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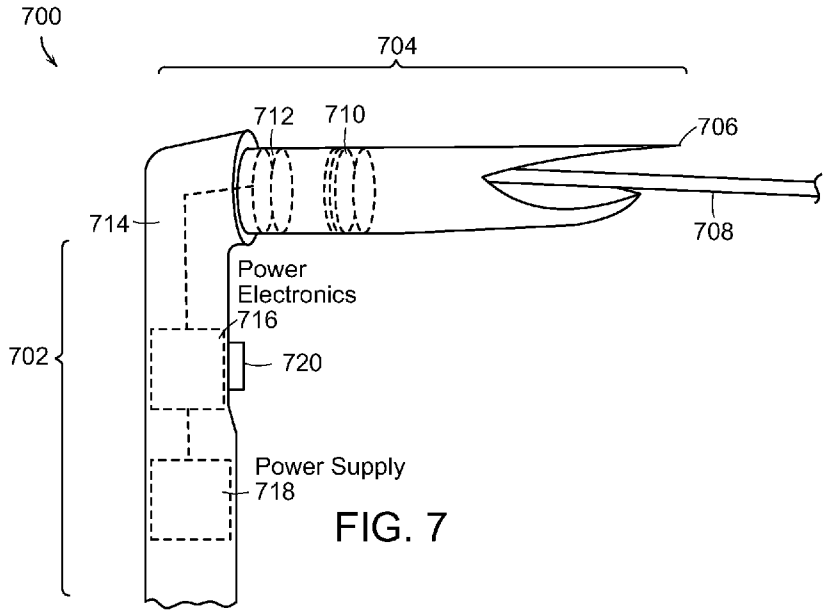


FIG. 7

(57) Abstract: Stitching apparatus and methods are provided for placing a stitch through a layer of material such as tissue. Preferred methods include piercing a needle element through tissue, engaging a thread with the needle, and pulling the thread through the tissue. The needle suitably releasably engages the thread, e.g. magnetic engagement of the needle and thread.

STITCHING APPARATUS AND METHODS

The present application claims the benefit of U.S. provisional application number 61/922,595, filed December 31, 2013, which is incorporated by reference herein in its entirety.

BACKGROUND

(a) Technical Field

The present invention relates to a stitching apparatus for placing a stitch through a layer of material such as tissue. In particular aspects, the present invention relates to stitching apparatus and methods that pierce through a layer of material such as tissue, engages a thread, and pulls the thread through the layer of material.

(b) Background Art

Stitches are often used in a myriad of industries to bind two pieces of material together. For example, the medical industry often uses stitches to suture layers of tissue together during surgical procedures, thereby allowing the layers of tissue to fuse while healing. A suture needle is typically used to force a suture thread through the separate layers of tissue to allow the suture thread to bind the tissue layers.

FIGS. 1-3B illustrate the configuration of a traditional suture needle used during medical procedures. As shown in FIG. 1, a typical suture needle 100 includes a needle body 102 having a needle point 104 on one end and a suture connection point 106 on the opposite

end. Suture connection point 106 connects suture needle 100 to a suture thread and may be of an eyeless configuration. For example, suture connection point 106 may be swaged to an end of the suture thread. Generally, suture needles are classified based on their length, diameter and percentage of curvature relative to a center location. As shown, for example, suture needle 100 has a needle length 112, a diameter 110, and is a "half circle" type of suture needle since its length 112 extends along exactly half the perimeter of a circle having center 114 and radius 116. Other common types of suture needles (not shown) include "quarter circle," "three eights circle," and "five eights circle" suture needles. Typically, longer suture needles (e.g., three eights circle needles) are used for large or superficial wounds while shorter suture needles (e.g., half circle or five eights circle needles) are used for cases in which access or room for manipulation is limited, such as in small and deep spaces.

FIGS. 2A-2B depict the use of a suture needle 200 coupled with a suture thread 206 to first layer of material 208. As shown in FIG. 2A, needle point 202 of suture needle 200 is inserted through material 208 at puncture point 212 by applying an insertion force to suture needle 200, thereby penetrating material 208. Additional insertion force may then be used to drive the remainder of suture needle 200 through material 208, as shown in FIG. 2B. Suture thread 206, which is coupled to suture needle at connection point 204, is pulled along when the insertion force is applied to suture needle 200, thereby pulling suture thread 206 through puncture point 212 and to the opposite side of material 208. This process may then be repeated with a second layer of material 210 to bind materials 208, 210 together using suture

thread 206.

FIGS. 3A-3B illustrate the use of surgical tools that are commonly used in conjunction with a suture needle, when a medical procedure is performed. As shown in FIG. 3A, a suture needle 300 attached to a suture thread 302 may be gripped using a needle holder 304. A user operating needle holder 304 grasps one end of needle holder 304 to apply a compressive force to suture needle 300 that allows suture needle 300 to be manipulated using needle holder 304. In FIG. 3B, a vessel anastomosis procedure is illustrated in which suture thread 302 has been threaded through a first vessel wall 308 and is in the process of being threaded through a second vessel wall 310. By manipulating needle holder 304, the user is able to apply an insertion force to suture needle 300 to pierce vessel wall 310 and insert suture needle 300 through vessel wall 310. Typically, the user also uses a pair of tweezers 306 to grip the portion of suture needle 300 that has protrudes from vessel wall 310 after insertion of suture needle 300 through vessel wall 310. The user may then continue applying an insertion force to suture needle 300 by continuing to push suture needle 300 through vessel wall 310 and/or by pulling suture needle 300 through vessel wall 310 using tweezers 306. As a result of this process, suture thread 302 will eventually extend through both vessel walls 308, 310. The process is then repeated any number of times in an alternating manner between vessel walls 308, 310 to form stitches using suture thread 302, thereby binding vessel walls 308, 310 together.

In the stitching process described above, a traditional suture needle is required to

have at least minimum length due to the use of a needle holder and tweezers. In other words, a traditional suture needle must be long enough to allow it to be gripped by both the needle holder and tweezers simultaneously, while still accounting for the thickness of the tissue. In addition, 3-4 times the amount of needle length space is needed in a traditional suture needle to prevent the needle from accidentally puncturing neighboring tissue. However, the size constraints on traditional suture needles also prevent them from accessing certain angles or surgical fields. For example, a traditional suture needle may be too large to access certain deep, small, narrow, or serpentine working spaces.

SUMMARY

We now provide systems and methods for passing a thread element through a material, particularly a suture through tissue of a subject that includes (a) piercing a needle element through tissue; (b) engaging a suture with the needle; and (c) pulling the suture through the tissue. Preferably, the needle element releasably engages the suture element e.g. the reliable engagement may be magnetic, mechanical or adhesive or other chemical releasable engagement. Magnetic releasable engagement of the needle and suture elements is particularly suitable for many systems.

We have found that the systems and methods of the invention can utilize a needle of particularly short dimensions (length) in comparison to traditional stitching tools. In the present methods, the needle element first pierces through tissue and then couples with and

withdraws the suture element through the tissue puncture point already established by the first piercing of the needle. This can enable use of a needle element of comparatively small dimensions and suturing can be accomplished within confined spaces relative to prior approaches where a suture material and needle element are initially coupled together and that suture/needle assembly is advanced together for the first time through tissue. Additionally, by first establishing a puncture point in accordance with the present methods, the suture material can be advanced through the puncture point in the tissue with little resistance.

In preferred system, a needle element may comprise a thread extractor which engages an end of the thread element such as a suture. An end portion of the needle element may comprise an enclosure that houses a thread extractor element and at least partially encases an end of the suture when the suture is engaged to the thread extractor element. In particular preferred systems, the thread extractor may comprise a magnet that engages a thread end portion by magnetically coupling the thread end portion to the thread extractor.

In additional preferred systems, the stitching apparatus includes a handle portion configured to be gripped by a user and an insertion portion coupled to the handle portion that is configured to be inserted through a layer of material. The insertion portion may include a needle tip configured to pierce through the layer of material when an insertion force is applied to the needle tip. The insertion portion also may include an elongated base coupling the needle tip to the handle portion and configured to transfer the insertion force from the handle portion to the needle tip. The insertion portion may further include a thread extractor

configured to engage a thread tip when the insertion portion has been inserted through the layer of material and further configured to transfer an extraction force from the handle portion to the thread tip to pull the thread tip through the layer of material.

In one embodiment, the needle tip and elongated base may define a hollow enclosure that houses the thread extractor and enshrouds the thread tip when the thread tip is engaged to the thread extractor. The elongated base and needle tip may also extend along an axis radial to the handle portion. Alternatively, the elongated base may extend from the handle portion along a curved path.

According to various embodiments, the thread extractor may include an adhesive material that adheres the thread tip to the thread extractor, a magnet (e.g., a permanent magnet, an electromagnet, etc.) that engages the thread tip by magnetically coupling the thread tip to the thread extractor, one or more apertures that engage the thread tip, or one or more protrusions that engage the thread tip. In embodiments that include an electromagnet, the handle of the stitching apparatus may also include electronics configured to provide electrical power to the electromagnet. The electronics may further include a battery housed by the handle portion that supplies power to the electromagnet or an electronic switch configured to control the supply of power to the electromagnet when activated by the user.

In another preferred embodiment, stitching methods are provided that include transferring an insertion force from a handle to a needle tip and piercing through a layer of material using the needle tip to insert an insertion portion through the layer of material. The

method also may include engaging a thread extractor of the insertion portion to a tip of a thread while the insertion portion is inserted through the layer of material. The method may further include transferring an extraction force from the handle to the tip of the thread. The method additionally may include pulling the thread through the layer of material by extracting the insertion portion from the layer of material.

In yet a further embodiment, stitching apparatus are provided that that includes means for transferring an insertion force from a handle to a needle tip. The stitching apparatus also may include means for piercing through a layer of material using the needle tip to insert an insertion portion through the layer of material. The stitching apparatus may further include means for engaging a thread extractor of the insertion portion to a tip of a thread while the insertion portion is inserted through the layer of material. The stitching apparatus additionally may include means for transferring an extraction force from the handle to the tip of the thread. The stitching apparatus also may include means for pulling the thread through the layer of material by extracting the insertion portion from the layer of material.

A variety of configurations of the disclosed stitching apparatus and methods will be suitable and preferred for many applications.

For instance, a magnet or other gripping force element may be molded or otherwise produced as a single unit with a needle element.

Alternatively, a magnet or other gripping force element may be separated (spaced and/or no physical attachment) to a needle element. In one preferred embodiment, the needle

element suitably is within the magnetic field of the unattached magnet or within the attractive field of other gripping force element (such as a vacuum). In such systems, the needle element itself suitably would not need to be magnetized.

In other preferred embodiments, the needle element in whole or part may be magnetized. In such embodiments, with use of a hollow needle, the hollow needle lumen may serve as a path for entry of the thread element.

Needle elements of a variety of designs and configurations suitably can be employed. For instance, in addition to a hollow needle element, a needle element without a lumen suitably may be utilized. Both sharp and blunt-ended needles may be suitably employed.

Also, as mentioned, a thread element may be engaged to a needle element through one or more of a variety of attractive forces. In many embodiments, use of a magnetic to engage the tread and needle elements will be preferred. Use of a vacuum also could be employed to engage the thread and needle elements. Mechanical and adhesive engagement of thread and needle elements also suitably can be utilized.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or

addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other features of the present invention will now be described in detail with reference to certain exemplary embodiments thereof illustrated the accompanying drawings which are given herein by way of illustration only, and thus are not limitative of the present invention, and wherein:

FIG. 1 is an illustration of a suture needle.

FIG. 2A is an image depicting a suture needle being inserted through a layer of material.

FIG. 2B is an image depicting the suture needle of FIG. 2A having been pulled entirely through the layer of material.

FIG. 3A is an illustration of a needle holder grasping a suture needle.

FIG. 3B is an illustration of a vessel anastomosis procedure being performed using the needle holder and suture needle of FIG. 3A with a pair of tweezers.

FIG. 4 is an image depicting a stitching apparatus, according to one exemplary embodiment.

FIG. 5 is an image depicting the insertion portion of a stitching apparatus in greater detail.

FIG. 6A is an image depicting an insertion force being applied to a stitching apparatus to puncture a layer of material.

FIG. 6B is an image showing a thread tip in close proximity to the stitching apparatus of FIG. 6A.

FIG. 6C is an image of the thread tip of FIG. 6B engaging a thread extractor of the stitching apparatus of FIGS. 6A-6B.

FIG. 6D is an image depicting an extraction force being applied to the stitching apparatus of FIGS. 6A-6C to pull the thread tip through the layer of material.

FIG. 7 is a schematic diagram of a stitching apparatus that uses an electromagnetic thread extractor.

FIG. 8 is a schematic diagram of a stitching apparatus having a curved insertion portion.

FIG. 9A is a cross-sectional view of the insertion portion of a stitching apparatus having locking protrusions.

FIG. 9B is a cross sectional view of a thread tip having apertures that engage the locking protrusions of FIG. 9A.

It should be understood that the appended drawings are not necessarily to scale, presenting a somewhat simplified representation of various preferred features illustrative of

the basic principles of the invention. The specific design features of the present invention as disclosed herein, including, for example, specific dimensions, orientations, locations, and shapes will be determined in part by the particular intended application and use environment.

In the figures, reference numbers refer to the same or equivalent parts of the present invention throughout the several figures of the drawing.

DETAILED DESCRIPTION

The present stitching apparatus and methods can provide numerous advantages. For instance, as discussed, the insertion portion of the stitching apparatus may be much shorter than that of traditional needles, such as suture needles. This can allow a user to be able to place stitches in traditionally inaccessible places. Additionally, the short insertion portion of the stitching apparatus can have less of a chance of accidentally puncturing neighboring tissue than traditional needles, when used in a surgical procedure.

Referring now to FIG. 4 of the drawings, a preferred stitching apparatus 400 is shown, according to an exemplary embodiment. Stitching apparatus 400 includes a handle portion 402 that can be gripped by either hand of a user to manipulate stitching apparatus 400. Stitching apparatus 400 also includes an insertion portion 404 that can be at least partially inserted through a layer of material by manipulation of handle portion 402 by a user.

Handle portion 402 of stitching apparatus 400 may be of any size or shape, according to various embodiments. In some cases, handle portion 402 may be ergonomically shaped to fit one or both hands of a user. The width of handle portion 402 may also be uniform or may

vary along the length of handle portion 402. For example, the width of handle portion 402 may be tapered closest to the junction between handle portion 402 and insertion portion 404, thereby minimizing the size of stitching apparatus 400 in the work area.

Insertion portion 404 of stitching apparatus 400 may be permanently affixed to handle portion 402 or may be detachable. In various embodiments, handle portion 402 and insertion portion 404 may be forged from a single piece of metal, insertion portion 404 may be welded or otherwise adhered to handle portion 402, or insertion portion 404 may engage an internal latching mechanism of handle portion 402 that prevents detachment of insertion portion 404 once latched to handle portion 402. In other embodiments, insertion portion 404 may releasably engage handle portion 402 via threading (e.g., insertion portion 404 may include threading and can be screwed into handle portion 402), a latching mechanism that can be actuated to release insertion portion 404 from handle portion 402 (e.g., via the push of a button, the movement of a switch, etc.), or any other mechanism that allows insertion portion 404 to be separated from handle portion 402.

Insertion portion 404 includes an elongated base 406 that extends radially from handle portion 402 at a substantially perpendicular angle, in one embodiment, or in other embodiments any other angle may be utilized including acute or obtuse angles. Elongated base 406 may generally be of a cylindrical shape with a circular or ovoid diameter. In other embodiments, elongated base 406 may extend from handle portion 402 along a curved path, as shown in greater detail in FIG. 8. Elongated base 406 may be solid or may include a

hollow portion that partially or fully extends along the length of elongated base 406. Any length can be selected for elongated base 406. Preferably, a minimal length for elongated base 406 is selected such that elongated base 406 is able to extend through the width of a layer of material while still allowing the greatest degree of movement for the operator.

At the end of insertion portion 404 opposite the junction between handle portion 402 and insertion portion 404 is a needle tip 408. Needle tip 408 is formed by tapering or beveling elongated base 406 in a direction away from handle portion 402 and is driven by elongated base 406 to pierce through a layer of material. The edge of such a bevel may be entirely blunt, entirely sharp, or only partially sharp. Additionally, as discussed above, insertion portion 404 need not comprise a lumen.

Referring now to FIG. 5, the insertion portion 404 of stitching apparatus 400 is shown in greater detail. As shown, elongated base 406 may be of a hollow, cylindrical shape having an unbeveled portion 414 and a beveled portion 412 that exposes interior 416 of the hollow base 406. In some cases, the length and location of beveled portion 412 along elongated base 406 may be selected to increase the user's vision of interior 416 of insertion portion 404. For example, beveled portion 412 may extend along a greater length of elongated base 406 than that of unbeveled portion 414. In one embodiment, unbeveled portion 414 has a length that corresponds to the width of the tissue through which a thread is to extend as part of a stitch. The diameter of interior 416 can be selected to be slightly

greater than the diameter of a thread tip affixed to the end of a thread such that the thread tip may be partially or fully inserted into interior 416 of elongated base 406.

In various embodiments, insertion portion 404 includes a thread extractor that engages a thread tip after insertion portion 404 has been driven through a layer of material. In configurations in which elongated base 406 is hollow, the thread extractor may be located within the hollow interior 406. In configurations in which elongated base 406 has a curved shape, the thread extractor may be located at any along the peripheral of elongated base 406 such that the thread extractor may engage the thread tip via a scooping action. The thread extractor may be located within unbeveled portion 414 along interior 416 and/or may extend from elongated base 406 into handle portion 402.

Referring now generally to FIGS. 6A-6D, the operation of stitching apparatus 400 is shown threading a piece of thread through a layer of material. As shown, one or more stitches can be applied between two layers of material 602, 604 using stitching apparatus 400, to bind materials 602, 604 together. Materials 602, 604 may be, but are not limited to, living tissues, fabrics, polymers, combinations thereof, or the like. Thus, stitching apparatus can be adapted for use with any number of different materials having varying thicknesses and durabilities.

In FIG. 6A, stitching apparatus 400 is manipulated by a user via handle portion 402 to drive at least a portion of insertion portion 404 through material 602 at puncture point 606. An insertion force (F_i) applied by the user via handle portion 402 is transferred through

elongated base 406 to needle tip 408. For example, the insertion force may be applied to needle tip 408 along an axis that extends through elongated base 406 and needle tip 408 radially from handle portion 402. When the insertion force is applied to needle tip 408, needle tip pierces material 602 at puncture point 606. Additional application of the insertion force causes insertion portion 404 to be driven through the material 602.

In FIG. 6B, a thread 612 is moved within proximity of insertion portion 406 of stitching apparatus 400. Thread 612 may be any form of thread (e.g., wire, fiber, etc.) suitable for binding materials 602, 604 together. In surgical applications, thread 612 may be a suture thread designed for use with organic tissue and may be composed of an absorbable or non-absorbable material. For example, thread 612 may be composed of an absorbable material such as catgut, polyglycolic acid, polyactic acid, polydioxanone, caprolactone, or the like. Exemplary non-absorbable materials include polypropylene, polyester, nylon, metallic wires, and the like. In some cases, thread 612 may be coated with a compound that reduces friction during the stitching process, has antibacterial properties, and/or produces a biological reaction in the subject of the procedure (e.g., acts as an anti-inflammatory, etc.).

At one end of thread 610 suitably is a thread tip 610 that has a diameter equal to or greater than that of thread 610. As shown, thread tip 610 may be sized appropriately for insertion into interior 416 of elongated base 406, if elongated base 406 has a hollow configuration. In such a case, the bevel of elongated base 406 used to form needle tip 408 may be used to visually align thread tip 610 with interior 416 thread tip 610 to be inserted

into elongated base 406. Thread tip 610 may be swaged or otherwise coupled to the end of thread 610 such that movement of thread tip 610 transfers a corresponding force to thread 610.

In FIG. 6C, thread tip 610 has been partially inserted into interior 416 of elongated base 406. The bevel of elongated base 406 acts to help retain thread tip 610 during insertion into stitching apparatus 400 and to provide the user with a visual indication of its progress. At full insertion into elongated base 406, thread tip 610 engages a thread extractor (not shown) that is located within interior 416 and couples thread tip 610 to stitching apparatus 400.

The internal thread extractor of stitching apparatus 400 may be of various configurations that permanently or releasably couple thread tip 610 to stitching apparatus 400. In one embodiment, the internal thread extractor may be a magnet and thread tip 610 may be composed of an oppositely polarized magnet or other material that exhibits magnetic properties when in the presence of a magnetic field. Thus, the thread extractor may exert a magnetic force that magnetically couples thread tip 610 to the thread extractor. The magnet of the thread extractor may be a permanent magnet or an electromagnet that is selectably powered to generate a magnetic field, in various embodiments. Thus, thread tip 610 may be released from the electromagnet at a later time either by removing the power to the electromagnet (e.g., to removing the magnetic force applied to thread tip 610) or by reversing

the polarity of the magnetic field (e.g., by creating a magnetic force in the opposite direction, thereby forcing thread tip 610 out of extended base 406).

In cases in which a magnetic force is used to couple thread tip 610 and stitching apparatus 400, extended base 406 and/or thread 612 may be formed using non-magnetic material to prevent misalignment of thread tip 610 during use. For example, extended base 406 may be constructed using ceramics, carbon fiber, or another such material that does not react to the magnetic field of the thread extractor and retains its rigidity enough to pierce through material 602. Similarly, thread 612 may be constructed using a non-magnetic material, such as nylon, to prevent thread 612 from accidentally being attracted to stitching apparatus 400.

In another embodiment, the thread extractor may be an adhesive material applied within interior 416 of elongated base 406. For example, interior 416 may be coated with a glue that adheres thread tip 610 to interior 416. In another example, both interior 416 and thread tip 610 may be coated with compounds that chemically react to form a bond (e.g., a polyurethane resin / polyester resin pair or the like).

In yet further embodiments, the thread extractor may correspond to protrusions and/or apertures located within interior 416 of extended base 406. For example, hook and loop fasteners may be affixed to the exterior of thread tip 610 and to interior 416 of extended base 406 to engage thread tip 610 to stitching apparatus 400. In another example, one or

more protrusions may be located within interior 416 that engage one or more slots located on thread tip 610 or vice-versa, as shown in more detail in FIGS. 9A-9B.

In FIG. 6D, an extraction force (F_e) is shown being applied to thread tip 610 to pull thread tip 610 and thread 612 through puncture point 606. The extraction force may be applied in substantially the opposite direction as the insertion force used to drive insertion portion 404 through material 602. During extraction, thread extractor transfers the extraction force exerted by the user on handle portion 402 to thread tip 610. Since the binding force exerted by thread extractor on thread tip 610 is greater than the extraction force, thread tip 610 is forced to move with insertion portion 404 back through puncture point 606, thereby extending thread 606 through material 602. After thread 612 has been threaded through puncture point 606, thread tip 610 may be decoupled from the thread extractor (e.g., by manually breaking the bond, by deactivating a magnetic bond, etc.). The steps depicted in FIGS. 6A-6D can then be repeated any number of times in an alternating fashion between materials 602, 604 to form stitches between the two using thread 606.

Notably, compared to traditional methods, there would be little resistance for thread to go through the puncture point 660, to another side of 602, since the puncture point 606 was pierced previously by the needle element, and the thread is now inside the hollow space 610'.

Referring now to FIG. 7, a schematic diagram of a stitching apparatus 700 is shown that uses an electromagnetic thread extractor. Similar to stitching apparatus 400, stitching apparatus 700 includes a handle portion 702 and an insertion portion 704 that includes a

beveled needle tip 706. Insertion portion 704 defines a hollow space through which thread tip 710 has been inserted. Thread tip 710 is coupled to thread 708 such that movement of either thread tip 710 or thread 708 causes the other to move.

In various embodiments, insertion portion 704 includes an electromagnet 712 that exerts a magnetic force on thread tip 710 when active. The polarity of electromagnet 712 may be selected such that, when current is supplied to electromagnet 712, the resulting magnetic field draws thread tip 710 towards electromagnet 712 and couples thread tip 710 to electromagnet 712. In one embodiment, electromagnet 712 is a solenoid having windings along the interior of insertion portion 704 and extending radially away from handle portion 702. In another embodiment, electromagnet 712 is located partially or fully outside of the interior of insertion portion 704. In such a case, electromagnet 712 may be configured such that the flux path of its resulting magnetic field passes through at least a portion of the interior of insertion portion 704, thereby exerting a magnetic force on thread tip 710.

Stitching apparatus 700 may include power electronics 716 that provide current to the windings of electromagnet 712 from a power supply 718 via wires 714, to induce a magnetic field. Power electronics 716 and/or power supply 718 may be housed within handle portion. For example, power supply 718 may include one or more batteries (e.g., storage cells, supercapacitors, etc.) that allow stitching apparatus 700 to be fully portable. In another example, power supply 718 may be external to stitching apparatus 700 (e.g., power supply 718 may be an external battery, a wall socket, etc. coupled to power electronics 716).

Power electronics 716 operate to control the flow of current to electromagnet 712 in one or more directions. For example, power electronics 716 may have two or three modes of operation. In a dual mode configuration, power electronics 716 may induce an attractive magnetic field when active (e.g., forcing thread tip 710 toward stitching apparatus 400) and remove the magnetic field when deactivated. In a tri-mode configuration, power electronics 716 may induce an attractive magnetic field, induce a repulsive magnetic field by reversing the polarity to electromagnet 712 (e.g., forcing thread tip 710 away from stitching apparatus 400), or remove the current to electromagnet 712 completely to deactivate the magnetic field. In one embodiment, power electronics 716 includes a switch 720 located on the exterior or handle portion 702 that controls the mode of operation of power electronics 716.

Referring now to FIG. 8, a stitching apparatus 800 is shown, according to an exemplary embodiment. Stitching apparatus 800 includes a handle portion 802 that is grasped by a user to manipulate stitching apparatus 800. Stitching apparatus 800 also includes a curved insertion portion 804 connected to handle portion 802. At the end of insertion portion 804 opposite handle portion 802 is a needle tip 812 used to puncture through a layer of material in response to the user applying a force to handle portion 802. Such an insertion force may be at least semicircular in direction, allowing the user to "hook" insertion portion 804 through the layer of material.

As discussed above, a variety of other systems may be used to engage thread element and needle elements, including a vacuum system, for example where the needle element would exert a vacuum force to attract and engage the thread portion to the needle element.

At the base of insertion portion 804 is a thread extractor 806 that engages a thread tip 808 connected to thread 810. Thread extractor 806 may extend outward from handle portion 802 or may be located at least a fraction of the way into the interior of handle portion 802. In one embodiment, thread extractor 806 includes a magnet that attracts thread tip 808, thereby coupling thread tip 808 to stitching apparatus 800. In some cases, insertion portion 804 and/or handle portion 802 may define a hollow space that shrouds thread tip 808 when coupled to thread extractor 806. When thread tip 808 is coupled to thread extractor 806, an extraction force may be transferred from handle portion 802 to thread tip 808 to pull thread 810 through the puncture point created by needle tip 812 in the layer of material.

Referring now to FIGS. 9A-9B, cross sectional views of an insertion portion 900 of a stitching apparatus and a thread tip 910 are shown, respectively. In FIG. 9A, insertion portion 900 defines a hollow space 902 having a diameter slightly larger than that of thread tip 910, allowing thread tip 910 to be inserted into insertion portion 900. Protruding radially inward from the periphery of hollow space 902 is a plurality of locking protrusions 904. One or more locking protrusions 904 may be used, in various embodiments.

Thread tip 910 may include any number of apertures 912 that correspond to protrusions 904 of insertion portion 900. Apertures 912 may extend radially inward from the

perimeter of thread tip 910 relative to an axis 914 that passes through the center of thread tip 910. Apertures 912 may be shaped such that two or more motions of insertion portion 900 and/or thread tip 910 causes protrusions 904 to engage apertures 912, thereby locking thread tip 910 into insertion portion 900. In some embodiments, apertures 912 of thread tip 910 may be of an "L" or "J" shape such that a first motion is used to insert protrusions 904 into apertures 912 and a second or subsequent motion is used to lock protrusions 904 into place. For example, thread tip 910 may be inserted into hollow space 902 of insertion portion 900 along axis 914, to first engage protrusions 904 with apertures 912. Thread tip 912 and/or insertion portion 900 may then be rotated about axis 914 to lock protrusions 904 into place on thread tip 910. Once locked into place, protrusions 904 transfer any subsequent force exerted to thread tip 910 along axis 914, such as an extraction force used to pull thread tip 910 through a layer of material.

In an alternate embodiment, apertures 912 may be located within hollow space 902 of insertion portion 900 and protrusions 904 may extend radially outward from thread tip 910. In yet another embodiment, apertures 912 and corresponding protrusions 904 may be distributed among thread tip 910 and insertion portion 900 such that each has at least one aperture and at least one protrusion.

The invention has been described in detail with reference to preferred embodiments thereof. However, it will be appreciated by those skilled in the art that changes may be made

in these embodiments without departing from the principles and spirit of the invention, the scope of which is defined in the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. A method for passing suture through tissue comprising:

(a) piercing a needle element through tissue,;

(b) engaging a suture with the needle, and

(c) pulling the suture through the tissue.

2. The method of claim 1 wherein the needle releasably engages the suture.

3. The method of claim 1 or 2 wherein the needle magnetically engages the suture.

4. The method of claim 1 or 2 wherein the needle mechanically engages the suture.

5. The method of claim 1 or 2 wherein the needle engages the suture by chemical bond.

6. A method stitching comprising:

piercing a needle element through a material;

engaging the needle element with a thread element while the needle extends through the material;

withdrawing the needle element with the engaged thread element through the material.

7. The method of claim 6 wherein the needle element comprises a thread extractor which engages an end of the thread element.

8. The method of claim 6 wherein the needle element releasably affixes to the thread element during the engaging.

9. The method of claim 6 wherein the needle element magnetically engages the thread elements.

10. The method of claim 6 wherein the needle element mechanically engages the thread element.

11. The method of claim 6 wherein the needle element engages the thread element by an adhesive.

12. A stitching apparatus comprising:

means for transferring an insertion force from a handle to a needle tip;

means for piercing through a layer of material using the needle tip to insert an insertion portion through the layer of material;

means for engaging a thread extractor of the insertion portion to a tip of a thread while the insertion portion is inserted through the layer of material;

14. A needle system comprising:

a) a needle element that comprises 1) an insertion portion configured to be inserted through a material and 2) a thread extractor configured to engage a suture element when the insertion portion has been inserted through the material; and

b) a suture element,

wherein the needle element and suture element each is configured to be releasably engaged together.

15. The system of claim 14 wherein an end portion of the needle element comprises an enclosure that houses a thread extractor element and at least partially encases an end of the suture when the suture is engaged to the thread extractor element.

16. The system of claim 14 or 15 wherein the needle element and suture element each comprise a magnet.

17. The system of claim 15 wherein the thread extractor comprises a magnet that engages the suture end portion by magnetically coupling the suture end portion to the thread extractor.

18. The system of anyone of claims 14 through 17 wherein the needle element and suture element each comprise mating mechanical engagements.

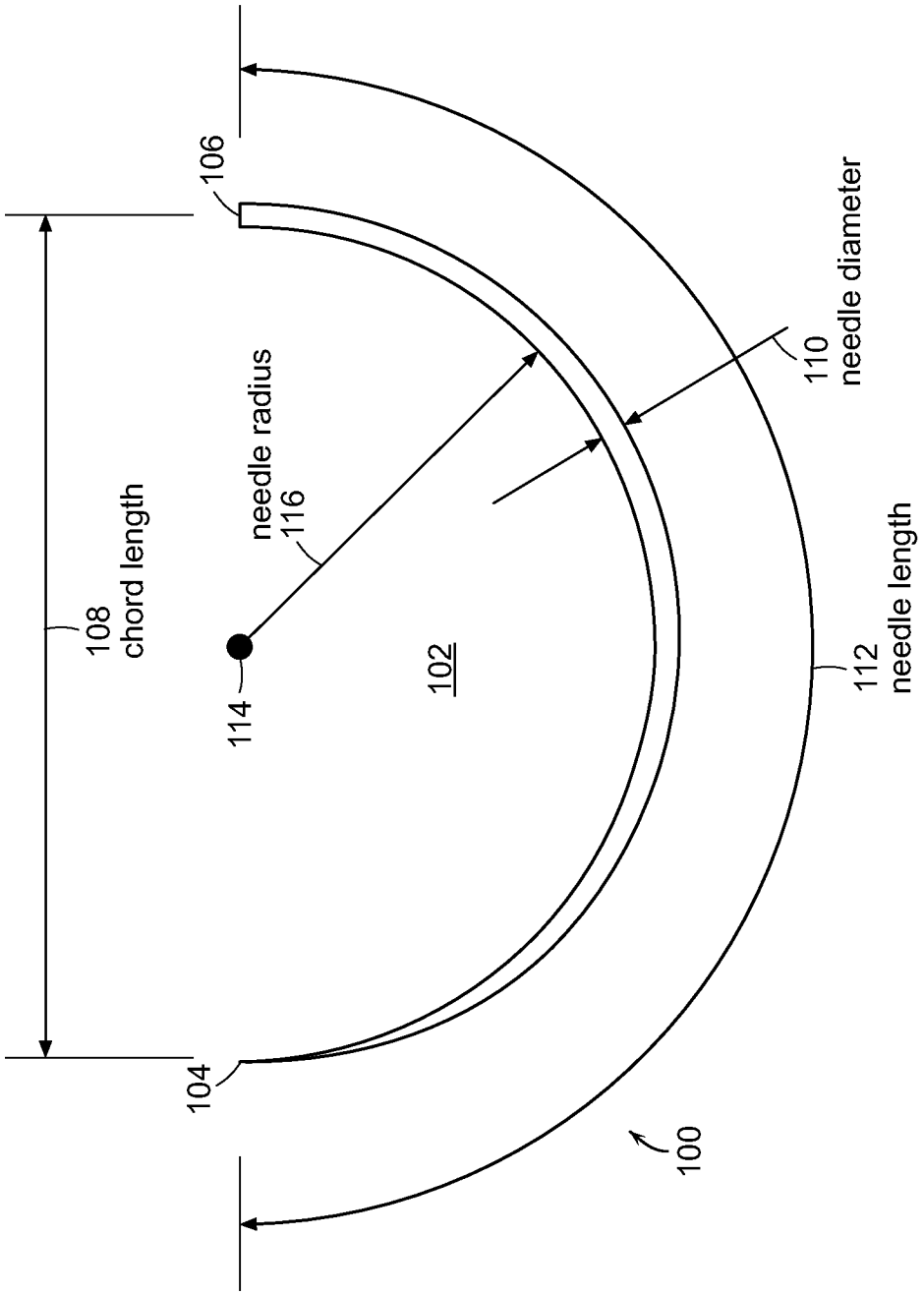

106
108
chord length
needle radius
116
110
needle diameter
102
114
112
needle length
104
100

FIG. 1

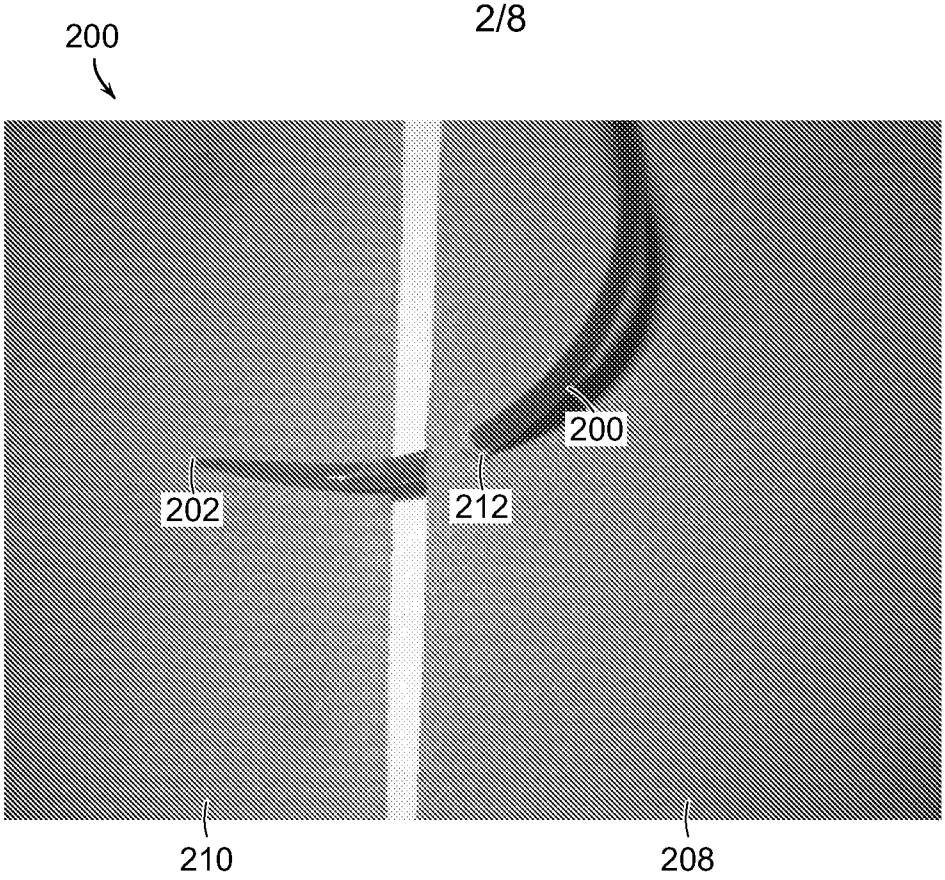


FIG. 2A

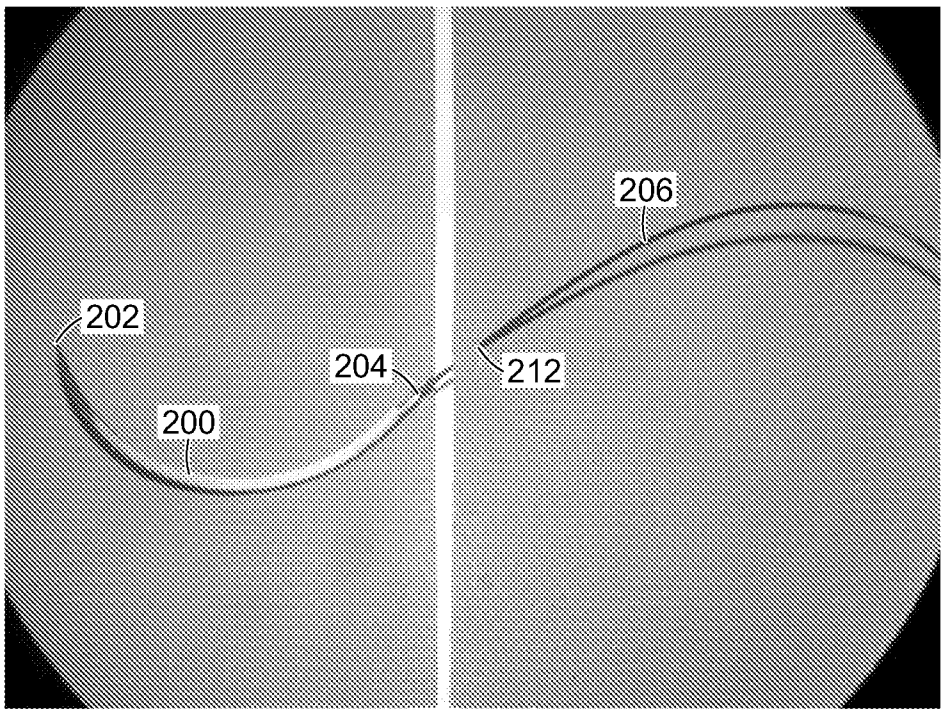


FIG. 2B

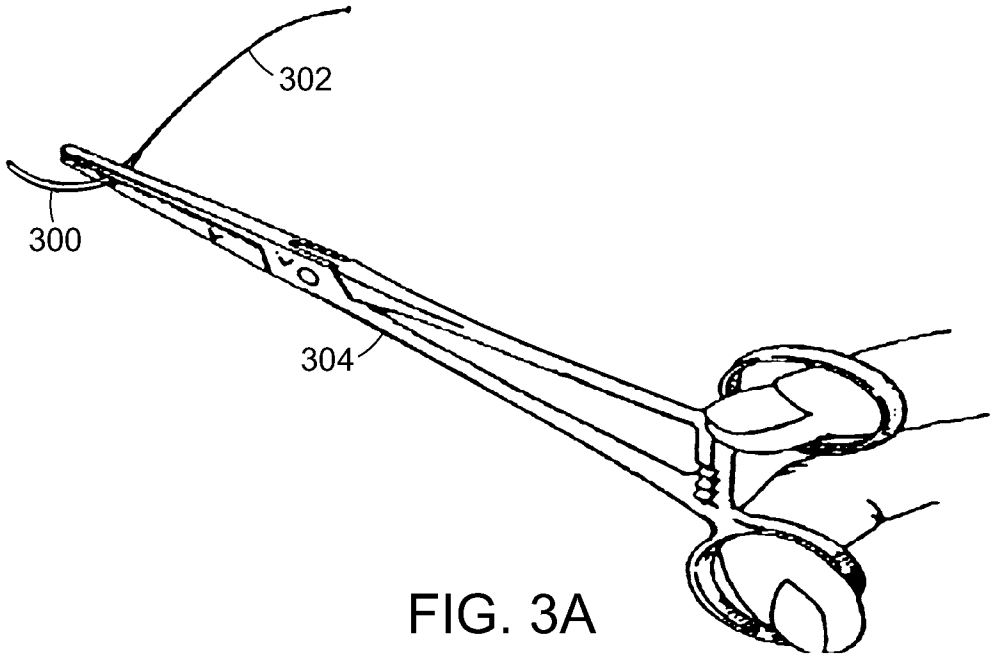


FIG. 3A

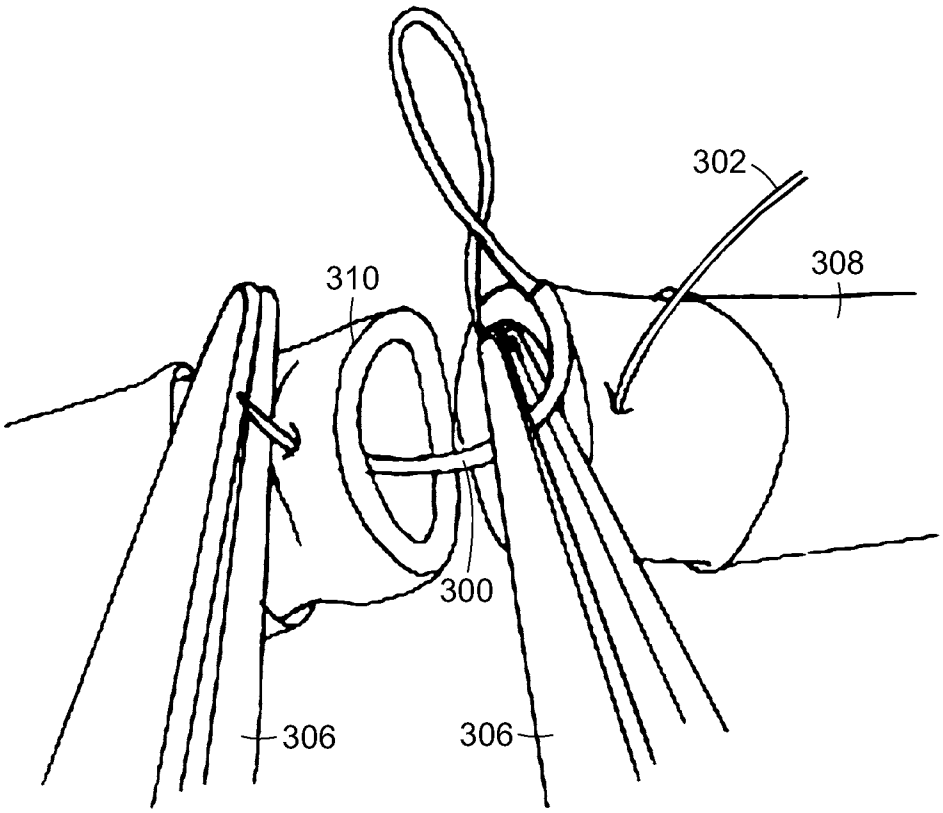


FIG. 3B

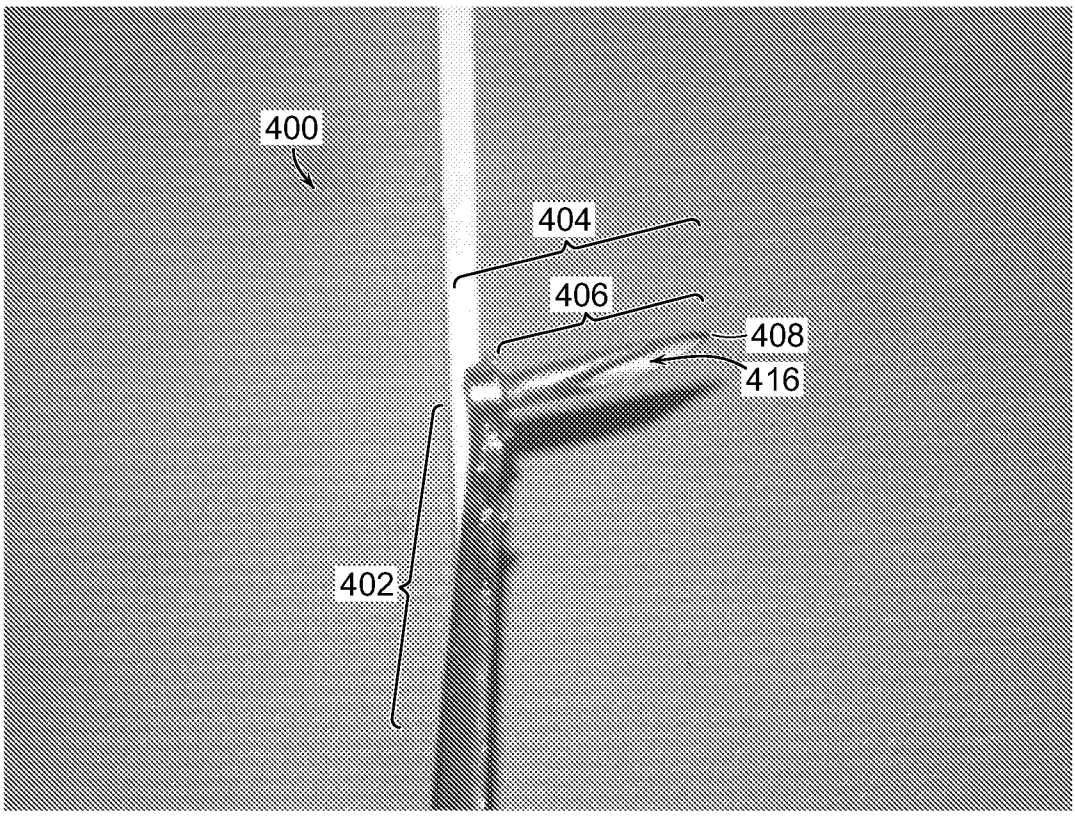


FIG. 4

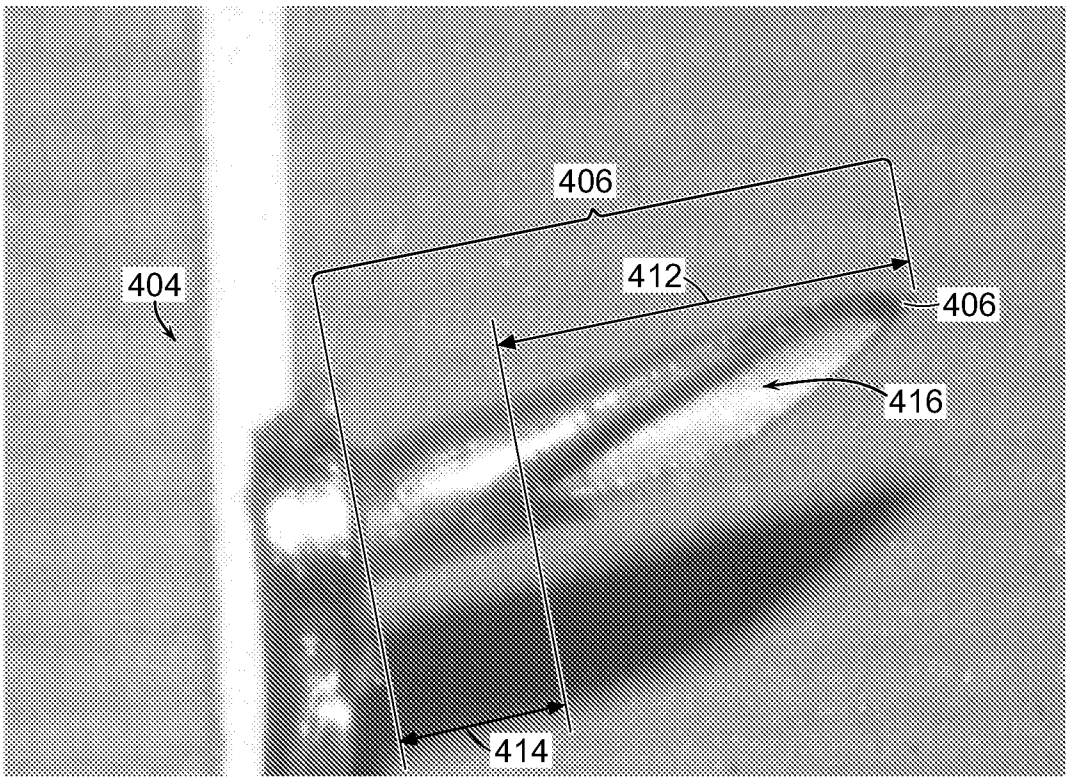


FIG. 5

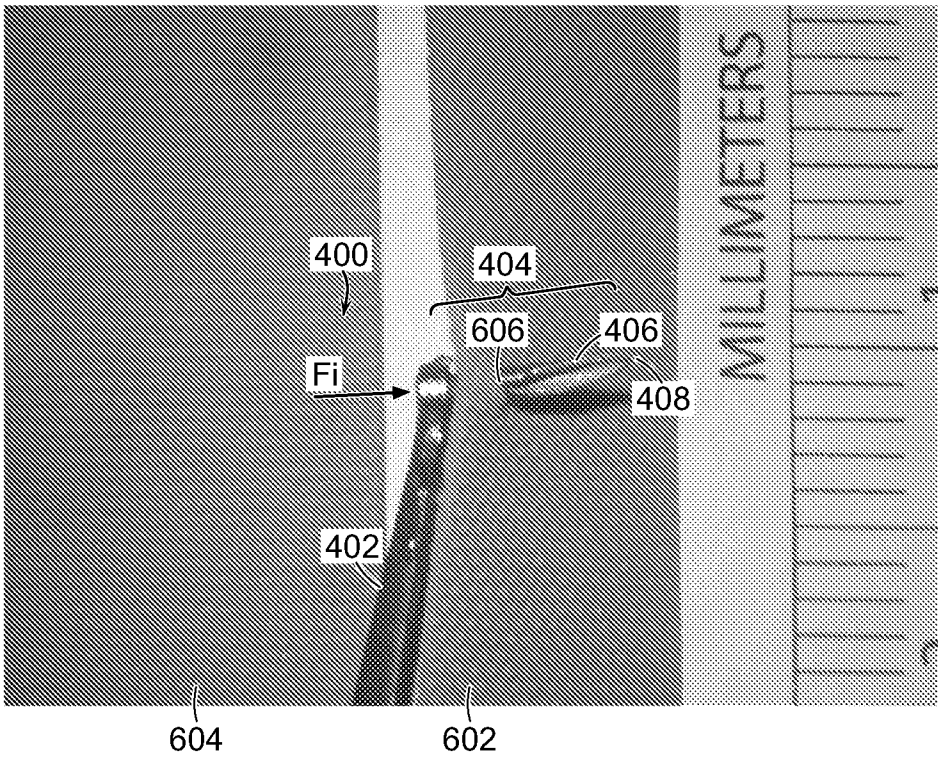

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408
402
604
602
MILLIMETERS

FIG. 6A

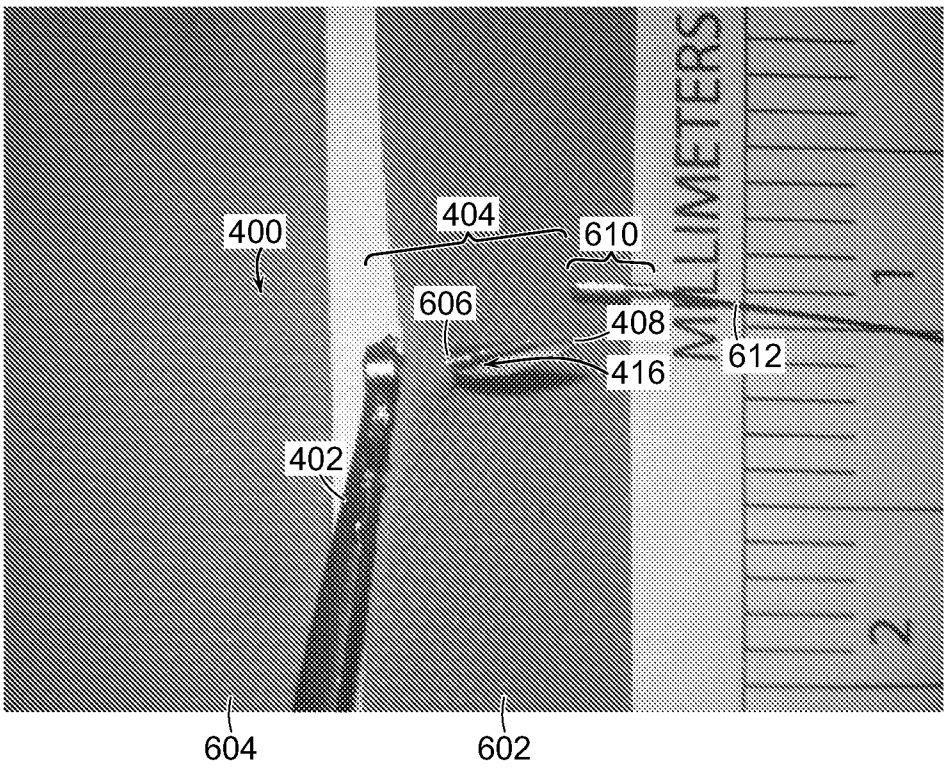

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602
MILLIMETERS

FIG. 6B

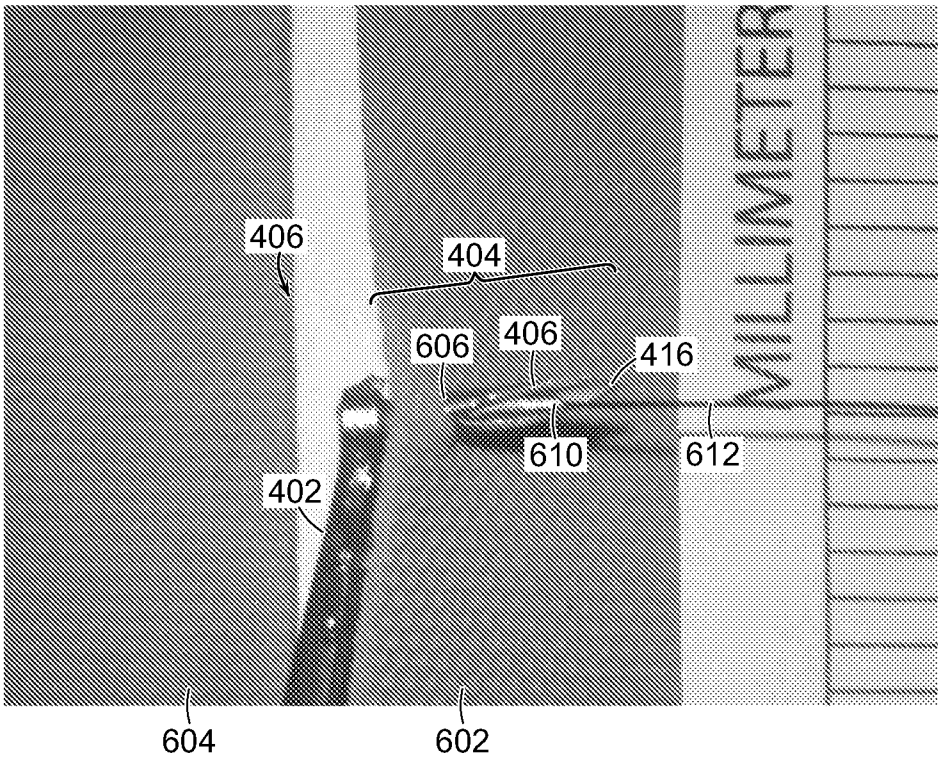

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FIG. 6C

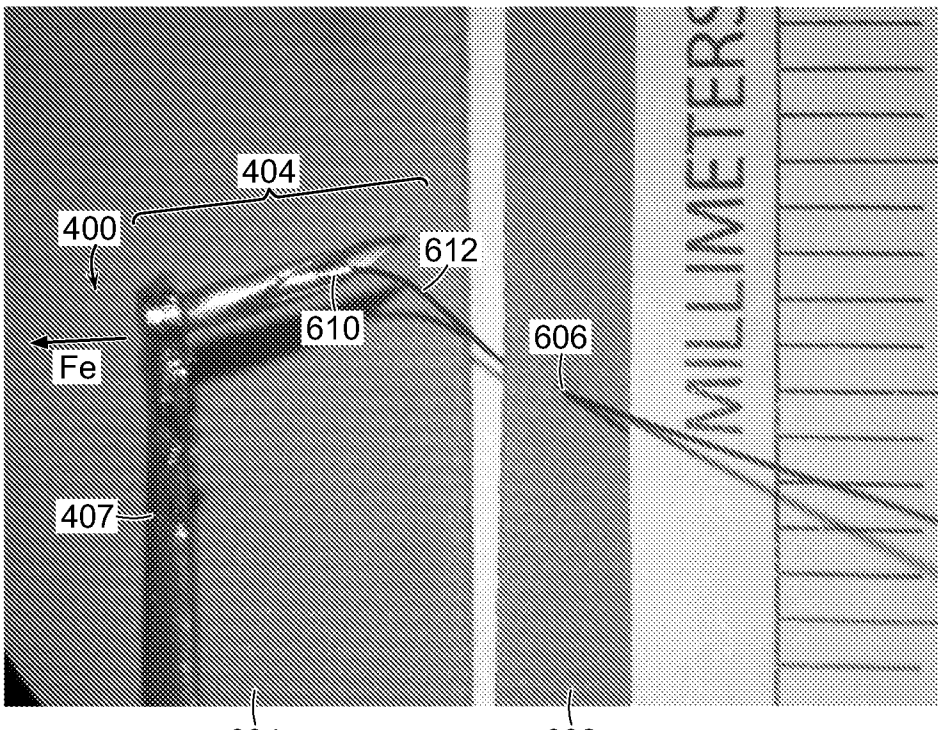

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FIG. 6D

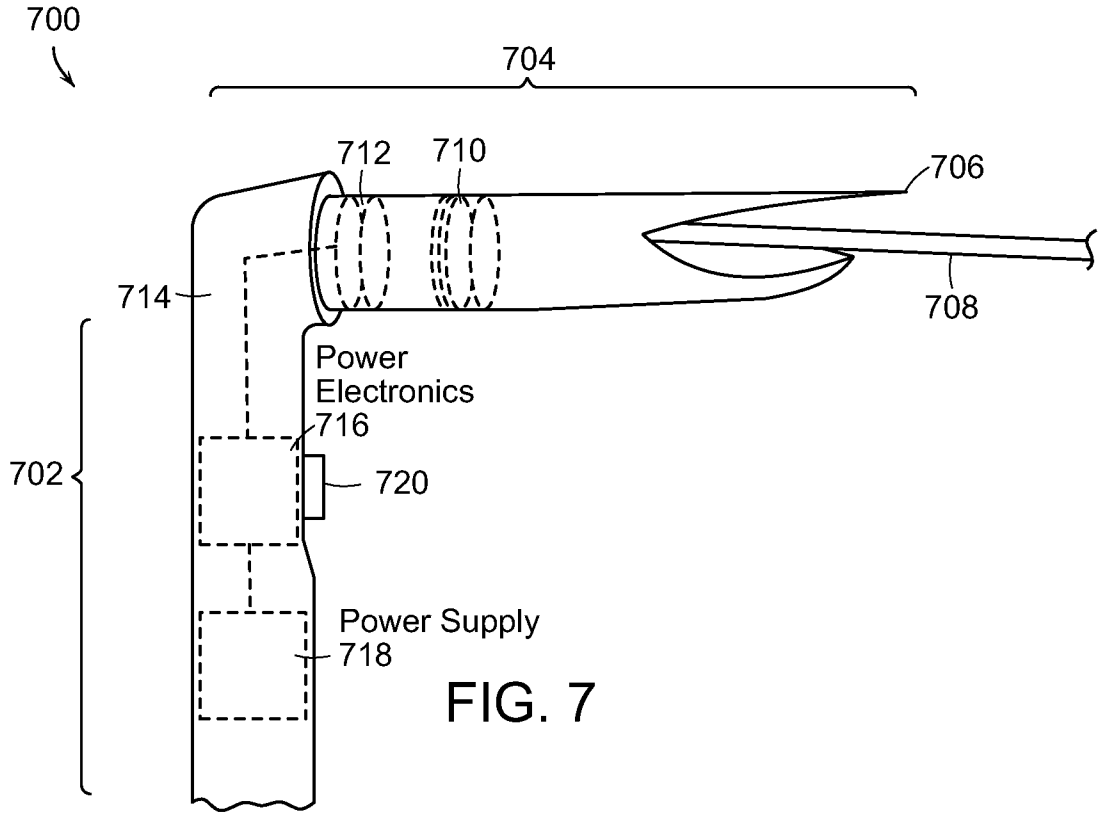

700
704
712
710
706
714
708
Power
Electronics
716
702
720
Power Supply
718

FIG. 7

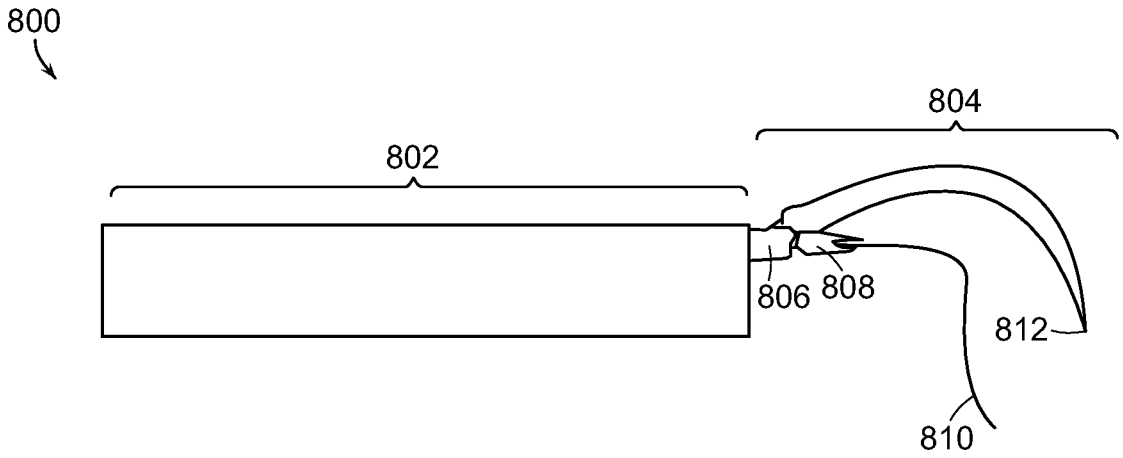

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810

FIG. 8

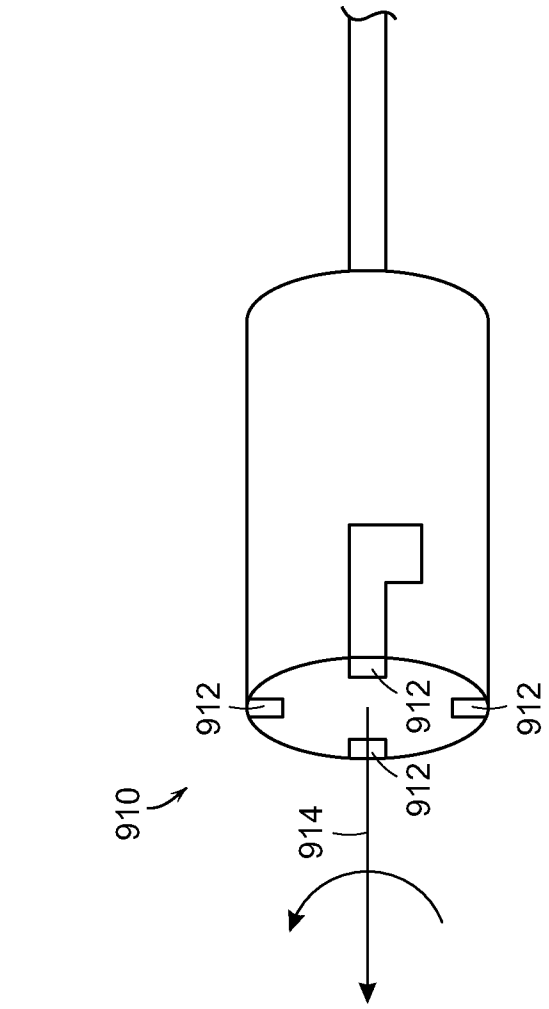


FIG. 9B

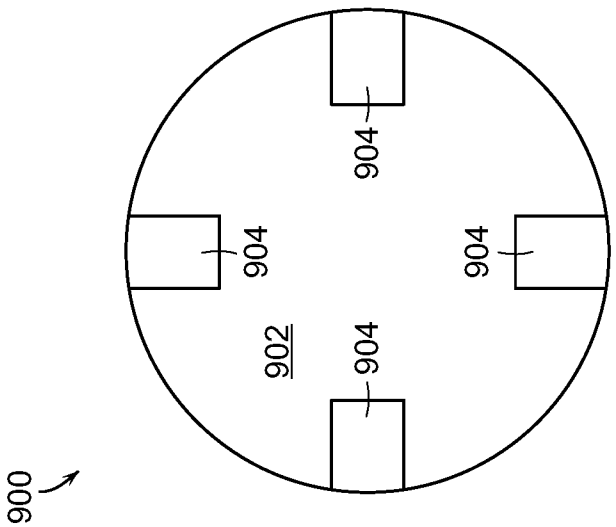


FIG. 9A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/071599

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/04(2006.01)i, A61B 17/062(2006.01)i

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)
A61B 17/04; A61B 17/06; A61B 17/062

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: suture, thread, extract, needle, magnet, extract

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007-0118153 A1 (FUNAMURA et al.) 24 May 2007 See paragraphs [0030]-[0053]; claims 1-7; and figures 1-14.	12,14,15
Y		16,17
Y	EP 0778004 B1 (KABUSHIKI KAISHA MATSUTANI SEISAKUSHO) 26 March 2003 See paragraphs [0021]-[0058]; and figures 1-10.	16,17
A	US 2003-0105474 A1 (BONUTTI, PETER M.) 05 June 2003 See paragraphs [0038]-[0067]; and figures 1-20.	12,14-17
A	US 2009-0318958 A1 (OCHIAI, DEREK H.) 24 December 2009 See the whole document.	12,14-17
A	WO 2011-025767 A1 (SMITH & NEPHEW, INC. et al.) 03 March 2011 See the whole document.	12,14-17

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 April 2015 (07.04.2015)	**07 April 2015 (07.04.2015)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea
Facsimile No. ++82 42 472 7140

Authorized officer
CHANG, Bong Ho
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/071599

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

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

1. ☒ Claims Nos.: 1-11
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-11 pertain to a method for treatment of the human body by surgery and thus relate to a subject matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

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.: 18
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/071599

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 6719765 B2	13/04/2004
US 2009-0318958 A1	24/12/2009	US 8403947 B2	26/03/2013
WO 2011-025767 A1	03/03/2011	None	