(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 February 2008 (21.02.2008)

PCT

(10) International Publication Number
WO 2008/020833 Al

(51) **International Patent Classification:**
A61B 17/16 **(2006.01)** *A61B 17/32* **(2006.01)**
A61B 17/17 **(2006.01)**

(21) **International Application Number:**
PCT/US2006/031677

(22) **International Filing Date:** 14 August 2006 (14.08.2006)

(25) **Filing Language:** English

(26) **Publication Language:** English

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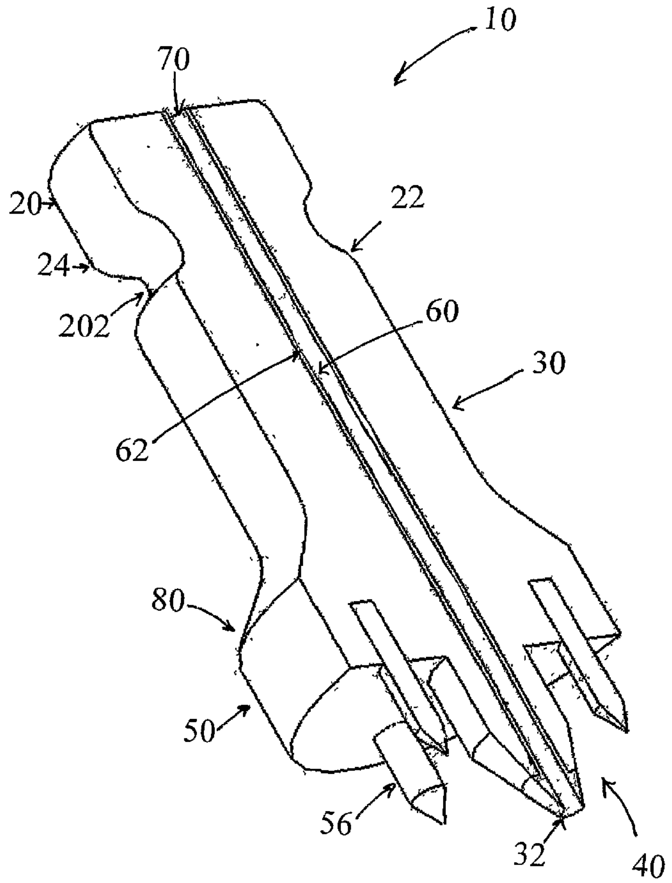
(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) **Title:** IMPROVED PEDICLE PUNCH



(57) Abstract: The present application relates to pedicle implements, in particular pedicle implants that involve screws and includes a handle, a pointy tip (32) , a shaft (30) , a cannula located therethrough and mini protrusions (56) used to prevent toggling. The crux is the ability of the user to create an accurate pilot hole via the pointy tip. In addition, the user has the ability to insert a pedicle probe through the cannula out through the pointy tip. This allows the user to perform the cannulation portion of the procedure without the use of any thrombatic agents .

WO 2008/020833 A1

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

Improved Pedicle Punch

Field of Invention

The present invention relates to a method and apparatus for use in spinal implant procedures and the like. More particular, the invention relates to a new and improved pedicle punch for use in forming pilot holes on the pedicles of vertebrae, the pilot holes having a diameter sufficiently wide to accommodate further instrumentation, and an initial trajectory path vector concentric to and aligned with the pedicle axis, whereby the penetration of the pedicle with a pedicle probe and the subsequent insertion into the pedicle of a pedicle screw is accomplished quickly, accurately, flawlessly and without breaking out of the pedicle during a spinal fusion operation. In addition the improved pedicle punch facilitates in the cannulation process during vertebral column surgery.

Background of Invention

Pedicle screw instrumentation is common in the lumbar spine and is gaining acceptance in the thoracic spine. The use of pedicle screw instrumentation in the spine has evolved over the last two decades. The initial use of pedicle screws began in the lumbar spine. As surgeons have become more comfortable with the complex anatomy required for accurate screw placement, the use of pedicle instrumentation has evolved to include their use in the thoracolumbar and thoracic spine. The impetus behind their increased use is a result of the many advantages that pedicle screw anchorage offers over traditional hook and rod constructs. Improved deformity correction and overall construct rigidity are two important advantages of pedicle screw instrumentation due its three-column control over the spinal elements. First, pedicle screw instrumentation obviates the need to place instrumentation within the spinal canal with its inherent risk of neurologic injury. Second, the placement of pedicle screws is independent of facet or laminar integrity and thus has been extremely useful in traumatic, neoplastic, and degenerative conditions. The benefit of pedicle screws in the thoracic spine has been tempered by the potential for catastrophic neurological or soft tissue injuries due to the close proximity of these structures. The narrow and inconsistent shape of the thoracic pedicles, especially in spinal deformity, makes their placement technically challenging. As a result, surgeons have employed a number of techniques to ensure the safe and efficacious placement of thoracic pedicle screws. Detailed anatomic landmarks used to determine pedicle location, intraoperative imaging including navigation, and neurophysiological monitoring are some of the techniques currently used by surgeons. The implementation of these techniques and a thorough understanding of the complex three-dimensional anatomy have allowed surgeons to successfully place thoracic and thoracolumbar pedicle screws.

Generally speaking, procedures for navigating the pedicle comprise the following steps: (1) decorticating the entry site using a burr and a high speed drill or a rongeur; (2) using an awl or a burr to penetrate the dorsal cortex of the pedicle and create a starter or pilot hole into the pedicle; (3) using a curved or straight pedicle probe to develop a path for the screw through the cancellous bone of the pedicle into the vertebral body (the process hereinafter referred to as "cannulation"). The advancement of the probe must be smooth and consistent and a sudden plunge suggests breaking out of the pedicle laterally. Furthermore, an increase in resistance indicates abutment against the pedicle or the vertebral body; (4) after cannulation, placing the pedicle sounding probe into the pedicle and then palpating the pedicle from within to make sure there is not a medial, lateral, rostral or caudal disruption in the cortex of the pedicle. Sound should also be used to determine that there is bone at the bottom of the pilot hole verifying that penetration of the ventral cortex of the vertebral body has not occurred; (5) after the pedicles have been probed, placing Steinman pins or K-wires bilaterally or unilaterally into the pedicles to confirm the trajectory and entry site, tapping the pedicle screw path if non-self tapping screws are used, and placing the permanent screws with the longest diameter that will not fracture the pedicle. The length of the screw can be determined by measuring the length of the Steinman pin/Kwire/pedicle probe from the pedicle entry site to a depth of 50-80 % of the vertebral body; and (6) after pedicle screw placement, decorticating the transverse process and the lateral aspects of the facet joints, connecting the screw to a longitudinal construct, usually a rod or a plate, securing the screws, and placing bone graft on the previously fusion bed. During the entire process the advancement of the probe, the placement of the K-wires, and. the ultimate advancement of the pedicle screws is monitored continuously via X-ray exposure or fluoroscopy.

These processes have many disadvantages including, among other things, a steep learning curve, caudal or medial penetration of the pedicle cortex which can result in dural or neural injury, and a very lengthy operative time with potential or significant blood loss, and an increased risk of infection. Furthermore, these processes only approximate or simulate screw placement indirectly, through a CT scan or MRI done prior to surgery and include fluoroscopic and frameless stereotactic guidance.

The use of X-rays, fluoroscopy, and MRI during these processes is also a drawback. The reality is that radiation is a hazard. Ionizing radiation has no safe, threshold of exposure below which it ceases to have adverse effects, although an arbitrary level is assumed. There has been a recent upward revision of risk estimates of radiation exposure but absolute levels of safe exposure remain unknown. Exposure to the surgical team as well as the patient during the spinal fusion process using fluoroscopy is a universal concern. Yet notwithstanding the use of all of this radiation, much appears in the literature with respect to the problems of misalignment of pedicle screws and the symptoms arising when the screws make contact with neural elements after breaking outside the pedicle cortex. Cutting into a nerve root or simply contacting the root gives rise to various postoperative symptoms, including dropped foot, neurological lesions, sensory deficits or pain.

The relevant and material prior art has tried to address some of these drawbacks. One example of improvements in the prior art that have tried to address these disadvantages is **United States Letters Patent No. U.S. 6,855,105 B2.** It is directed to a system and method for insertion of pedicle screws which seeks to eliminate the guesswork and error-prone modalities of the prior art and claims to provide the surgeon with direct confirmation during the surgical procedure that the pedicle probe is in the right position for forming a path for the proper placement of the pedicle screw. The system and method comprises an endoscopic pedicle probe for use during spinal surgery to form a path in a pedicle for reception of a pedicle screw. The probe has an enlarged proximal end for cooperation with the hand of the surgeon so that the probe can be pushed through the pedicle in a controlled manner, and an elongated hollow shaft terminating in a distal tip end. A fiber optic cable or endoscope is placed in the hollow shaft and connected with a monitor to enable the surgeon to visually observe the structure adjacent the tip end of the probe during surgery, whereby the probe may be accurately placed in the pedicle for subsequent accurate placement of the pedicle screw in the path formed with the probe.

Another example, is **United States Letters Patent No. 5,573,537,** It is directed to a combination reaming and probing instrument and a method for its use to install pedicle screws. The instrument provides a step-down screw hole in a pedicle. It includes an end member for rotatable connection with a power source, a probe for providing a pilot hole in the pedicle and a side-cutting reamer member for providing an anchor hole for a pedicle screw positioned about the pilot hole. The arrangement is such that the instrument is self centering in part due to the presence of the probe in the pilot hole.

A further example is **United States Letters Patent No. 5,361,766** for a quick release bone probe and x-ray marker for use in spinal implant procedures to enter the pedicle of a vertebrae. It comprises a probe having a proximal end and a distal end with fastening means on the proximal end and a handle. The handle has gripping means and further includes fastening means for selectively engaging the proximal end of the probe. The distal end of the probe is shaped to pierce the pedicle of a vertebrae. The probe includes marking means for determining the depth the distal end projects into a pedicle and marking means for selectively distinguishing a right probe from a left probe on interoperative x-rays.

Yet another example is **United States Letters Patent No. 4,790,297** which is directed to a spinal fixation method and system which allows direct screw fixation to the vertebral bodies to produce the potential for a very stable fusion. Blunt guide wires inserted into the pedicles help preclude penetration of the anterior cortex while permitting more accurate screw placement with the assistance of X-ray imaging.

Still another example in the prior art is **United States Letter Patent No. 5,196,015** which is directed to a procedure for spinal pedicle screw insertion in spinal vertebrae in a manner to reduce the likelihood of nerve damage caused by improper screw placement. It comprises the following steps: a screw opening is started in part of a skeletal region, e.g., a pedicle of a lumbar vertebra and an electric potential of a certain magnitude is applied to the inner surface of the opening while the patient is observed for nervous reactions such as leg twitching. The opening continues to be formed while the electric potential is applied until a desired hole depth is obtained in the absence of nervous reaction to the potential. The direction in which the screw opening is being formed is changed to a direction other than the last direction, after observing patient reactions to the electric potential when the screw opening was being formed in the last direction. A tool for carrying out the procedure includes a handle and a probe tip extending from the handle for forming an opening in bone tissue. Stimulator circuitry arranged inside the handle produces an electric potential of a predetermined level, and the potential is applied to the probe tip while the tool handle is manipulated to urge the probe tip into the bone tissue.

Another example is **United States Letters Patent No. 4,907,577** directed to a spinal transpedicle drill which is adapted for providing a safe route for drilling, including an I-shaped body, a guiding base and a positioning base. The jig provides a precise location for drilling to prevent deviation of the drilling direction so as to prevent injury during surgery to the nerve root or spinal cord.

Yet another example is **United States Letters Patent No. 4,586,497** directed to a drill fixation device and method for vertebral cutting. The device includes a carrier mounting the drill for guided movement relative to a base and a squeeze grip connected between the base and carrier to enable a surgeon to selectively impart such movement to the drill. A foot plate is fixed relative to the base in spaced relationship to the carrier so as to be in the path of the bit of a drill mounted on the carrier. In use, the foot plate is positioned beneath the bone material to be cut to apply counterforce to the bone material as the drill cuts and shield nerve tissue from harm by the bit.

However, all of the improvements set forth above and many others, both patented and unpatented, focus on changing and improving traditionally accepted practices and procedures for pedicle screw insertion, after the initial steps of using a burr or an awl to penetrate and create starter holes, entry ports, or pilot holes in the dorsal cortex of the vertebrae pedicle, have taken place. Thus, these improvements have done nothing to change the steep learning curve of the surgeons, or to significantly reduce the very high misplacement rate of pedicle probes. While pedicle disruption does not necessarily cause neural deficit, keeping the pedicle probe and ultimately the pedicle screw within the pedicle is one sure way to prevent it altogether. Further, these improvements do absolutely nothing to significantly reduce the amount of radiation, the amount of time it takes to complete the pedicle insertion and the steps necessary for it.

As was discussed above, procedures for navigating the pedicle comprise the initial steps of decorticating the entry site using a burr and a high speed drill or a rongeur; and using an awl or a burr, with the aid of X-rays or fluoroscopy, to penetrate the dorsal cortex of the pedicle and create a starter or pilot hole into the pedicle. Other procedures include burning to create the pilot hole on the pedicle. There are significant drawbacks with these steps as well.

If the initial pilot holes on the pedicles are accomplished through burning, such markings are impermanent. Further, they do not create the necessary 3-4 mm starting hole required for the next instrumentation tools, i.e. the probe and ultimately the pedicle screws.

If, on the other hand, burring or an awl is used to create all the stalling or pilot holes, they cannot be created without moving the x-ray or fluoroscopic image while utilizing the burr. Further, the burring of starting or pilot holes can cause significant bleeding thereby requiring the administration of thrombotic agents during the procedure to stop the blood flow. This bleeding can be further aggravated if, as a result of false burring starts, a large number of starting but useless holes are created. Finally, because fluoroscopy has to frequently be repeated after the starting or pilot hole is created because burring cannot be done safely under the fluoroscopic view, the method often requires two or three attempts with image guidance, thus significantly increasing the time it takes to complete the pedicle screw insertion. More importantly however, even with the two or three attempts with image guidance, the fluoroscopy image does shift during the burning or burring, thereby making it impossible to set a pilot hole trajectory path whose vector is totally aligned with the pedicle axis right from the very beginning of the pedicle penetration process. Consequently, when the surgeon proceeds to the next step of inserting the probe or any other instrument he will use to enlarge the pedicle path, in preparation of the insertion of the pedicle screw, he must correct the initial vector of the pilot hole trajectory path and compensate for any errors or deviations thereof from the pedicle axis, if the insertion of the pedicle screw is to proceed smoothly and with out pedicle break through. This only adds to the time it takes to complete the process and increases the radiation used during the process even further.

The present invention, as mentioned above, also relates to cannulation during the pedicle screw procedure. One will now discuss in more detail the present invention, in particular, a pedicle punch that facilitates cannulation during pedicle screw implants.

In general a cannula is a flexible tube, which when inserted into the body may be used to withdraw fluid, insert medication or as in the present invention allow Lenke gearshifts, endoscopic probes, and the like to be inserted into the pedicle. Cannulae normally come with a trocar (a sharp pointed needle) attached which allows puncture of the body to get into the intended space.

Before the cannulation process begins, a posterior cortical breach first must be established on the pedicle, usually via any of the different methods as discussed in applicant's previous filed patent application, such as the burring method, the burning method or the punch method. A number of surgical instruments have been implemented to successfully cannulate thoracic pedicles. The two most common instruments include a gearshift device probe and a cervical curette. Another device that has been implemented with pedicle cannulation is Safe Path, a blunt-tipped, nonaggressive drill that seeks the cancellous portion of the pedicle. The pedicle punch of the present invention may be used with any of the aforementioned devices.

One will now discuss the utility of the present invention, for illustrative purposes one will discuss the present invention when used with a Lenke gearshift. A curved Lenke gearshift or a straight curette (3-0 cervical) may be used to probe or mature the intended screw path within the pedicle. The gearshift may be inserted via the cannula of the present invention. Once the neurocentral junction of the pedicle is reached (typically at a depth of 20 mm) the gearshift is removed and reinserted with the curved tip facing away from the surgeon. Positioning the pedicle probe tip medially assists in guiding the probe medially within the vertebral body. Next, the pedicle tract is palpated with a ball-tipped probe to verify the presence of a bony floor and an intact four-wall boundary. If a violation of bony integrity is noted at this point, redirecting the gearshift may be necessary in order to assure safe screw placement. The pedicle path is then tapped (preferably undertapped by 0.5-1.0 mm compared to the diameter of the selected screw) and the tract is repalpated with the ball-tipped probe to detect for any bony breaches. The pedicle screw is now inserted. Following screw insertion, intraoperative imaging is then performed to verify acceptable screw positioning. Triggered EMG testing may be used to evaluate for proper lower thoracic screw placement (T8-T12), while motor-evoked potential (MEP) monitoring assists in monitoring spinal cord function for all thoracic levels instrumented. Once all screws are placed and the applicable screws have been tested via triggered EMG the rod can be docked to complete the construct.

Even though most pedicle implant procedures are successful there is need for improvement. That is, after a posterior cortical breach is established, via the burring method or the burning method, the surgeon would first have to arrest the bleeding associated with these pedicle screw implant methods, before inserting one of the aforementioned probes.

Another drawback of the pedicle screw implant procedure is that the patient, surgeon, and medical staff are exposed to deleterious amounts of radiation, more specifically those deleterious amounts of radiation associated with fluoroscopy during the pedicle screw implant procedure. One way surgeons can protect themselves is with eyewear, thyroid shields, and lead aprons. However, studies with cadavers have shown that the surgeon's hands are still at a high risk of radiation exposure. In one study average fluoroscopy exposure time was 9.3 s per screw. and the average hand dose rate was 58.2 mrem/min. The internationally recommended maximum limit for annual hand radiation exposure is 50,000 mrem. In the same study a significant increase in hand dose rate was noted when placement of the screw was on the same side of the beam source as well as when a heavier cadaver was imaged.

Thoracic and thoracolumbar pedicle screw instrumentation is proving to be a safe and reliable method of obtaining rigid segmental fixation of the thoracic spine. A thorough understanding of the complex 3D spinal anatomy is required to safely place this type of instrumentation. The biomechanical benefits that are derived from using pedicle screw instrumentation in all forms of spinal pathology are the driving force behind more and more surgeons incorporating thoracic and thoracolumbar pedicle screw placement into their practices. Surgeons however, must be well versed in the placement of complex spinal instrumentation in order to accurately and safely use this method of instrumentation in all types of spinal disorders.

Accordingly, there is a need for a pedicle screw insertion system and method which creates a pedicle starter hole having a trajectory path vector in complete alignment with the pedicle axis right from the very beginning of the process, thereby eliminating any need on the part of the surgeon to correct or compensate for any deviations of the pilot hole's trajectory path vector from the pedicle axis during the subsequent steps of the process. Furthermore, the present invention, because of its unique design aids surgeons inthe pedicle cannulation step via a pedicle punch that incorporates a cannula.

Objects of the Invention

It is therefore an object of the present invention to provide a method and apparatus for use in spinal implant procedures wherein the penetration of the pedicle with a probe and subsequent insertion of the pedicle screw is accomplished quickly, accurately, flawlessly and without breaking out of the pedicle path.

It is a further object of the present invention to provide a method and apparatus for use in spinal implant procedures that will significantly decrease the surgeons' learning curve, the caudal or medial penetration of the pedicle cortex thereby significantly reducing dural or neural injury, the time normally associated with such procedures, the blood loss and the risk for infection.

It is an even further object of the present invention to provide a method and apparatus for use in spinal implant procedures that will significantly reduce the exposure of both the surgical team and the patient to radiation exposure and more particularly to fluoroscopic radiation exposure.

It is still another object of the present invention to provide a method and apparatus for use in spinal implant procedures which will significantly minimize the administration of thrombotic agents during the pedicle insertion process.

Another object of the present invention is to provide a method and apparatus for use in the spinal implant procedures which will prevent the creation of false burring starts and significantly reducing the number of starting or pilot holes.

It is a further object of the present invention to provide a method and apparatus for use in spinal implant procedures in which the starter hole or pilot hole has a trajectory path whose vector is in complete alignment with the pedicle axis right from the very beginning of the pedicle penetration process.

It is yet another object of the present invention to provide a method and apparatus for use in a spinal implant procedure wherein the surgeon no longer needs to correct the initial vector of the trajectory path of the pilot hole nor compensate for any errors or deviations thereof from the pedicle axis.

Another object of the present invention is to provide a method and apparatus that allows the surgeon to know the exact starting point of the pedicle, without any guessing, and create such starting point without burring.

A further object of the present invention is to provide a method and apparatus for use in spinal implant procedures that provides hemostasis and prevents over-penetration or plunging into the spinal cord.

Yet another object of the present invention is to provide a method and apparatus for use in spinal implant procedures which allows two surgeons to conduct the instrumentation on the patient's spine at the same time, thereby dramatically reducing the time normally associated therewith.

It is still another object of the present invention to provide an apparatus for use in spinal implant procedures which allows the surgeon to create a posterior cortical breach on the pedicle and insert a pedicle probe in one step via a cannula.

These objects, as well as other objects and advantages will become apparent from the following disclosure.

Summary Of The Invention

According to the present invention there is provided an improved pedicle punch for use in a pedicle screw insertion process. The pedicle punch of the present invention is designed to be easily positioned against a vertebra pedicle in a proper position. The pedicle punch is designed to be readily positioned in complete alignment with the centrally located pedicle axis of the vertebra pedicle through minimal use of imaging technology. Once properly positioned the punch may be deployed into the vertebrae pedicle quickly and effectively to create a pilot hole having (i) a diameter wide enough to accommodate the instrumentation of the next step in the pedicle screw insertion process; and (ii) a trajectory path vector that is totally aligned with the pedicle axis of the vertebrae pedicle.

The pedicle punch is formed from at least two different materials. The first is a radiation translucent material and the second, a radiation opaque material. The pedicle comprises, in general, a proximal end, a distal end, a composite shaft, joining the two ends. The proximal end can have any shape that is ergonomically designed to provide a driving surface for the pedicle punch. The proximal end provides a driving surface for forcing the pedicle punch into the vertebrae pedicle. This surface must be made of a material that will not shear or break, causing a portion of the punch to become separate from the remainder of the punch. Separation of a portion of the pedicle during treatment could contaminate the site where the treatment is occurring, causing infection, a puncture, etc. The composite shaft is attached to and projects from the proximal end and terminates to a sharp conical spike or pointy tip. The composite shaft has a radiation opaque central core running transversely though it's entire length and a radiation translucent outer covering or layer surrounding at least a portion of the central core. The radiation opaque center core extends beyond the radiation translucent outer layer to form the bottom section having a sharp point or pointy tip of the shaft. The outer coating or cover may have an outwardly protruding lip that is located on the composite shaft adjacent to the sharp conical spike or pointy tip, right on the widest diameter thereof and preferably concentric thereto.

According to the present invention there is also provided a method for the use of the inventive pedicle punch comprising the steps of (a) accurately mapping the outer perimeter of the pedicle and the axis thereof; (b) placing the pedicle punch on the pedicle just mapped; c) moving and positioning the pedicle punch until the radiation opaque central core and the pedicle perimeter are bull's eyed; at the desired location (d) once the bull's eyed, deploying the pedicle punch into the mapped vertebrae pedicle using an appropriate force to form a pilot hole having (i) a diameter wide enough to accommodate the instrumentation of the next step in the pedicle screw insertion process; and (ii) a trajectory path vector that is totally aligned with the pedicle axis of the vertebrae pedicle.

In the present invention the pedicle punch includes a cannula, which allows the surgeon to probe the pedicle without removing the pedicle punch. The cannula, preferably centrally located, which alloλvs a pedicle probe to be inserted to facilitate cannulation. The addition of the cannula in the present invention improves on the relevant and material prior art. For example, the unique design of the pedicle punch allows allows the surgeon to leave it attached to the pedicle being operated on, which allows the surgeon to insert the pedicle probe into the pedicle without the need for any thrombotic agents, because the lip of the pedicle punch prevents blood flow out of the pilot hole, Whereas in the prior art the burring of starting or pilot holes can cause significant bleeding thereby requiring the administration of thrombotic agents to stop the blood flow before the insertion of the probe. In addition, since the pedicle punch of the present invention is not removed the surgeons can use it as a guide, thus reducing exposure of the surgeon's hands to the harmful trace amounts of radiation.

Brief description of the drawings

While the specification concludes with claims which particularly point out and distinctly claim the present invention, it is believed that the present invention will be better understood from the following detailed description taken in conjunction with the accompanying drawings in which like numerals represent identical elements and wherein:

Figure 1 is a diagram illustrating a vertebra with its pedicle section shown from all angles.

Figure 2 is a pedicle after screw insertion.

Figure 3 is a perspective view of the pedicle punch according to the invention without a cannula.

Figure 4 is a longitudinal side view thereof showing the pedicle punch without a skirt.

Figure 5 is a perspective view of the pedicle punch as depicted in Fig. 3.

Figure 6 is a side view of the pedicle punch as depicted in Fig. 3.

Figure 7 is longitudinal sectional view of the pedicle punch depicted in Fig. 3 showing the metal core as it traverses the punch from the proximal end of the punch to the distal point down to the sharp point of the shaft.

Figure 8 is a bottom view of the pedicle punch as depicted in Fig. 3.

Figure 9 is another embodiment of the pedicle punch of the present invention.

Figure 10 is a top view of the pedicle punch depicted in Fig. 9.

Figure 11 is another embodiment of the pedicle punch of the present invention.

Figure 12 is a bottom view of the pedicle punch depicted in Fig. 11.

Figure 13 is a perspective view of another embodiment of the pedicle punch of the present invention that includes a cannula.

Figure 14 is a longitudinal side view of the pedicle punch depicted in Fig. 13.

Figure 15 is a cut-away view of the pedicle punch depicted in Fig. 13.

Figure 16 is a side view of the pedicle punch depicted in Fig. 13 with the cannula emphasized.

Figure 17 is a longitudinal side view of the cannula implemented with the pedicle punch depicted in Fig. 13.

Figure 18 is a top view of the radiation opaque tip of the pedicle punch depicted in Fig. 13.

Detailed description of the invention

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

Referring more specifically to the drawings, Figures 1-2 generally depicts a pedicle. The pedicle punch 10 is designed to replace currently available technology and tools currently being used to create pilot holes in pedicle vertebrae during spinal fusion surgical procedures including awls, drills, etc., and more particular during the pedicle screw insertion process. The pedicle punch has been engineered to be readily positioned against the vertebrae pedicle, in the desired alignment with the centrally located pedicle axis through minimal use of imaging technology, such as for example x-rays, fluoroscopy, virtual fluoroscopy, etc., and once properly positioned to be deployed into the vertebrae pedicle quickly and effectively.

Once deployed into the pedicle, pedicle punch 10 remains in position on the vertebrae pedicle until such time as the surgeons remove it to proceed to the next instrumentation step in the pedicle screw insertion process. When removed, the pedicle punch 10 leaves behind, on the vertebrae pedicle, a starter hole, also known as a pilot hole (hereinafter "a pilot hole") having a diameter of preferably 3-4 mm wide and a trajectory path vector that is totally aligned with the pedicle axis of the vertebrae pedicle. In many instances, the pedicle punch provides for almost a perfect pilot hole without undue difficulty. Thus, the surgeons will not have to engage in any further burring, or hole making, or checking with K-wires to determine whether in fact they have correctly identified the central pedicle axis of the pedicle vertebrae before proceeding to the next step. Accordingly, not only will the inventive pedicle punch 10 help create the desired pilot hole, but it will allow the surgeon to reduce a significant amount of time from the pedicle screw insertion process, as well as reduce a significant amount of deleterious radiation to which the surgical team and the patient are exposed to, and minimize the amount of bleeding during the procedure.

The pedicle punch 10 is formed of both radiation translucent and radiation dense material. The radiation translucent material could be any material that allows the radiation of imaging technology used during the pedicle screw insertion processes, to pass right though the material so that the material is not reflected on the viewing screen. Preferred radiation translucent materials include glass, ceramic and plastic materials that will not shatter when subjected to a driving force from e.g., a hammer, punch, etc. Furthermore, the radiation translucent material must also be very strong so that it can sustain the forces used on it during the deployment of the pedicle punch 10 into the vertebrae pedicle without cracking, shearing, splintering, etc. In the preferred embodiment of the pedicle punch 10 the radiation translucent material used is a plastic material such as polyester or nylon based material or blends thereof. Suitable plastic materials include polyester methyl ketone (PMK), Kevlar, polycarbonate, glass filled nylon and polypropylene. The material should be chosen not only for its ability to allow radiation through and its strength, but also for the low manufacturing costs associated therewith. The overall length of the pedicle punch 10 will be commensurate with the application.

Referring to Figure 3 is one embodiment of the present invention. The pedicle punch 10 comprises a proximal end, or head 20, a distal end 40 and a composite shaft or body 30 connecting the two ends. The overall shape of the punch can vary based on a number of factors, such as, the desired thickness, the overall length, the shape of the head which receives a driving force, the shape of the body which facilitates handling, etc. In a preferred embodiment there may be an outwardly protruding lip, or base 50 extending from a skirt portion 80 of body 30, as seen in FIGS. 3, 5-7, 9, 11 and 13-16. In another embodiment shaft 30 may have a generally cylindrical shape with no skirt as seen in Fig. 4. Although the drawings show a generally circular cross section for the pedicle punch, it will be appreciated that the punch may have any suitable cross section so that it may be easily handled.

During use and deployment, the pedicle punch 10 will be held by its head 20 or along the shaft or body 30. Thus, the head 20 can be bulbous or any disk shaped, or knob shaped, mushroom shaped etc. or any shape for that matter that provides a head for receiving a driving means that forces the pedicle punch into the pedicle. Preferably, the shape is ergonomically designed to act as the handle of the pedicle punch 10. In a preferred embodiment the head 20 may have a waist 20a, which may be defined by proximal side 22 and a distal side 24 where the proximal side can have a different cross section than the composite shaft 30.

In the preferred embodiment as shown in Figures 13-16 the composite shaft or body 30 is attached to and projects from generally the center of the proximal side 22 of head 20 of the pedicle punch 10 and ends in a sharp preferably conical spike or pointy tip 32 at the distal end 40 of the pedicle punch 10. Body 30 may be defined as having a skirt portion 80 and a base or lip portion 50, as seen in Figs. 10, 12 and 18. It will be appreciated that the tip need not be conical as long as it is sharp and can pierce the surface of the pedicle. The body 30 comprises a radiation opaque or radiation dense center core 60 (hereinafter "the center core 60") and a radiation translucent outer layer 62 encasing the center core 60. Where the cross section of the body 30 is circular the translucent outer layer is preferably concentric to the center core 60. Where other configurations are used for the cross section, the center core 60 is preferably in the center of the composite shaft 30. Under imaging technology the composite shaft is radiation translucent on the outer layer 62 and radiation dense, or radiation opaque, in its center core 60, thereby appearing on the screen as a single round dot. The center core 60 runs transversely, preferably along the entire length of the pedicle punch. In another embodiment, it runs the length from the center of the distal end 24 at the proximal end 20, to the very tip of the distal end 40, extending sufficiently beyond the distal edge of the outer layer 62 to form the bottom half of the sharp conical point or pointy tip 32 of the shaft 30, at the distal end 40 of the pedicle punch 10. The distal end 40 of the pedicle punch 10 can be generally perpendicular to the center axis that extends from one end of the center core to the sharp tip. In another embodiment, the distal end 40 may be recessed or may be conical in shape with the sharp tip extending from the conical portion of the distal end. As shown in Figure 13, the distal end may be in the form of a flat ring having a raised center portion. The present invention allows the surgeon to insert the pedicle probe into the pedicle without the need for any thrombotic agents, because the lip of the pedicle punch prevents blood flow out of the pilot hole. The center portion is preferably made from the same material as the outer layer 62. The conical portion of the outer layer may have a first section, having a side wall and generally in the shape of a dish or ring with an open center. On top of the ring there is a truncated conical section of the outer layer 62 also having an open center. The open center is for receiving the radiation opaque center core 60.

It is the radiation dense or radiation opaque center core 60 that allows the pedicle punch 10 to be placed concentrically with the vertebrae pedicle and in perfect alignment with the pedicle axis, and to ultimately create a pilot hole on the vertebrae pedicle that also has a trajectory path vector in direct alignment with the pedicle axis. This alignment can be assisted by the presence of additional radiation dense pins that form a bull's eyed configuration when seen under radiation. These pins 56 extend from the distal end of the punch as shown in Figure 3. These pins are made of a radiation dense material as is the central core.

In the preferred embodiment, metal is used to form the radiation opaque or radiation dense center core 60. Metal imparts great strength to the bottom end of the sharp conical spike or pointy tip 32 of the distal end 40 of the pedicle punch 10 and to the entire composite shaft 30. Such strength renders the pedicle punch 10 capable of not only creating the pilot hole, as defined above, when deployed on the vertebrae pedicle, but of also sustaining the forces necessary to create the pilot hole without chipping, disintegrating, or otherwise compromising the integrity of the pedicle punch 10. Any metal that is radiation opaque can be used for the dense center core 60. A preferred metal is one having a Durometer hardness of 40 and up. The metal is preferably a casehardened metal. One preferred radiation opaque material is stainless steel. By the term radiation opaque and radiation translucent is meant a material when used in the core 60 will give a radiation fingerprint different from the material used in the cover or coating, so that the location where the sharp tip of the pedicle punch is can be ascertained under radiation.

The specifications for the diameter of the entire sharp conical spike or pointy tip 32 comprising partly radiation translucent and partly radiation opaque material, from its widest point and tapering distally to form the pointy tip, will range so that when the pedicle punch 10 is deployed in the pedicle and thereafter removed therefrom, it leaves behind a pilot hole having dimension of 3-4 mm. Obviously, if a larger pilot hole is desired then the diameter will be changed analogously. However, the smallest diameter at the most distal pointy tip end should preferably be no greater than about 0.25 mm, for maximum penetrating power.

The outwardly protruding base 50 is located on the shaft 30, adjacent to the sharp conical spike or pointy tip 32, and where the widest diameter of the sharp conical spike or pointy tip 32 begins, and concentric thereto. It has a proximal side 52 and a distal side 54. The distal side 54 of the outwardly protruding lip 50 is provided with at least three teeth, knobs or mini protrusions 56, as seen in Fig. 8, to prevent toggling of the pedicle punch 10, once it is deployed in the vertebrae pedicle. In one embodiment tip 32 may have a generally ribbed portion 32a that extends from the bottom of tip 32 to the distal side 54, as seen in Fig. 11. In yet another embodiment pedicle punch 10 may not have any"pms"567 as seerf in ɪ'Ig. y.

The pins that surround the center core are secured to the outer layer by any suitable means. Preferably, the pins are embedded in the outer layer so that they will not break off during use. The purpose of the pins is to provide a "bull's eye" or "cross hairs" arrangement of the sharp tip at the center so that when radiation is applied, the site where the pedicle punch is inserted is illuminated to facilitate insertion in the proper position, as well as aid in determining whether the pedicle is in the proper position. The pins also help to secure the pin in position after the punch has been inserted into the pedicle. Although four pins are depicted in the Figure, it will be appreciated that two or more pins, preferably three or more pins, will accomplish the desired bull's eye arrangement. In another embodiment, the pins may be replaced with a raised ring of a radiation opaque material. This raised ring forms the outer ring of the bull's eye and preferably has a sharpened outer surface.

The pedicle punch of the present invention may be formed by any suitable means. One method is by extruding the outer covering about the center core 60. Another method of forming the punch is by a casting method such as die casting.

Turning one's attention to Figures 15-17, one can see cannula 70 of pedicle punch 10 of the present invention. Cannula 70 may be a generally cylindrical in shape, which may extend from head 20 to the proximal pointy tip 32 of base 50. It will be appreciated by those skilled in the art that cannula 70 will be sized and shaped so as to be able to receive all pedicle probes in the known art. Cannula 70 may be constructed from any suitable material known in the art, such as plastics, plastic materials include polyester methyl ketone (PMK), Kevlar, polycarbonate, glass filled nylon and polypropylene. The material should be chosen not only for its ability to allow radiation through and its strength, but also for the low manufacturing costs associated therewith. Cannula 70 has inner surface 71a and outer surface 71b. In one embodiment outer surface 71b may be in contact with inner core 60, or in a preferred embodiment outer surface 71b may not be in contact with inner core 60. With the latter embodiment an insulation layer may be utilized. In normal operation, after the posterior cortical breach has been performed by the surgeon. The surgeon will then insert the appropriate pedicle probe. For example, a surgeon may implement the Lenke gearshift to perform the initial cannulation process, thus after the pilot hole is created the surgeon may then feed the pedicle probe through the cannula portion of the pedicle punch.

The thickness of the outwardly protruding base 50 is not critical so long as it does not interfere with the proper location of the pedicle punch. However, it can generally range anywhere from 1-2mm in thickness. Once the pedicle punch is deployed into the pedicle, the outwardly protruding base 50 comes in direct contact with the pedicle and effectively seals any wound that is created by the pedicle punch as it is being deployed thereby imparting a hemostatic characteristic to the pedicle punch 10, as well. Consequently, the presence of the outwardly protruding base 50 in combination with the fact that the punch is left in the wound, minimizes bleeding tremendously and eliminates the use of thrombotic agents to stop the blood flow. Since excessive bleeding is no longer a critical problem, the present process might be expanded to be used with patients normally not recommended for spinal fusion surgery due to their inability to properly clot.

The method for using the inventive pedicle punch 10 described above, comprises the following steps: (a) using an image generating apparatus, such a fluoroscope, to accurately map the pedicle and the axis thereof. The pedicle will be depicted as a circle on the apparatus screen, with the center point of the circle corresponding to the central axis of the pedicle; (b) placing the pedicle punch 10 on the vertebrae pedicle just mapped; c) manipulating, moving and positioning the pedicle punch 10 until such time that the radiation translucent central core 60, which will appear as a solid dot on the screen of the image generating apparatus, is located right in the center of the circle corresponding to the pedicle just mapped, concentric to and in complete alignment with the mapped pedicle axis to form a bull's eye (the solid center core 60 dot in the center and the pedicle circle concentrically aligned around said dot); (d) once the bull's eye is achieved on the screen of the image generating apparatus, deploying the pedicle punch 10 into the mapped vertebrae pedicle using an appropriate force generating tool such as a surgical mallet; and (e) confirming the exact placement of the pedicle punch with the image making instrument and leaving the pedicle punch in place until needed to be removed. The surgeon is now ready for identification of the next pedicle and its axis and the steps are repeated until all of the pedicle punches are placed at all levels to be instrumented. Upon completion of the placement of the pedicle punches, the surgeon is ready to remove the pedicle punches one by one, and for each perfect pilot hole left behind on the vertebrae pedicle by the pedicle punch, to proceed to the next step of instrumentation in the pedicle screw insertion process.

In an alternate embodiment of the inventive pedicle punch described above, head 20 is provided with a groove for the purpose of providing the surgeon with a better grip on the pedicle punch 10.

In yet another embodiment of the invention described herein above, either the outer perimeter of head 20 or the outer perimeter of the outwardly protruding base 50 is further provided with an opaque material, such that when the central core 60 is "bull's eyed" with the pedicle, the bull's eye comprises a center dot and two outwardly extending concentric circles, as opposed to one circle concentric to the center dot, as described hereinabove.

It is clear then from all of the above, that incorporating the pedicle punch 10 and the method of use thereof into spinal implant procedures and more particular into pedicle screw insertion processes accomplishes all of the invention's objectives as set forth hereinabove. It leads to the penetration of the pedicle with a probe and subsequent insertion of the pedicle screw quickly, accurately, flawlessly and without breaking out of the pedicle path. Its ease of use significantly decreases the surgeons' learning curve, in that it allows the surgeon to know the exact starting point of the pedicle, without any guessing. It practically eliminates dural or neural injury. It dramatically reduces the time normally associated with such procedures not only because it reduces the steps necessary for the creation of the perfect pilot hole, but because it can accommodate two surgeons working at the same time on one patient. Its minimum use of image making instruments and the speed at which the pedicle axis can be mapped and "bull's eyed", dramatically reduces the exposure of both the surgical team and the patient to radiation exposure and more particularly to fluoroscopic radiation exposure.

Its significant reduction of bleeding, partly because the burring of pilot holes is completely eliminated, thereby also eliminating the creation of pilot holes due to mistaken identification of pedicle axes, partly because the pedicle punch is left in the pilot holes until such time as the surgeons are ready, and partly because of the hemostatic effect of the pedicle punch due to its protruding lip, the inventive pedicle punch minimizes the administration of thrombotic agents during the pedicle insertion process. Finally, it unequivocally creates the perfect pilot hole, i.e., a pilot hole having (a) a diameter that is sized perfectly to accept the next instrument; and (b) a trajectory path vector in complete alignment with the pedicle axis right from the very beginning of the pedicle penetration process. Thus, the surgeon saves even more time, since he does not have to correct the initial vector of the trajectory path of the pilot hole nor compensate for any errors or deviations thereof from the pedicle axis.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description shall be interpreted as illustrative and not in a limiting sense. In the view above it will be seen that several objects of the invention are achieved and other advantageous results attained, as defined by the scope of the following claims.

What is claimed is:

1. A pedicle punch for establishing pilot holes in vertebra pedicles when deployed thereon during pedicle screw insertion processes, said punch comprising:

a proximal end and a distal end;

a shaft distally projecting from generally about said proximal end and terminating in a truncated conical spike at said distal end;

a lip outwardly projecting from and fixedly connected to said shaft, adjacent to said sharp conical spike and concentric thereto;

a radiation opaque center core running longitudinally along the entire length of the pedicle punch, from said proximal end, through said shaft and lip outwardly projecting therefrom, to the very tip of said distal end; said radiation opaque center core having an orifice extending through said core from said proximal end to said truncated conical spike and;

a radiation translucent outer layer concentrically surrounding and encasing said radiation opaque center core, running along the entire length of the pedicle punch but stopping short a short distance from the very tip of said distal end to allow said radiation opaque center core to extend sufficiently beyond the distal edge of said radiation translucent outer layer and form the bottom of said truncated conical spike of said shaft.

2. The pedicle punch according to claim 1, wherein said radiation translucent material is selected from the group of radiation translucent materials consisting of plastics, metals, and ceramics.

3. The pedicle punch according to claim 1, wherein said radiation translucent

material is plastic.

4. The pedicle punch according to claim 1, wherein said radiation opaque material is metal.

5. The pedicle punch according to claim 1, wherein said lip further comprises at least two mini-protrusions to stabilize the pedicle punch as it is deployed into the vertebra pedicle.

6. The pedicle punch according to claim 5, wherein said mini-protrusions are radiation opaque.

7. The pedicle punch according to claim 1, wherein the lip further comprises four mini-protrusions to stabilize the pedicle punch as it is deployed into the vertebra pedicle.

8. The pedicle punch according to claim 7, wherein said four mini-protrusions are radiation opaque.

9. The pedicle punch according to claim 5 wherein said protrusions have a sharp point on a surface thereof.

10. The pedicle punch according to claim 7 wherein said protrusions have a sharp point on a surface thereof.

11. The pedicle punch according to claim 1 further comprising a tethering means attached to said pedicle punch for easy retrieval of said pedicle punch.

12. The pedicle punch according to claim 1, wherein said truncated conical spike further comprises means for stabilizing the pedicle punch once deployed on the vertebra pedicle.

13. The pedicle punch according to claim 12, wherein said means for stabilizing said pedicle punch are one or more barbs.

14. The pedicle punch according to claim 13, wherein said means for stabilizing said pedicle punch are serrations.

15. The pedicle punch according to claim 1, wherein said lip has a composite shape with a proximal circuniferentially narrow end, a distal circumferentially wide end and an angled edge there between; said proximal circumferentially narrow end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said distally circumferentially wide end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said lower end of said proximal outer edge and said upper end of said distal outer edge being connected with said angled edge, such that said angled edge is angularly transverse to the central

longitudinal center axis of said center core to form a slightly sloped shoulder towards said distal circumferentially wide end.

16. A pedicle punch for establishing pilot holes in vertebra pedicles when deployed thereon during pedicle screw insertion processes, said punch comprising:

a proximal end and a distal end;

a shaft distally projecting from generally about the center of said proximal end and terminating in a truncated conical spike at said distal end, said spike having a sharp edge, said truncated conical spike being provided with means for stabilizing the pedicle punch once deployed on the vertebra pedicle;

a lip outwardly projecting from and fixedly connected to said shaft, adjacent to said truncated conical spike and concentric thereto, said lip having a composite shape with a proximal circumferentially narrow end, a distal circumferentially wide end and an angled edge there between; said proximal circumferentially narrow end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said distally circumferentially wide end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said lower end of said proximal outer edge and said upper end of said distal outer edge being connected with said angled edge; such that said angled edge is angularly transverse to the central longitudinal center axis of said center core to form a slightly sloped shoulder towards said distal circumferentially wide end;

a radiation opaque core running longitudinally along the entire length of the pedicle punch, from said proximal end, through said shaft and lip outwardly projecting therefrom, to the very tip of said distal end, said radiation opaque center core having an orifice extending through said core from said proximal end to said truncated conical spike; and

a radiation translucent outer layer concentrically surrounding and encasing said radiation opaque center core, running along the entire length of the pedicle punch but stopping short a short distance from the very tip of said distal end to allow said radiation opaque center core to extend sufficiently beyond the distal edge of said radiation translucent outer layer and form the bottom of said truncated conical spike of said shaft.

17. A pedicle punch for establishing pilot holes in vertebra pedicles when deployed thereon during pedicle screw insertion processes, said punch comprising:

a proximal end and a distal end;

a shaft distally projecting from generally about the center of said proximal end and terminating in a truncated conical spike at said distal end, said spike having a sharp edge;

a lip outwardly projecting from and fixedly connected to said shaft, adjacent to said truncated conical spike and concentric thereto, said lip having a composite shape with a proximal circumferentially narrow end, a distal circumferentially wide end and an angled edge there between; said proximal circumferentially narrow end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said distally circumferentially wide end having a relatively short outer edge parallel to the central longitudinal axis of said radiation opaque center core with an upper end and a lower end; said lower end of said proximal outer edge and said upper end of said distal outer edge being connected with said angled edge, such that said angled edge is angularly transverse to the central longitudinal center axis of said center core to form a slightly sloped shoulder towards said distal circumferentially wide end;

a radiation opaque center core running longitudinally along the entire length of the pedicle punch, from said proximal end, through said shaft and Hp outwardly projecting therefrom, to the very tip of said distal end, said radiation opaque outer core having an orifice extending through said core from said proximal end to said truncated conical spike;

a radiation translucent outer layer concentrically surrounding and encasing said radiation opaque center core, running along the entire length of the pedicle punch but stopping short a short distance from the very tip of said distal end to allow said radiation opaque center core to extend sufficiently beyond the distal edge of said radiation translucent outer layer and form the bottom of said truncated conical spike of said shaft; and

at least two radiation opaque mini-protrusions to stabilize the pedicle punch as it is deployed into the vertebra pedicle, said at least two mini-protrusions fixedly attached to and distally extending from said lip.

18. A method for the creation of pilot holes in pedicle vertebrae during pedicle screw insertion processes, comprising the steps of:

(a) accurately mapping the outer perimeter of the pedicle and the axis thereof;

(b) placing a pedicle punch on the pedicle just mapped, said pedicle punch comprising a proximal end and a distal end, a shaft distally projecting from generally about the center of said proximal end and terminating in a truncated conical spike at said distal end, said spike having a sharp edge, a lip outwardly projecting from and fixedly connected to said shaft, adjacent to said truncated conical spike and concentric thereto, a radiation opaque center running longitudinally along the entire length of the pedicle punch, said radiation opaque center core having an orifice extending through said core from said proximal end through said truncated conical spike, through said proximal end, through said shaft and lip outwardly projecting therefrom, to the very tip of said distal end and a radiation translucent outer layer concentrically surrounding and encasing said radiation opaque center core, running along the entire length of the pedicle punch but stopping short a short distance from the very tip of said distal end to allow said radiation opaque center core to extend sufficiently beyond the distal edge of said radiation translucent outer layer and form the bottom of said sharp conical spike of said shaft;

(c) moving and positioning said pedicle punch until said radiation opaque center core and the pedicle's perimeter are bulls' eyed;

(d) once said radiation opaque center core and said pedicle perimeter are bulls' eyed, deploying the pedicle punch into the mapped vertebrae pedicle using an appropriate force to form a pilot hole having a diameter wide enough to accommodate the instrumentation of the next step in the pedicle screw insertion process and a trajectory path vector that is as closely aligned to the pedicle axis of the vertebrae pedicle as possible.

19. A pedicle punch, the pedicle punch used to establish pilot holes in vertebra

pedicles when deployed thereon during pedicle screw insertion processes comprising:

a head portion at the proximal end of said punch, said head portion having a first cross section;

a waist portion having a second cross section smaller than the first cross section of said head portion;

a body portion extending from said waist portion, said body portion having a third cross section larger than said second cross section;

a skirt portion extending from said body portion and a base portion ending in a distal end, said punch having a shaft distally projecting from the center of said proximal end and terminating to a truncated conical spike at said distal end;

a radiation opaque center core running longitudinally along the entire length of the pedicle punch, through said proximal end, through said shaft and lip outwardly projecting therefrom, to the very tip of said distal end; said radiation opaque center core having an orifice extending through said core from said proximal end to said distal end , said spike having a sharp edge about said orifice and;

a radiation translucent outer layer concentrically surrounding and encasing said radiation opaque center core, running along the entire length of the pedicle punch but stopping short a short distance from the very tip of said distal end to allow said radiation opaque center core to extend sufficiently beyond the distal edge of said radiation translucent outer layer and form the bottom of said sharp conical spike of said shaft.

20. The pedicle punch according to claim 19 wherein said first cross section is generally the same as said third cross section.

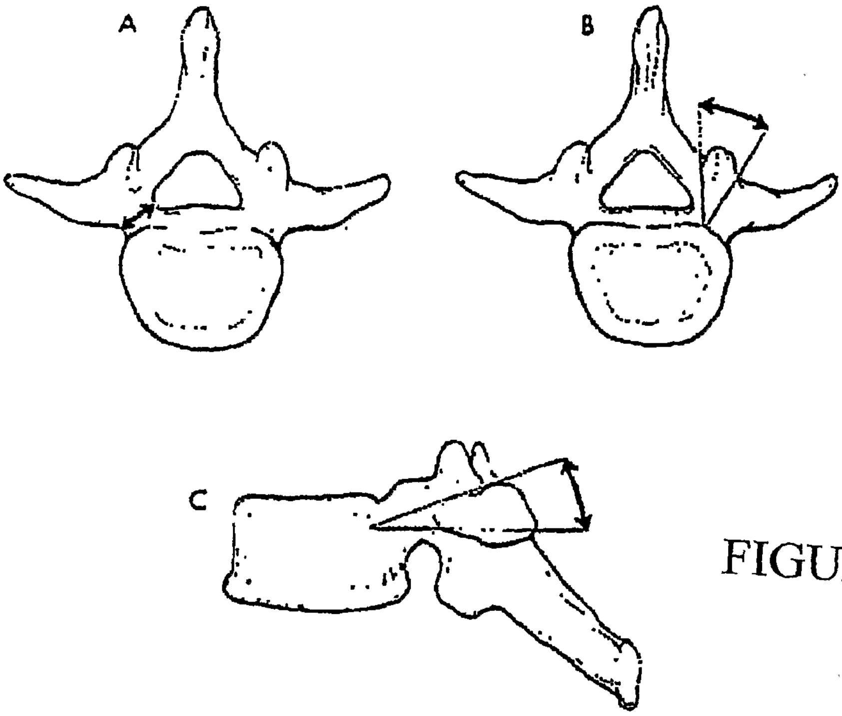


FIGURE 1

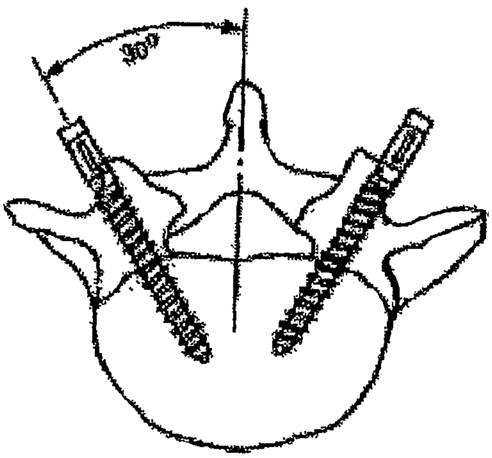


FIGURE 2

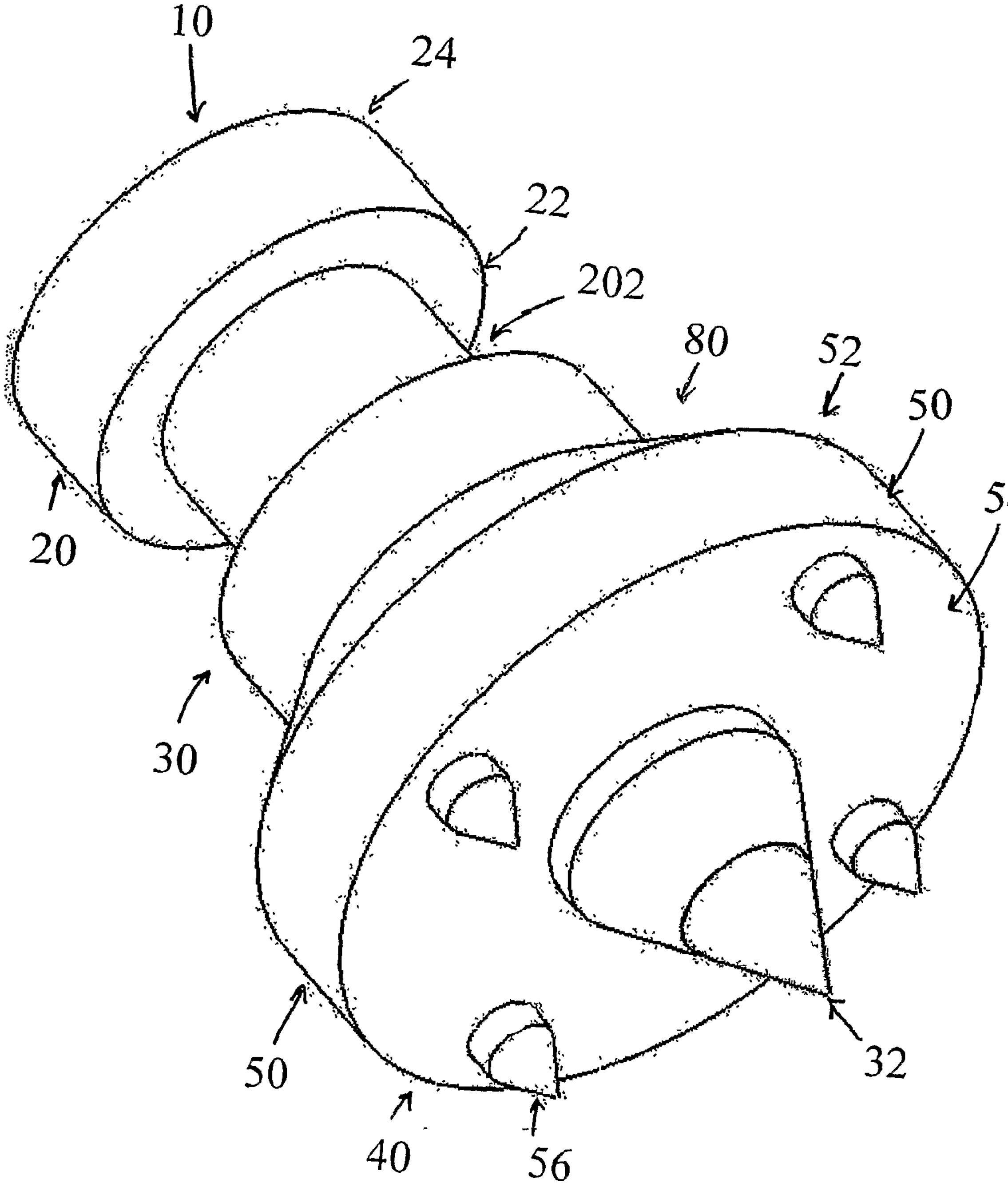


FIGURE 3

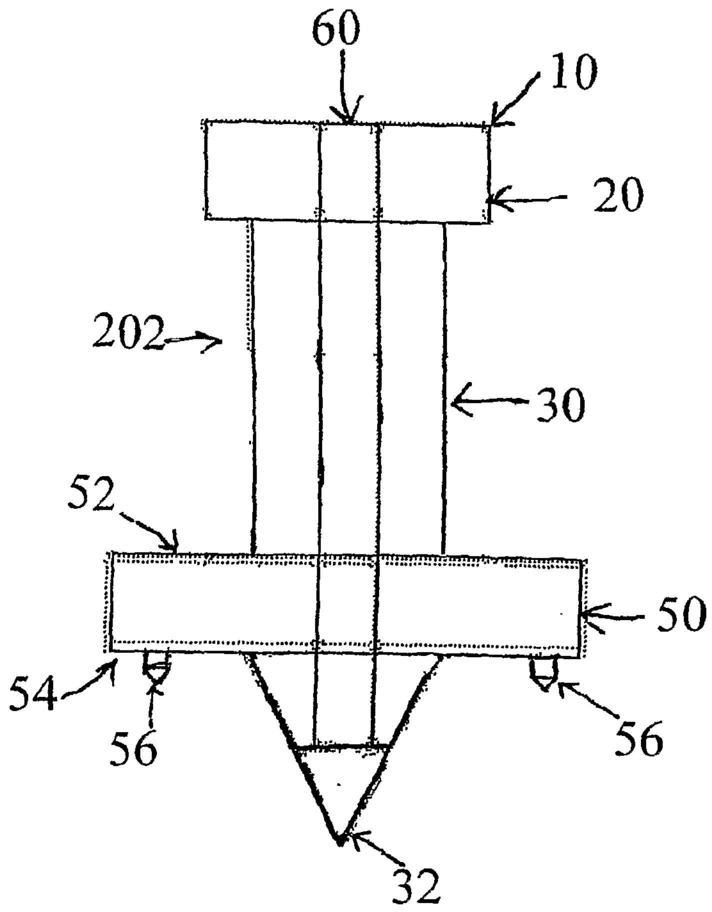


FIGURE 4

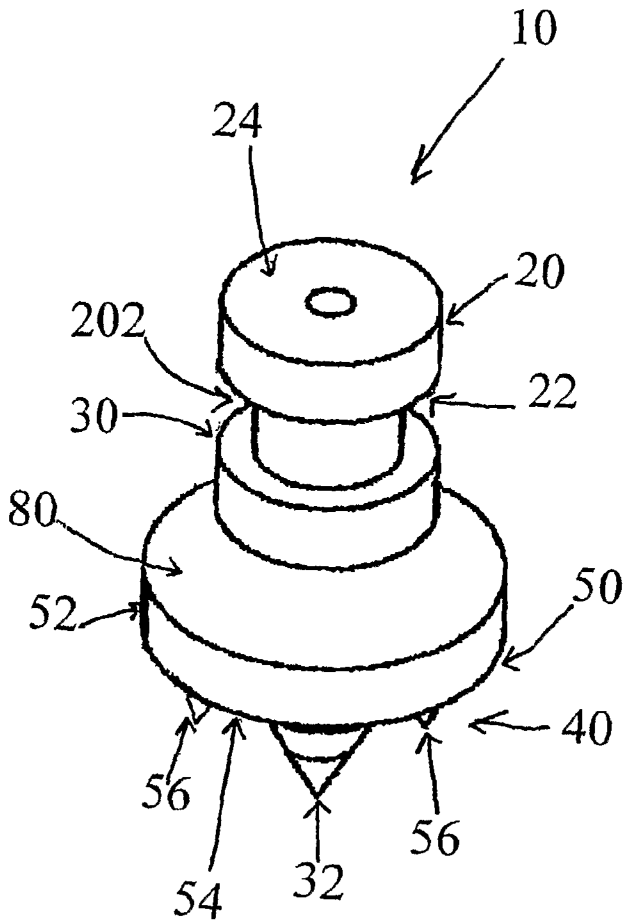


FIGURE 5

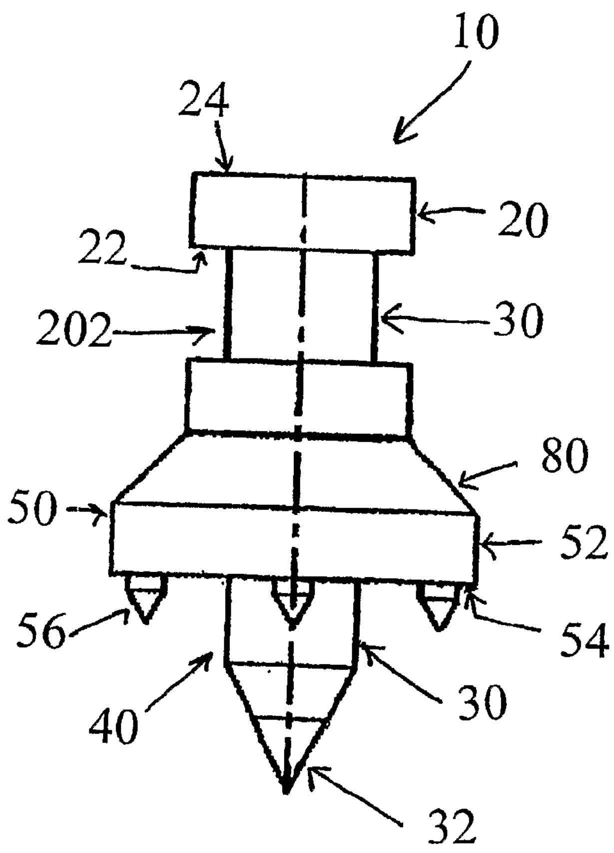


FIGURE 6

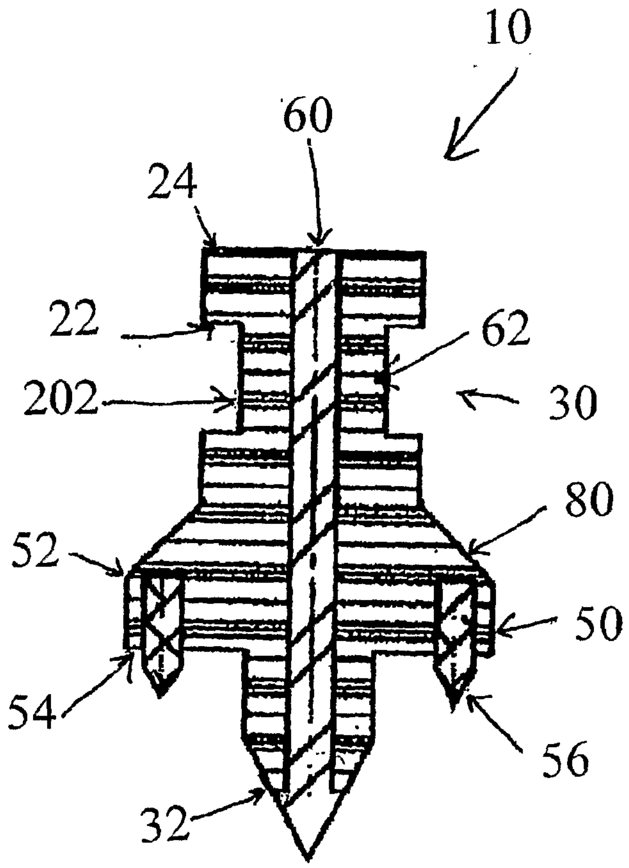


FIGURE 7

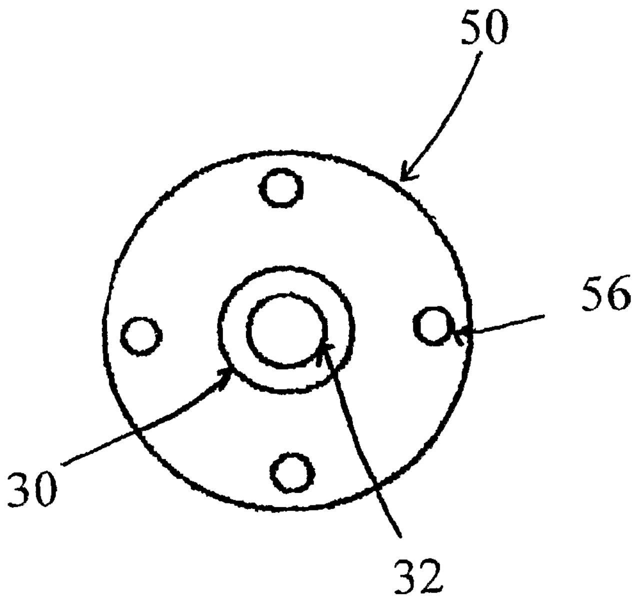


FIGURE 8

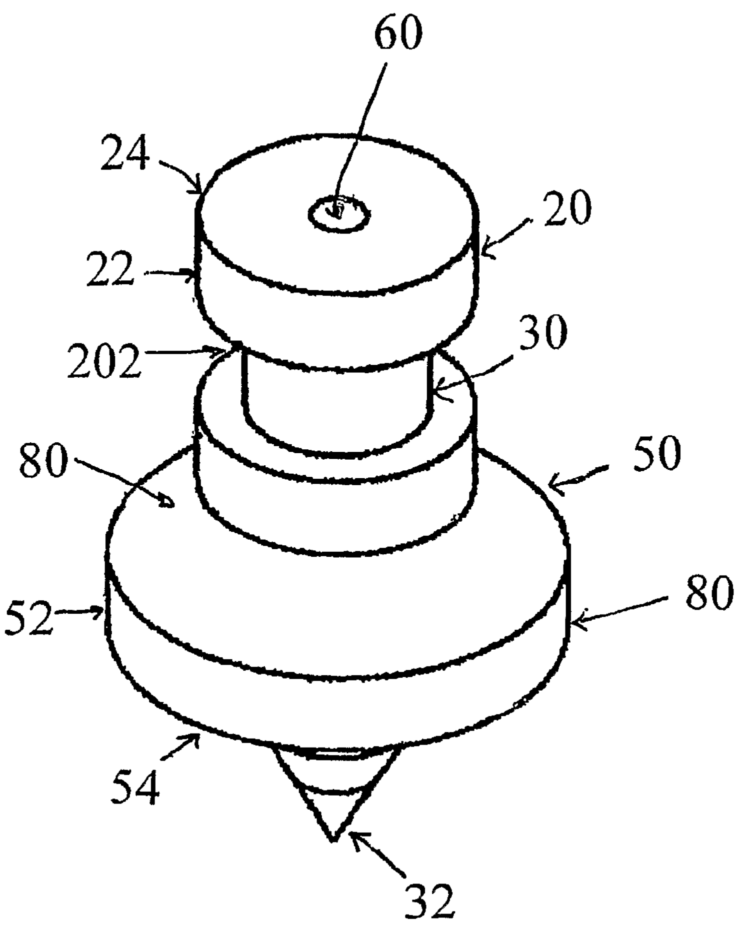


FIGURE 9
(another embodiment)

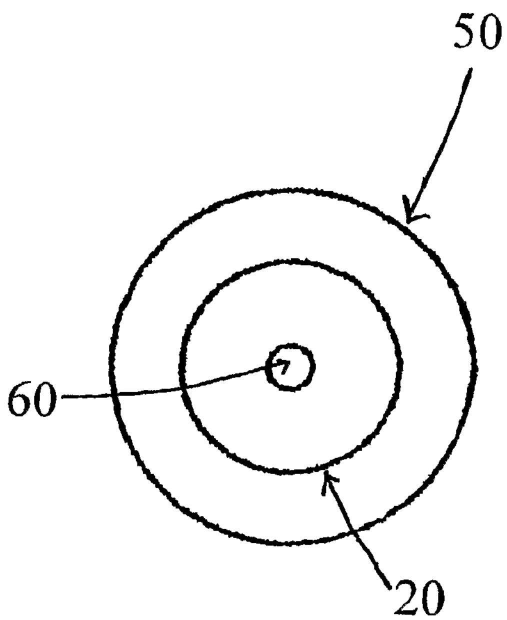


FIGURE 10

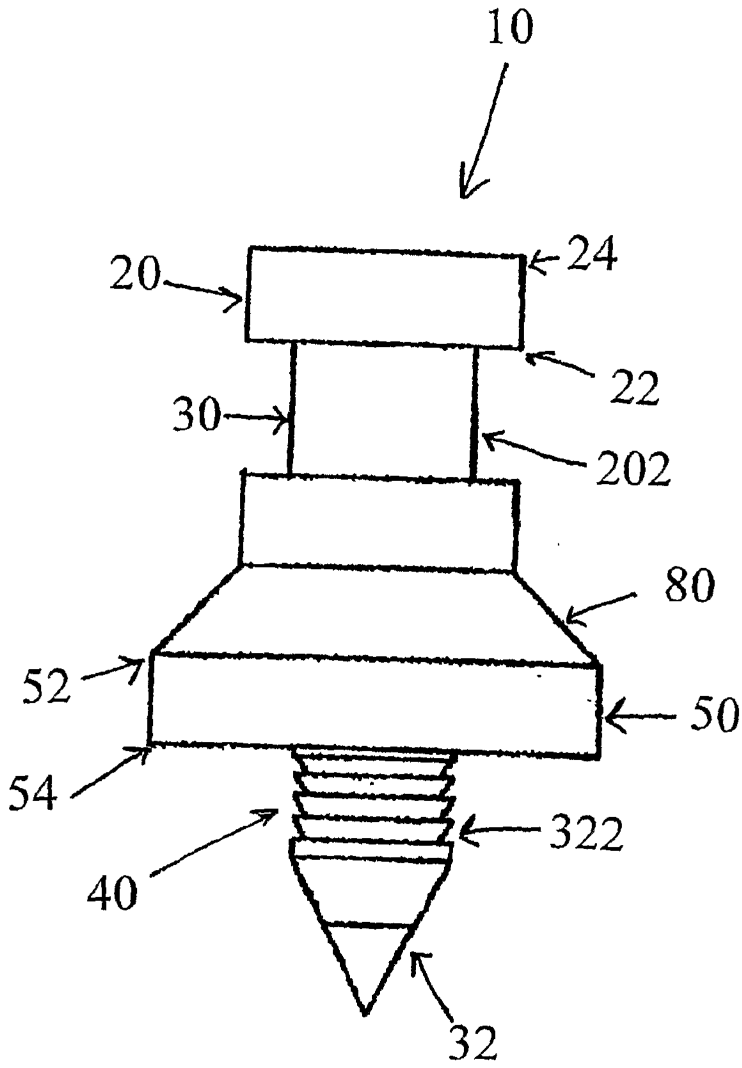


FIGURE 11

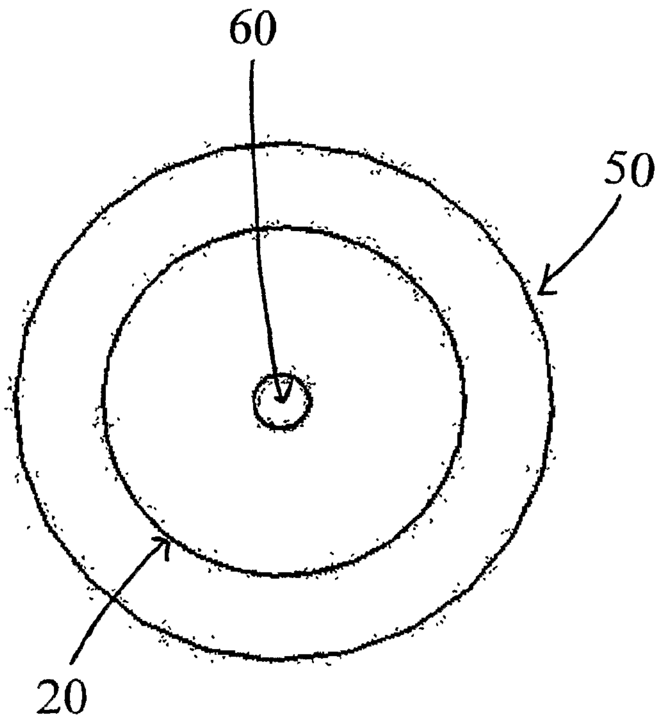


FIGURE 12

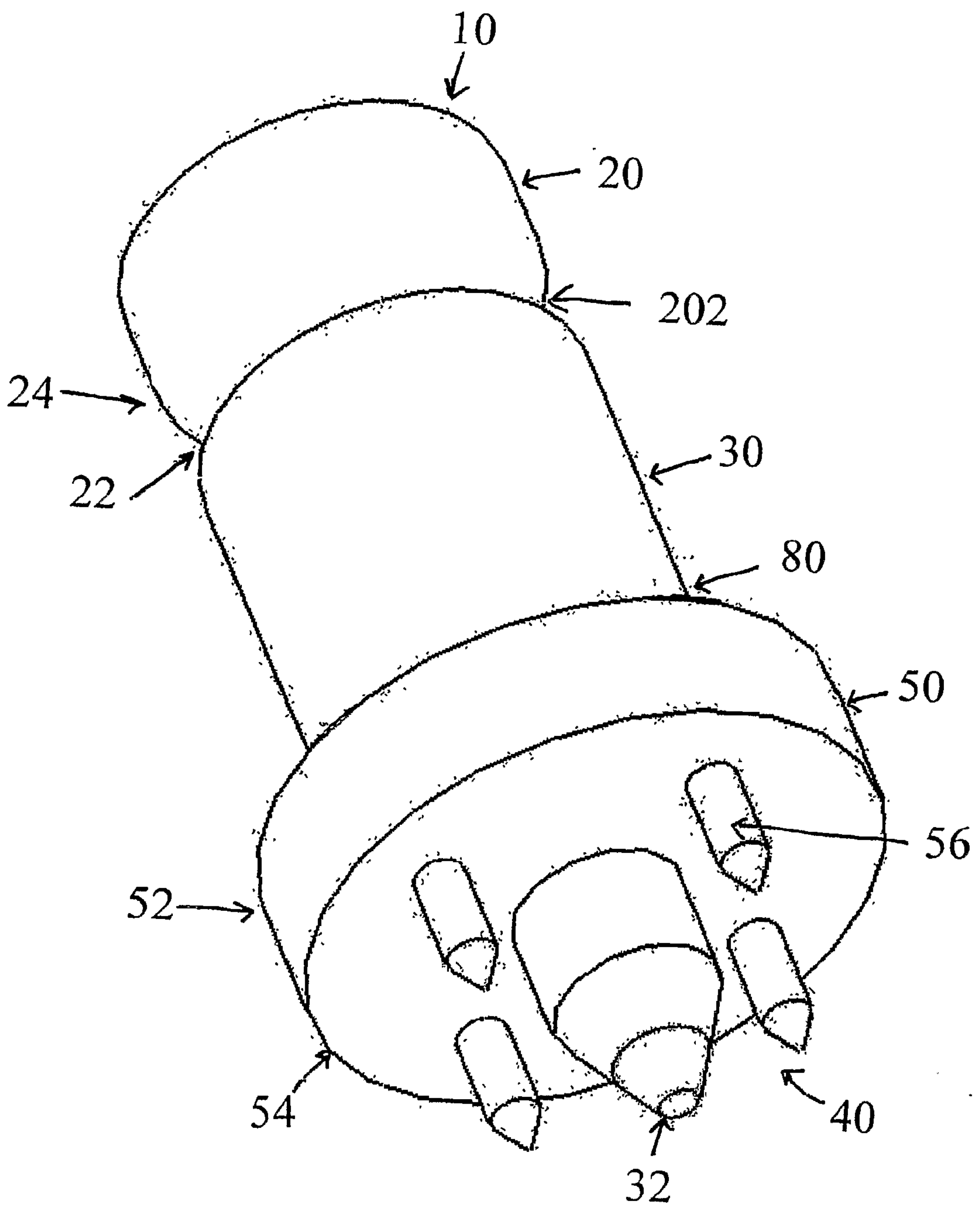


FIGURE 13

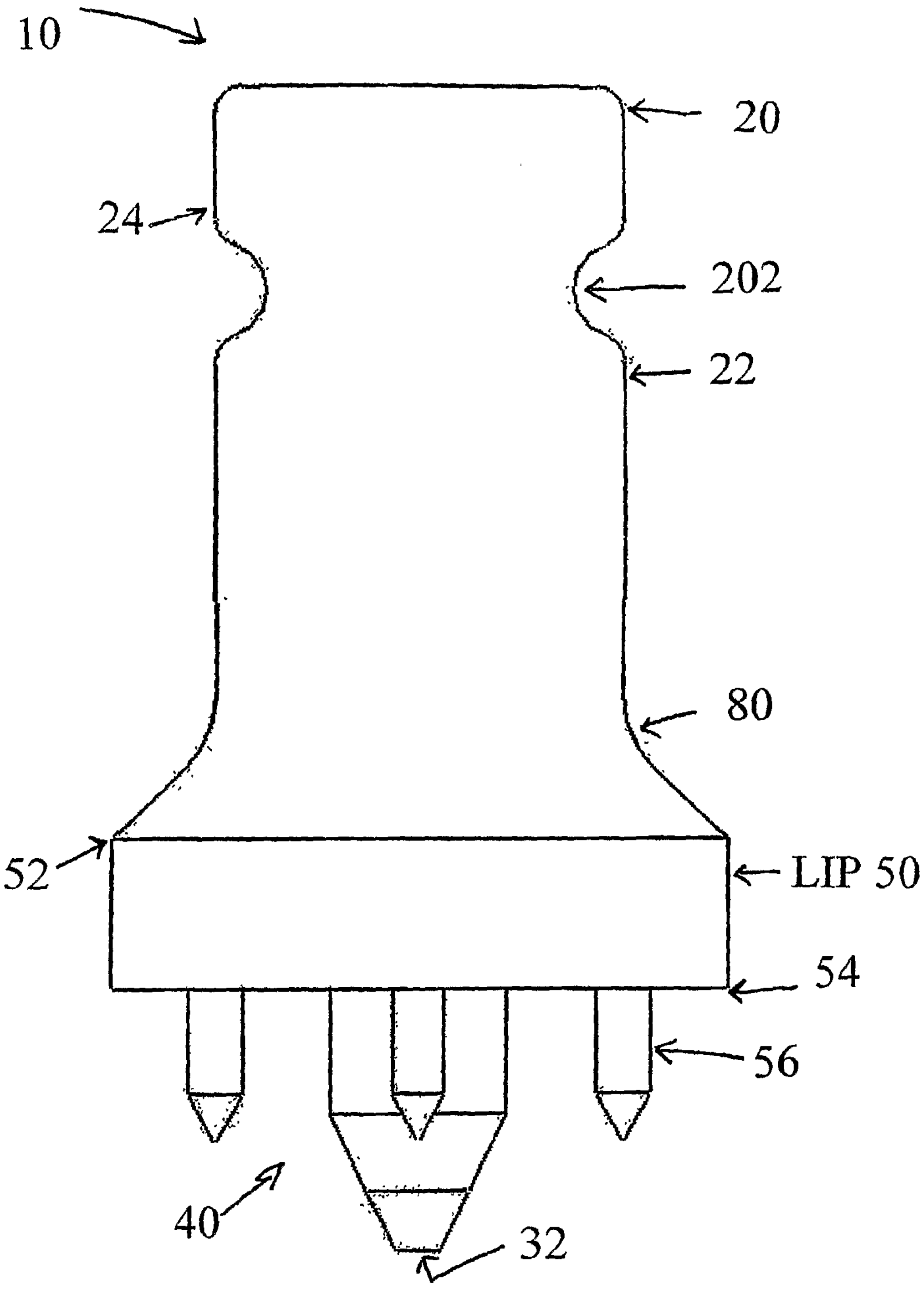


FIGURE 14

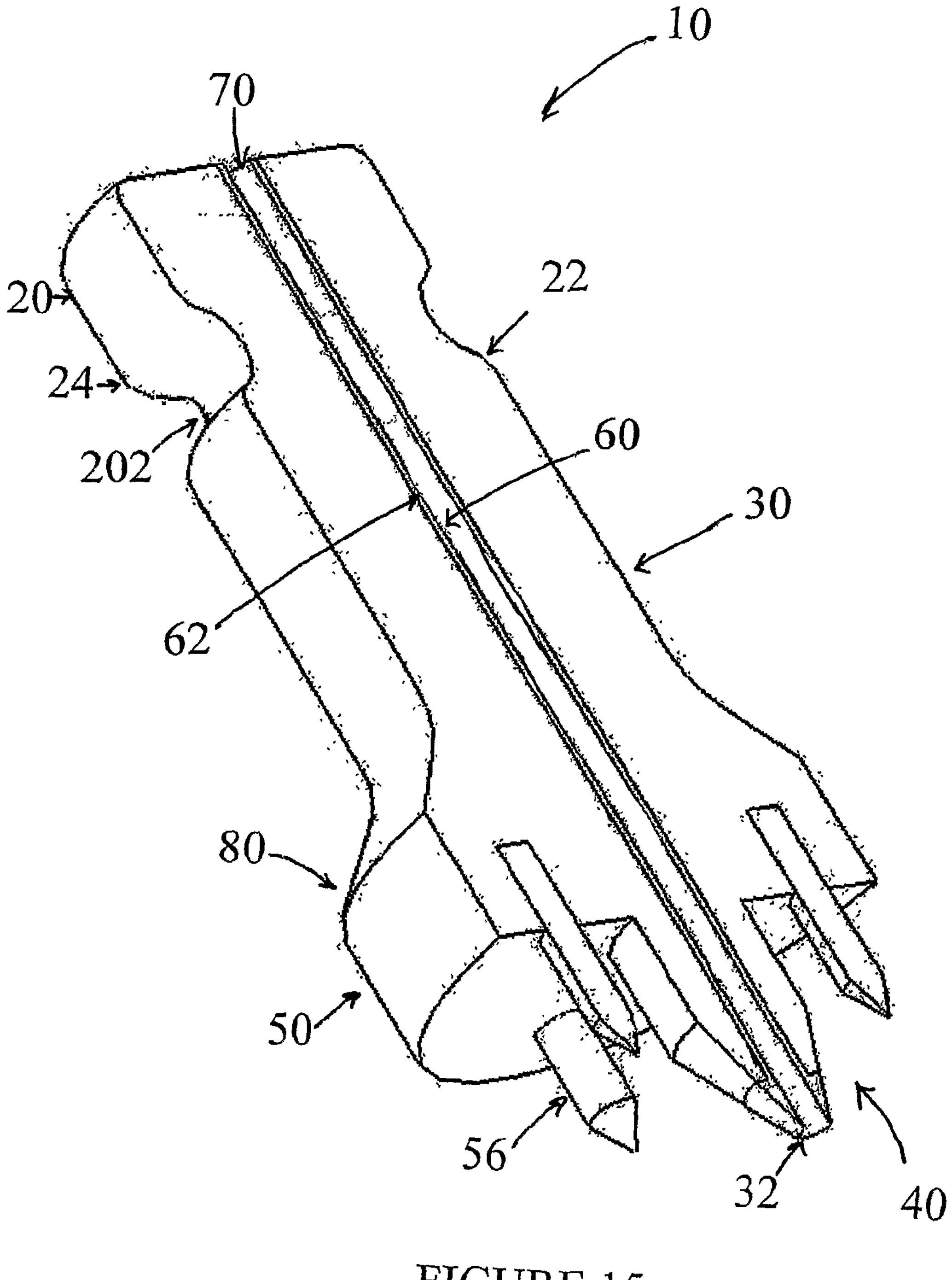


FIGURE 15

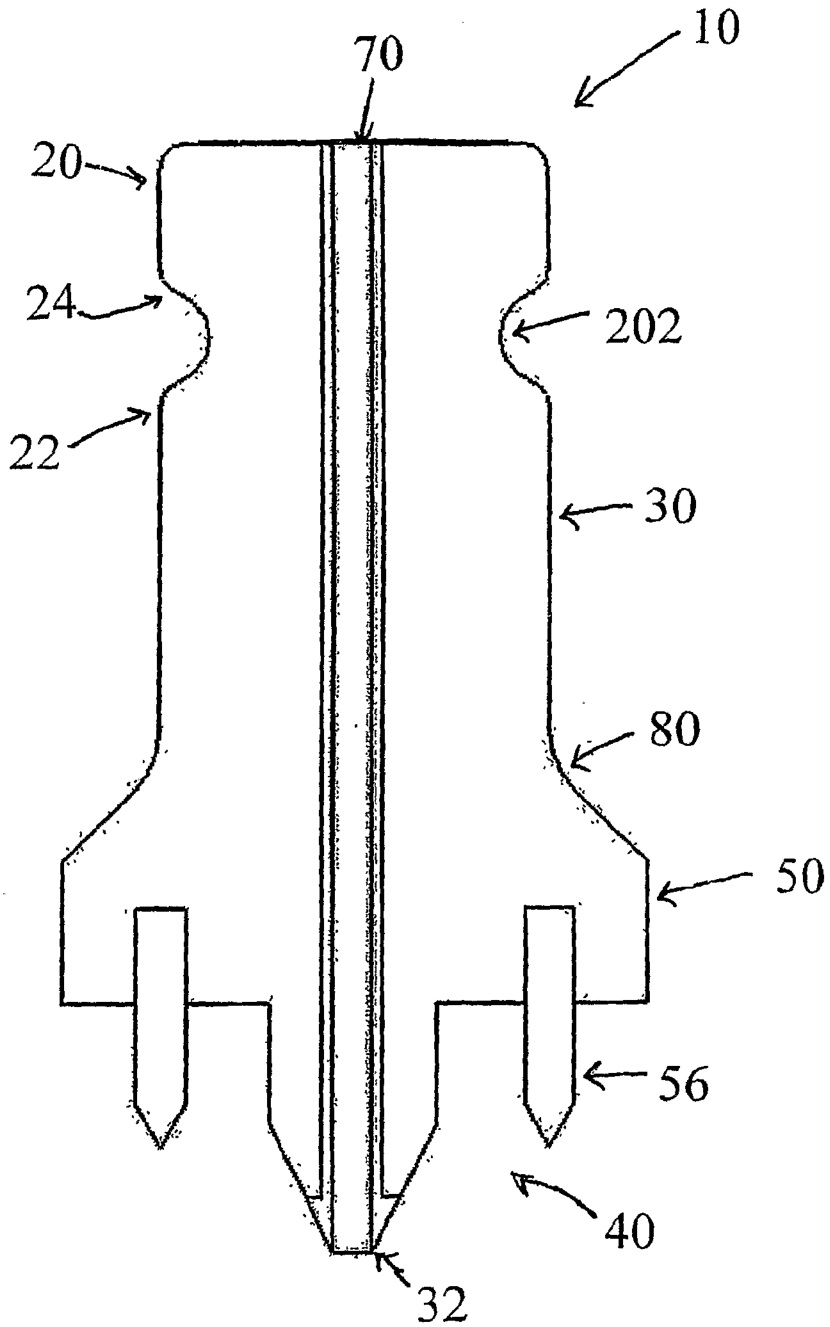


FIGURE 16

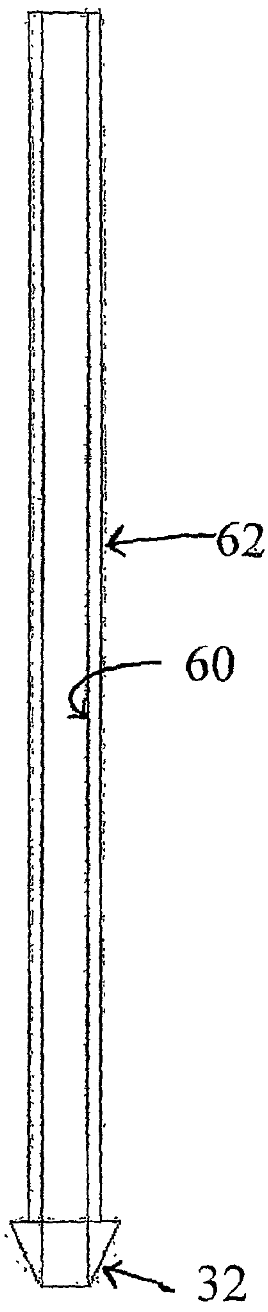


FIGURE 17

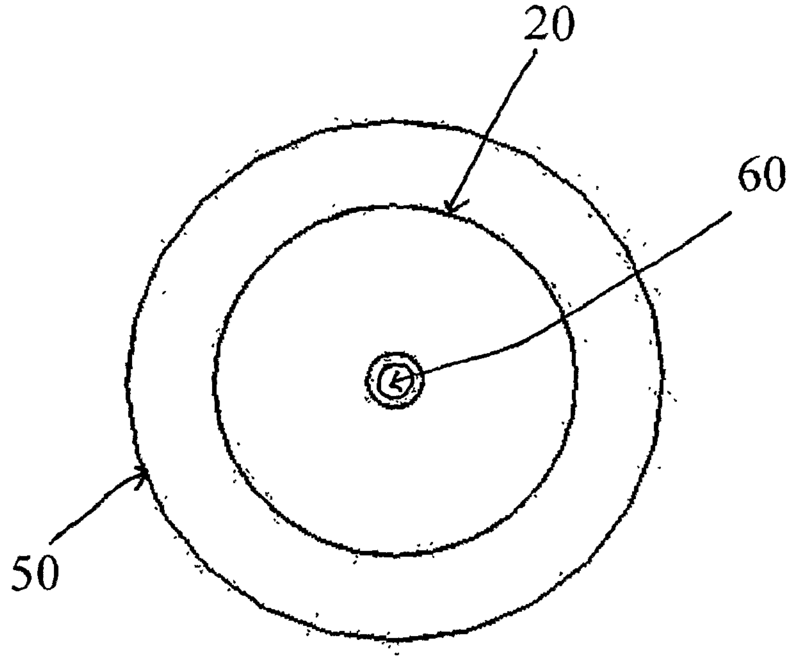


FIGURE 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/031677

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 A61B17/17 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document with indication where appropriate, of the relevant passages	Relevant to claim No
A	EP 1 393 687 A (MICHELSON GARY K [US]) 3 March 2004 (2004-03-03) column 6, paragraph 32 - column 7, paragraph 32 column 28, paragraph 124 - column 31, paragraph 134 figures 31-34	1,16,17, 19
A	EP 1 488 747 A (SDGI HOLDINGS INC [US]) 22 December 2004 (2004-12-22) column 1, paragraph 1-5 columns 3-4, paragraph 10 column 13, paragraph 79 - column 14, paragraph 82 column 16, paragraph 87 figures Ia-If	1,16,17, 19

-/-

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

[X] See patent family annex

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier 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 parson 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
28 March 2007	05/04/2007

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	Kakoullis, Marios

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/031677

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 2006/167461 A1 (HAWKINS JOHN R [US] ET AL) 27 OuIy 2006 (2006-07-27) page 1, paragraph 13 - page 2, paragraph 16 page 4, paragraph 95-98 page 6, paragraph 110-112 page 8, paragraph 124 figures 1B.12A-12C.18 -----	1,16,17, 19
A	US 2005/137612 A1 (ASSELL ROBERT L [US] ET AL) 23 June 2005 (2005-06-23) page 11, paragraph 194 - page 12, paragraph 210 figures 11-13B -----	1,16,17, 19

International application No.
PCT/US2006/031677

INTERNATIONAL SEARCH REPORT

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.: 18
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/US2006/031677

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
EP 1393687	A	03-03-2004	EP	1393688	A2	03-03-2004
			EP	1393689	A2	03-03-2004
			EP	1402832	A2	31-03-2004
			EP	1402833	A2	31-03-2004
			EP	1402834	A2	31-03-2004
			EP	1402835	A2	31-03-2004
			EP	1402836	A2	31-03-2004
EP 1488747	A	22-12-2004	AT	274844	T	15-09-2004
			AU	3744699	A	01-11-1999
			CA	2327501	Al	21-10-1999
			DE	69919857	Dl	07-10-2004
			DE	69919857	T2	01-09-2005
			EP	1069864	A2	24-01-2001
			ES	2228037	T3	01-04-2005
			JP	2002511301	T	16-04-2002
			WO	9952453	A2	21-10-1999
			US	2002156481	Al	24-10-2002
			US	6428541	Bl	06-08-2002
			US	2004097932	Al	20-05-2004
			US	2002022847	Al	21-02-2002
US 2006167461	Al	27-07-2006	AU	2004227987	Al	21-10-2004
			BR	PI0408872	A	11-04-2006
			CA	2521054	Al	21-10-2004
			EP	1608270	A2	28-12-2005
			JP	2006521899	T	28-09-2006
			KR	20060021823	A	08-03-2006
			MX	PA05010560	A	09-03-2006
			US	2005027300	Al	03-02-2005
			WO	2004089224	A2	21-10-2004
US 2005137612	Al	23-06-2005	AU	2004283727	Al	06-05-2005
			CA	2543295	Al	06-05-2005
			EP	1691848	A2	23-08-2006
			KR	20060132588	A	21-12-2006
			US	2005137601	Al	23-06-2005
			US	2005137602	Al	23-06-2005
			US	2005137604	Al	23-06-2005
			US	2005165406	Al	28-07-2005
			US	2005137605	Al	23-06-2005
			US	2005149049	Al	07-07-2005
			US	2005149034	Al	07-07-2005
			US	2005137607	Al	23-06-2005
			WO	2005039651	A2	06-05-2005