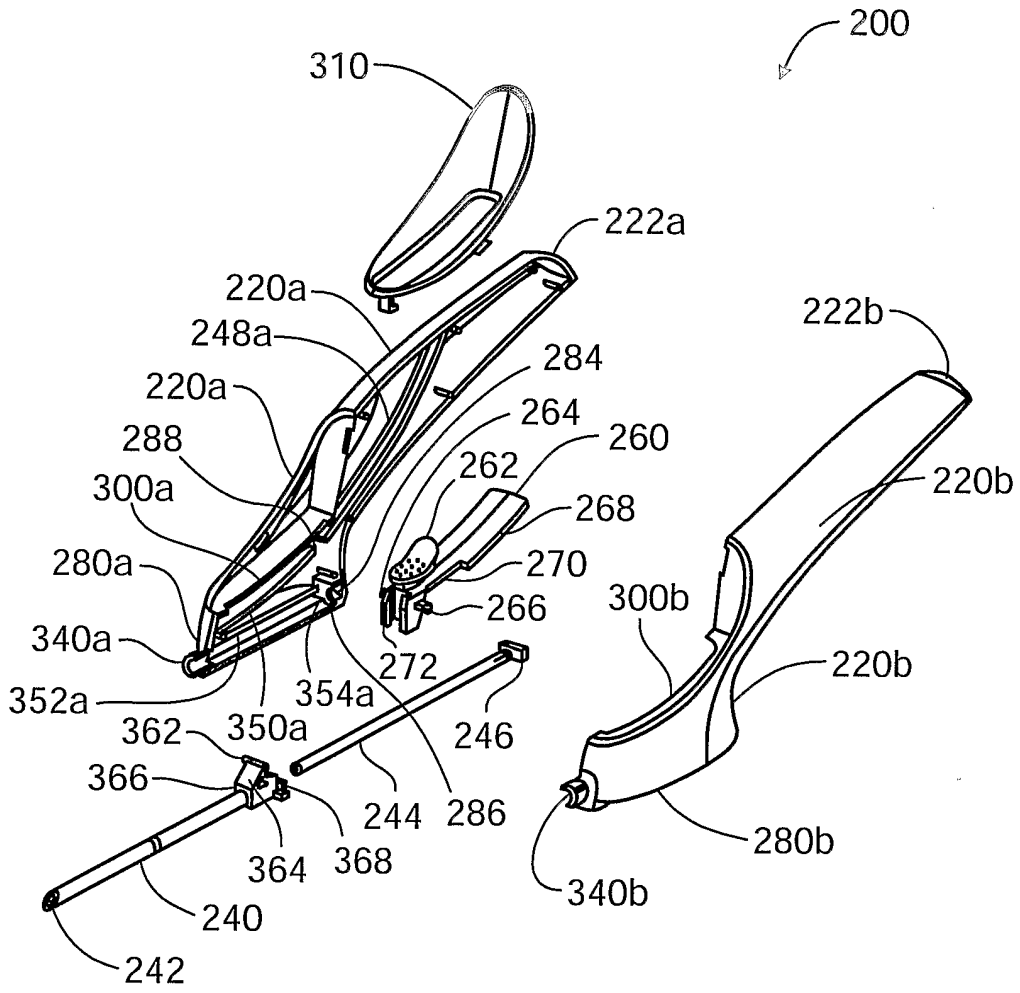


FIG. 2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354a
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220b
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280b
340b

FIG. 3

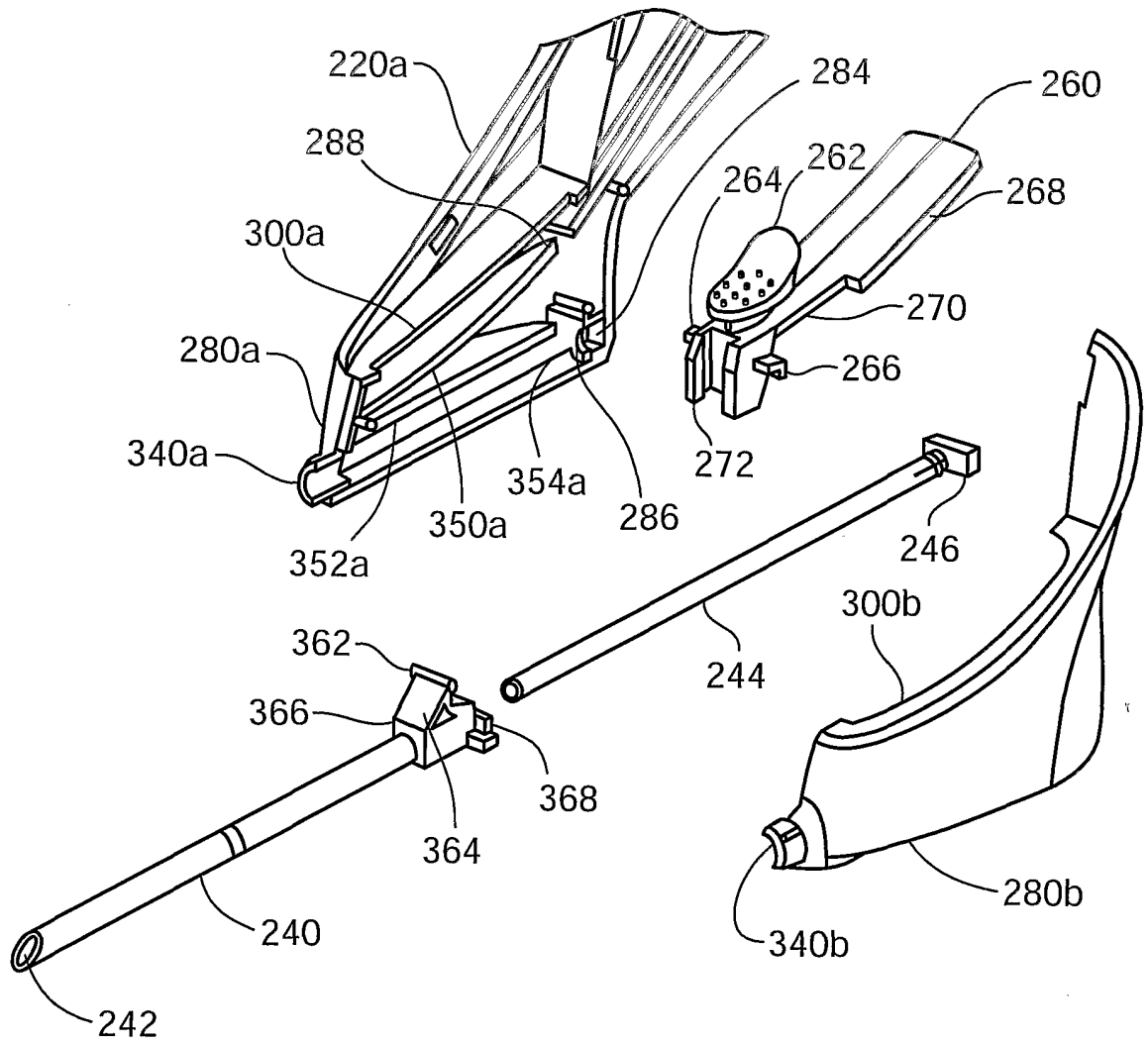
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FIG. 3a

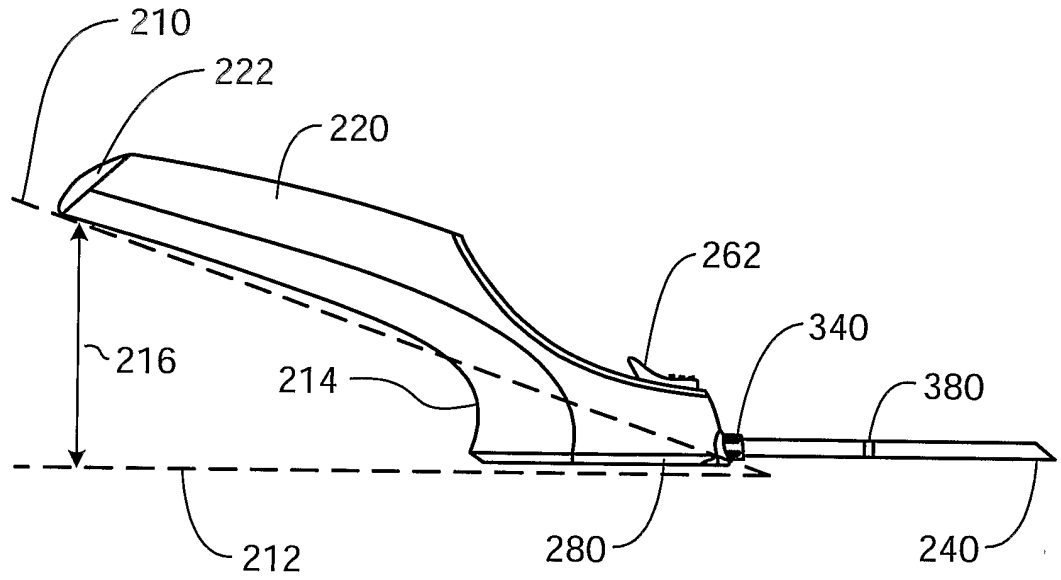

FIG. 4

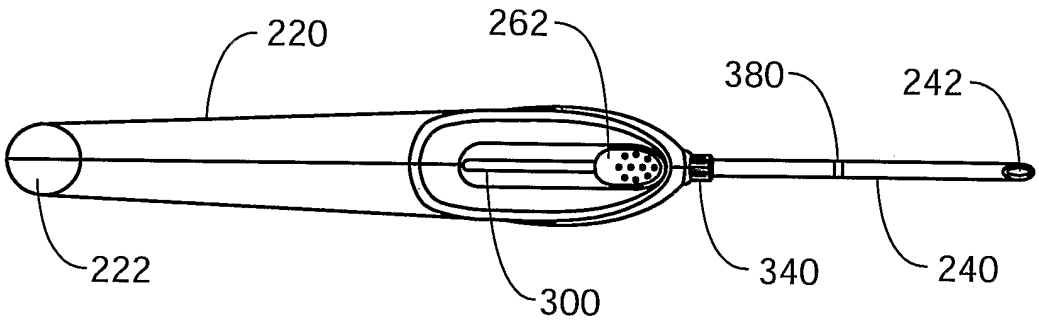

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/US2004/010354

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M37/04 A61B17/34

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 A61B

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, 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 Y	WO 99/33512 A (ALZA CORP) 8 July 1999 (1999-07-08) page 6, line 21 - page 8, line 14	1-3, 5-14,18 4
X Y	US 4 661 103 A (HARMAN S MITCHELL) 28 April 1987 (1987-04-28) figures 1-4	1-3,18 4
A	US 5 810 769 A (SCHLEGEL KARL-HEINZ ET AL) 22 September 1998 (1998-09-22) column 3, line 62 - column 6, line 14; figures 1-7	1-14,18
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☐ 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 September 2004	15/09/2004

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Cuiper, R

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/010354

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. [X] Claims Nos.: 15-17
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

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

Information on patent family members

International Application No
PCT/US2004/010354

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