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(54) **LUMBAR SPINE PEDICLE SCREW GUIDE**

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A61B 17/70 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7083*** (2013.01)

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USPC ..... 606/54–59, 96, 104, 324, 86 A
See application file for complete search history.

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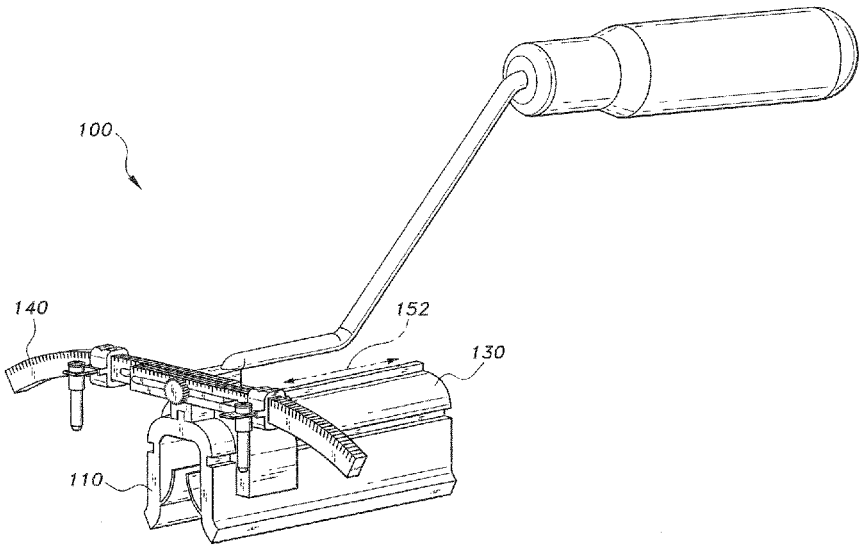
(57) **ABSTRACT**

The lumbar spine pedicle screw guide has a base for covering at least one exposed spinous process of the lumbar vertebra and a sliding top disposed over the base and configured for movement over the length of the base along a first axis. At least one calibration arm having a straight portion and a curved portion is movably connected to the sliding top and configured for movement along a second axis perpendicular to the first axis. A pedicle access unit is mounted on each calibration arm and is capable of being secured at different locations thereon. The sliding top can be adjusted to align the calibration arms with a selected vertebra so that medical instruments and a screw can be accurately guided through the pedicle access unit into a pedicle of the selected vertebra.

12 Claims, 5 Drawing Sheets



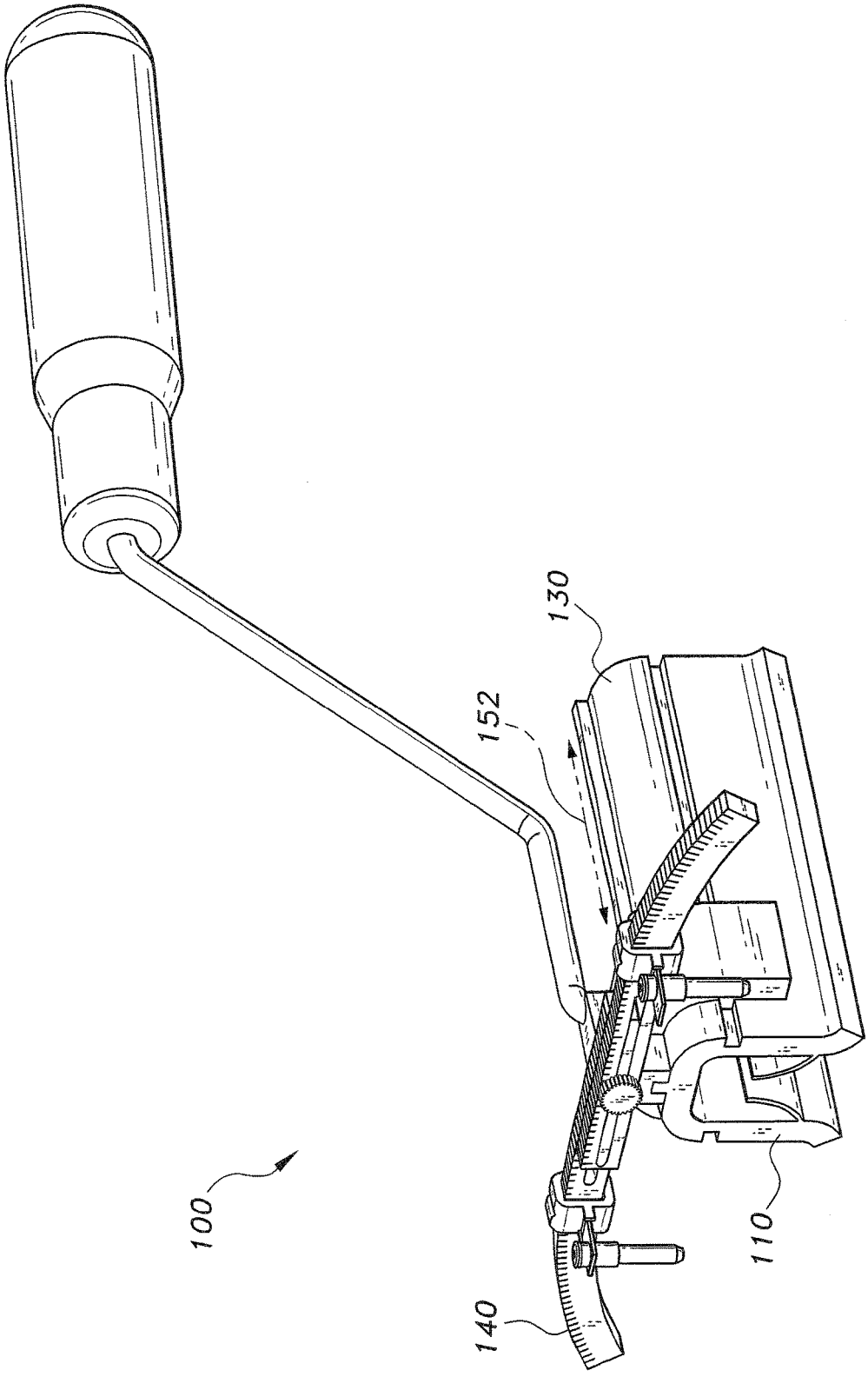


FIG. 1

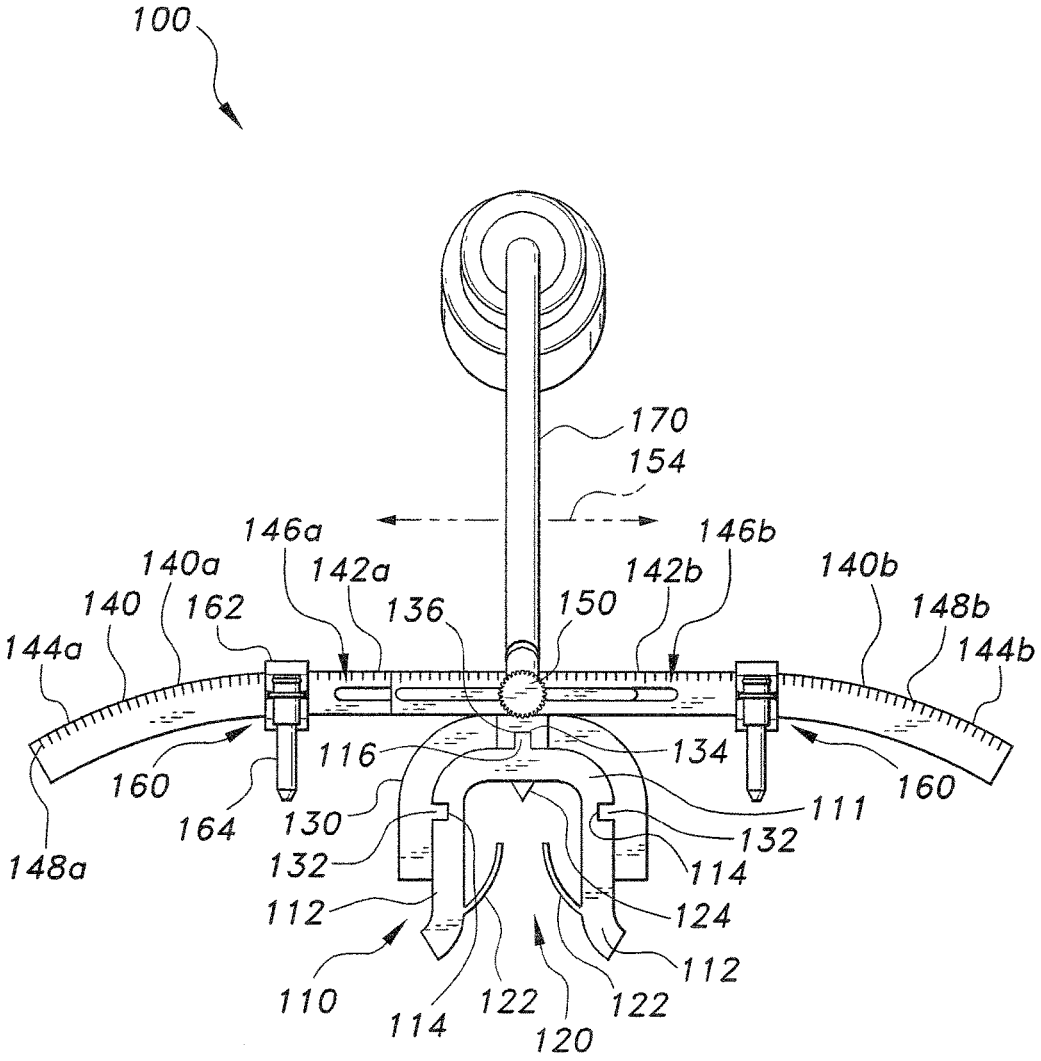

100
170
154
146a
146b
140a
142a
142b
140b
140
162
136
150
148b
144a
144b
160
116
134
160
164
130
111
132
148a
132
114
112
124
112
110
114
122
122
120

FIG. 2

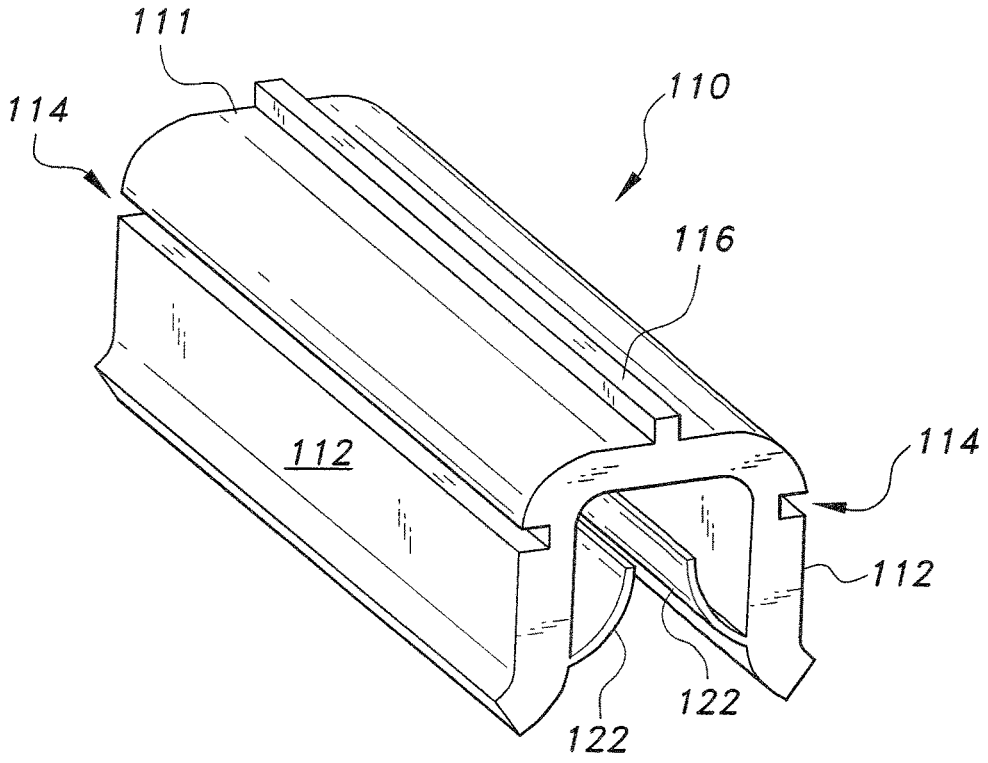


FIG. 3A

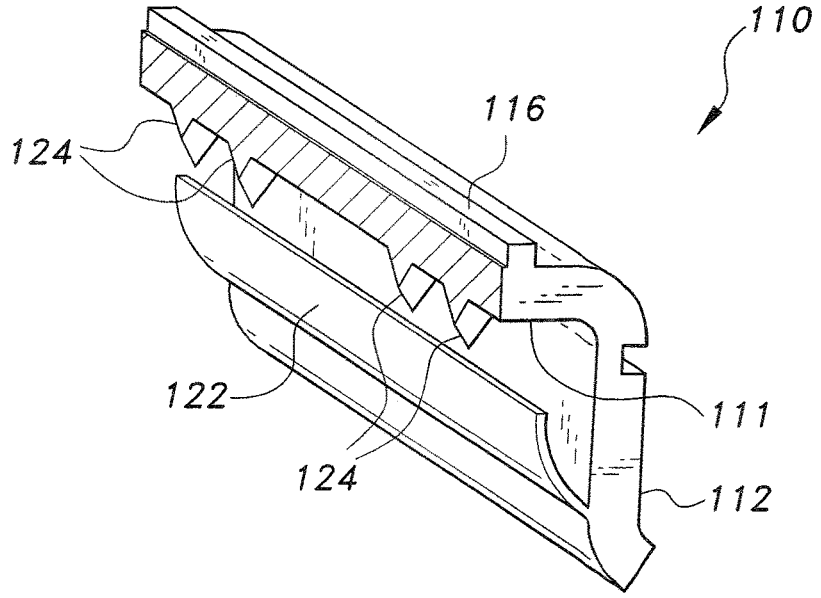


FIG. 3B

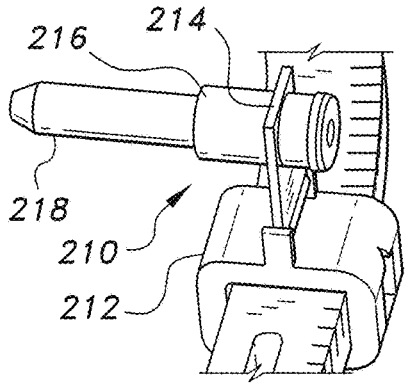


FIG. 4A

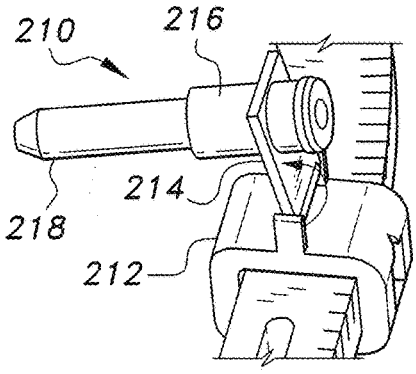


FIG. 4B

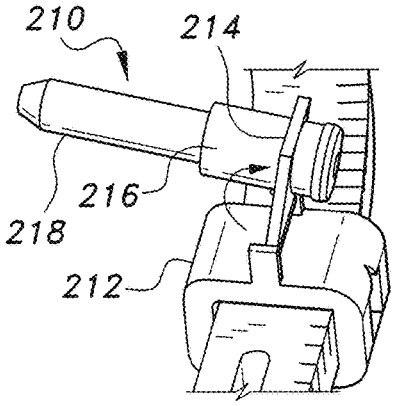


FIG. 4C

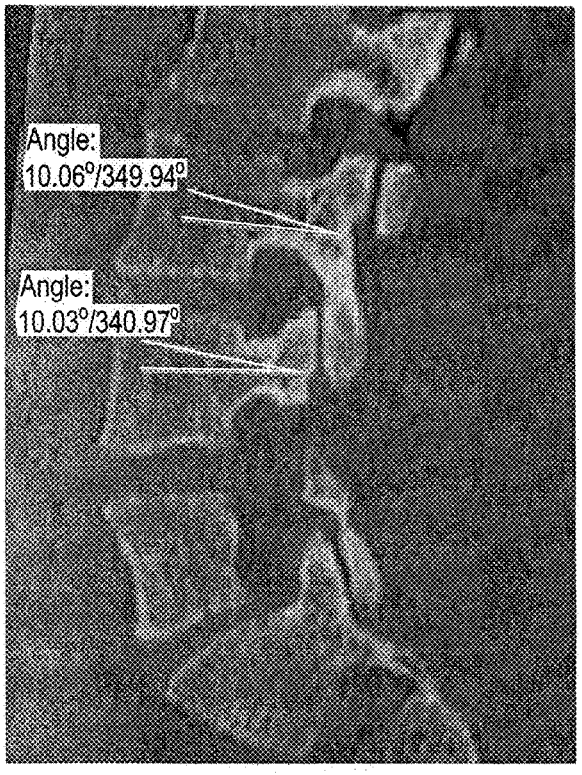


FIG. 4D

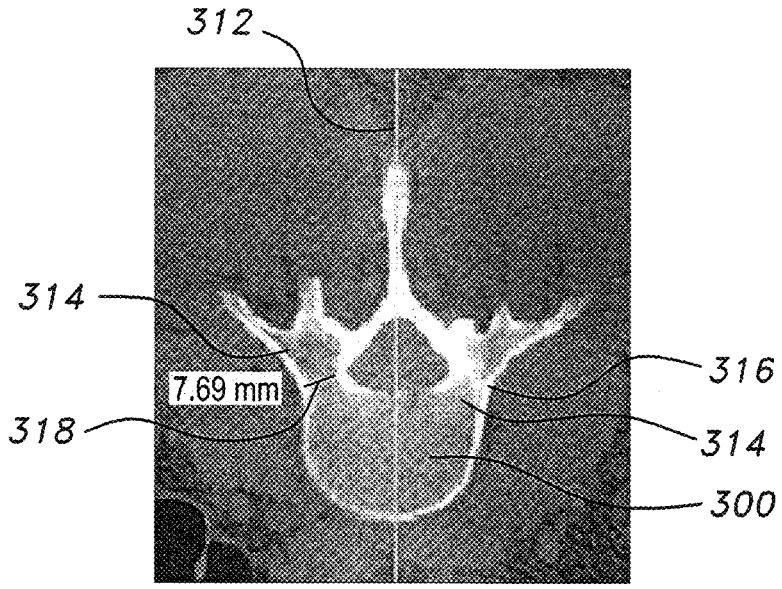

312
314
7.69 mm
318
316
314
300

FIG. 5A

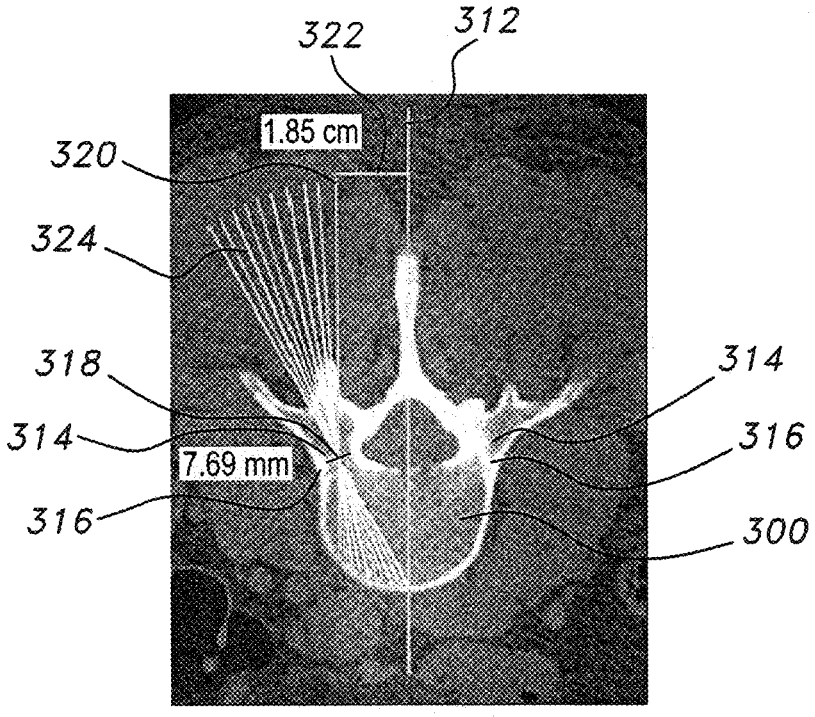

322
312
1.85 cm
320
324
318
314
7.69 mm
316
314
316
300

FIG. 5B

LUMBAR SPINE PEDICLE SCREW GUIDE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to pedicle screw instrumentation, and more particularly to a lumbar spine pedicle screw guide for improving the accuracy of pedicle screw insertion and the safety of instrumentation used in pedicles of the lumbar vertebrae.

2. Description of the Related Art

Pedicle screw instrumentation is the main method used to achieve instrumented fusion between the vertebrae in thoracic and lumbar spine regions. The process typically requires insertion of pedicle screws with accuracy and precision in order to avoid injury to the near-by nerve roots and achieve adequate fixation. Various techniques have been developed to improve the accuracy of pedicle screw placement. Such techniques, however, often require complex or expensive equipment in order to achieve a high rate of accuracy (e.g., greater than 90%). Consequently, free-hand techniques, having lower success rates and accuracy (e.g., 68%-80%), are the most commonly used techniques.

Pedicle guides used with free-hand techniques can sometimes incorporate parts that must be inserted under the bone, which is not recommended because of the risks in neurologic injury and not recommended for patients with spinal canal narrowing (i.e., stenosis). Additionally, such pedicle guides do not facilitate procedures on two pedicles of the same vertebra at the same device position, thereby resulting in increased x-ray usage and potential variability in pedicle screw placement. Such pedicle guides also fail to address instrumentation of multiple vertebrae, despite the fact that spinal fusion typically requires instrumentation of two or more adjacent vertebrae.

Thus, a lumbar spine pedicle screw guide solving the aforementioned problems is desired.

SUMMARY OF THE INVENTION

The lumbar spine pedicle screw guide includes a base for covering at least one exposed spinous process of the vertebra; a midline stabilization system within an interior portion of the base for reducing deviation of the base from a central alignment along the first axis of the midline of the vertebra; a sliding top disposed over an exterior surface of the base, the sliding top being configured for movement over a length of the base along the first axis; at least one calibration arm having a straight portion and a curved end, the at least one calibration arm being movably connected to the sliding top and configured for movement along a second axis perpendicular to the first axis; and a pedicle access unit mounted on each of the at least one calibration arm and capable of being secured at different locations thereon, the pedicle access unit having a hollow interior for receiving medical instruments therethrough. The sliding top can be adjusted to align the at least one calibration arm with a target vertebra. The medical instruments and a screw can be accurately guided through the pedicle access unit into a pedicle of the target vertebra.

These and other features of the present invention will become readily apparent upon further review of the following specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is perspective view of a lumbar spine pedicle screw guide according to the present invention.

FIG. **2** is a front elevational view of the lumbar spine pedicle screw guide of FIG. **1**.

FIG. **3**A is a perspective view of the base for the lumbar spine pedicle screw guide of FIG. **1**.

FIG. **3**B is a perspective view in section of the base of FIG. **3**A.

FIG. **4**A is perspective view of an alternative embodiment of a pedicle access unit for the lumbar spine pedicle screw guide of FIG. **1**, shown angled normal to the calibration arm.

FIG. **4**B is perspective view of the pedicle access unit of FIG. **4**A, shown angled 10° downward.

FIG. **4**C is perspective view of the pedicle access unit of FIG. **4**A, shown angled 10° upward.

FIG. **4**D is radiograph view of a lumbar spine illustrating screw trajectories resulting from different angulation.

FIG. **5**A is radiographic view showing a vertebra requiring pedicle screws.

FIG. **5**B is a radiographic view showing trajectories achievable using the lumbar spine pedicle screw guide of FIG. **1**

Similar reference characters denote corresponding features consistently throughout the attached drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a lumbar spine pedicle screw guide **100** in accordance with the present invention. The lumbar spine pedicle screw guide **100** generally includes a base **110**, a sliding top **130**, and at least one calibration arm **140**. The base **110** is configured to cover at least one exposed spinous process of the lumbar vertebra. Exposure of spinous processes is typically necessary when performing various types of surgical procedures, such as pedicle cannulation, on the vertebra. The base **110** is designed to be centered in the midline of the spine when covering the spinous processes.

Referring additionally to FIG. **2**, the base **110** has a general U-shaped configuration defined by a top portion **111** and two leg portions **112**. The base includes a side track **114** on the outer surface of each leg portion **112**. Each side track **114** extends along the entire length of the base **110**. Additionally, a key or top protrusion **116** is formed on the outer surface of the top portion **111** and also extends along the entire length of the base **110**.

The base **110** incorporates a midline stabilization system **120** designed to prevent tilting and deviation from midline of the spine. More particularly, the base **110** includes curved edge portions **122** that extend upward and inward from each leg portion **112**. The curved edge portions **122** extend along the entire length of the base **110**, and define an opening that is designed to maintain the base along the midline of selected vertebrae. Additionally, the base **110** includes at least one pair of anchors **124** extending downward from the inner surface of the top portion **110**. The anchors **124** are positioned along the centerline of the top portion **111**, and configured to engage a particular spinous process. Accordingly, the curved edge portions **122** and anchors **124** function prevent movement and deviation of the base **110** (and lumbar spine pedicle screw guide **100**) during surgical procedures.

As can be seen with additional reference to FIG. **3**B, the guide **100** may incorporate additional pairs of anchors **124** provided on the base **110**. Each pair of anchors **124** is appropriately spaced in order to engage an individual spinous process. For example, a single pair of anchors **124** would only engage a single spinous process, two pairs of anchors **124** would engage two spinous processes, etc. As

will be discussed in greater detail below, the inclusion of multiple pairs of anchors **124** allows medical personnel to perform surgical procedures on multiple vertebrae with the least amount of intra-operative x-rays.

Referring to FIGS. **1** and **2**, the sliding top **130** is disposed over the exterior surface of the base **110**. The sliding top **130** has a U-shaped cross-section which corresponds to that of the base, but has a shorter length. Such a configuration allows the sliding top **130** to be moved back and forth along a first axis **152** which is parallel to the length of the base **110**. As best viewable in FIG. **2**, the sliding top **130** includes two side protrusions **132** configured to engage the side tracks **114** of the base **110**. The sliding top **130** also includes a keyway or top track **134** configured to engage the key or top protrusion **116** of the base **110**. Since the sliding top **130** has a shorter length than the base **110**, the combination of tracks and protrusions define a track mechanism **136** that allows it to be moved to different locations along the length of the base **110**. An arm and handle assembly **170** may be provided on the sliding top **130** in order to facilitate movement along the base **110**.

The lumbar spine pedicle screw guide **100** includes at least one calibration arm **140***a* positioned along a second axis **154** that is perpendicular to the first axis **152**. The calibration arm **140***a* includes a straight portion **142***a* and a curved end **144***a*. The straight portion **142***a* of the calibration arm **140***a* includes a slot or groove **146***a* that facilitates movement along the second axis **154**, and allows locking of the calibration arm **140***a* to the sliding top **130** at a desired position. A locking screw **150** is used to secure the calibration arm **140***a* to the sliding top **130**. As illustrated in FIGS. **1** and **2**, the calibration arm **140***a* contains a plurality of graduated indicia or calibration marks **148***a*. Thus, medical personnel can adjust the position of the calibration arm **140***a* for a particular patient and/or surgical procedure and apply the locking screw **150** to maintain its position relative to the sliding top **130**.

A pedicle access unit **160** is mounted on the calibration arm **140***a*. The pedicle access unit **160** is configured such that it can be secured to the calibration arm **140***a* at different positions. The pedicle access unit **160** includes a mount **162** and a guide cylinder **164**. The mount **162** includes an opening configured to receive the calibration arm **140***a* therethrough. The mount **162** can therefore be moved to different positions on the straight portion **142***a* and curved end **144***a* of the calibration arm **140***a* in accordance with target measurements from the midline of the pedicle.

Various locking means, such as a screw, can be used secure the mount **162** to a desired position. The guide cylinder **164** is dimensioned and configured to receive and guide appropriate medical instruments during such procedures as pedicle cannulation. As previously discussed, the calibration arm **140***a* contains a plurality of calibration marks **148***a*. The mount **160** can be positioned, in part, by using the calibration marks such that the guide cylinder **164** is capable of precisely guiding the medical instrument (e.g., pedicle owl or pedicle finder). A small introducer (not shown) can also be passed through the middle of guide cylinder **164** in order to reduce its internal diameter and allow the use of smaller instruments (e.g. Jamshidi needle).

As illustrated in FIGS. **1** and **2**, the lumbar spine pedicle screw guide **100** preferably includes a second calibration arm **140***b* that is also positioned along the second axis **154**. Additionally, the second calibration arm **140***b* is positioned in an overlapping configuration relative to the (first) calibration arm **140***a*. The second calibration arm **140***b* can also be configured to include a straight portion **142***b* and a curved end **144***b*, as well as calibration marks **148***b*. A slot or groove **146***b* is also provided in the straight portion **142***b* of the second calibration arm **140***b* to facilitate movement along the second axis **154**. The overlapping configuration of the calibration arms **140***a*, **140***b* allows the use of a single locking screw **150** for securing both calibration arms **140***a*, **140***b* to the sliding top **130**.

The second calibration arm **140***b* similarly contains a pedicle access unit **160** configured such that it can be secured at different positions. The pedicle access unit **160** also includes a mount **162** and a guide cylinder **164**. As illustrated in FIGS. **1** and **2**, the mount **162** also includes an opening configured to receive the calibration arm **140**, and allow movement to different positions on the straight portion **142***b* and curved end **144***b* of the calibration arm **140***b*. Thus, it is possible to perform pedicle cannulation on both sides of the vertebra without having to move and readjust the lumbar spine pedicle screw guide **100**. Hence, the number of imaging exposures required to obtain necessary measurements of the vertebra can be reduced, when compared to conventional methodologies that require two separate procedures for each vertebra.

Often, it is necessary to perform pedicle cannulation on multiple adjacent vertebras. Such procedures typically require multiple imaging exposures to obtain necessary measurements related to the target vertebrae. Certain imaging procedures (e.g., x-rays), however, can be harmful to the patient, while others can be costly (e.g., CT scans, etc.). In the present guide **100**, the sliding top **130** can be moved along the base **110** so that pedicle cannulation can be performed on one or more adjacent vertebrae without the need to reset the base **110** relative to the patient's spine. Furthermore, the number of imaging exposures is also reduced. More particularly, the lumbar spine pedicle screw guide **100** can be positioned such that multiple pairs of anchors **124** in the base **110** contact adjacent spinous processes. Next, the sliding top **130** can be moved to align the calibration arms **140** with a first target vertebra. The pedicle access units **160** are then aligned based on imaging measurements in order to perform pedicle cannulation on both sides of the first target vertebra. Next, the sliding top **130** can be moved to align the calibration arms **140** to the adjacent target vertebra without having to move the base **110** out of contact or alignment with the spinous processes. The pedicle access units **160** can then be aligned to perform pedicle cannulation on the adjacent target vertebra.

FIGS. **4**A-**4**C illustrate a pedicle access unit **210** in accordance with an alternative embodiment. The pedicle access unit **210** also includes a mount **212** and guide cylinder **218** similar to those previously described. According to the illustrated embodiment, however, a bracket **214** can be pivotably secured to the mount **212** in order to occupy different angles. After being pivoted, the bracket **214** can be locked in position using various methodologies such as screws, spring loaded bearings, etc. The bracket **214** also has a sleeve **216** that receives the guide cylinder **218**. The guide cylinder **218** may be directly or removably connected to the bracket **214**. The pedicle access unit **210** facilitates constrained angulation of ±10°, thereby accommodating different patient anatomy and different starting points based on a lateral x-ray image. Thus, insertion of the pedicle screw can be conducted with straight, lower, and upper angulation. As can be seen in FIG. **4**D, such features can accommodate a low starting point for the targeted vertebra on the left.

FIGS. **5**A and **5**B illustrate measurement and alignment techniques that can be used by the lumbar spine pedicle screw guide **100** for performing pedicle cannulation. First, a

preoperative axial CT scan or MRI is taken for a target vertebra **300**. A mid-vertebral line **312** that bisects the target vertebra into two equal halves is defined. Next, the portion of the pedicle **314** having the narrowest diameter is identified. This is also known as the isthmus **316**. The pedicle midpoint **318** at the isthmus **316** is used as a reference for a line that is parallel to the mid-vertebral line **312**. Thus, the reference line **320** identifies the first trajectory for the pedicle access unit **160**. The distance between the mid-vertebral line **312** and the reference line **320** defines a calibration distance **322** for pedicle access unit **160**. Additional trajectory lines **324** can be obtained by adjusting the pedicle access unit **160** along the calibration arm **140** to aim at the pedicle midpoint **318**.

It is to be understood that the present invention is not limited to the embodiments described above, but encompasses any and all embodiments within the scope of the following claims.

We claim:

1. A lumbar spine pedicle screw guide, comprising:

an elongated base adapted for covering at least one exposed spinous process of a vertebra, the base having an interior portion and a midline stabilization system within the interior portion for reducing deviation of the base from a central alignment with the spinal cord along a first axis;

a sliding top slidably disposed over an exterior surface of the base, the sliding top being configured for movement over the length of the base along the first axis;

at least one calibration arm having a straight portion and a curved end, the at least one calibration arm being movably connected to the sliding top and configured for movement along a second axis perpendicular to the first axis, the sliding top being slidable along the base to align the at least one calibration arm with a target vertebra; and

a pedicle access unit mounted on the at least one calibration arm and selectively secured at different locations thereon, the pedicle access unit having a hollow interior for receiving medical instruments therethrough;

whereby the medical instruments and a pedicle screw can be accurately guided through the pedicle access unit into a pedicle of the target vertebra.

2. The lumbar spine pedicle screw guide according to claim **1**, wherein:

the base has an inverted U-shaped configuration including a top portion and two leg portions; and

said midline stabilization system comprises:

a curved edge portion extending upward and inward from each of the leg portions of the base and extending along the length of the base; and

at least one pair of anchors extending downward from the top portion along a centerline of the base.

3. The lumbar spine pedicle screw guide according to claim **1**, further comprising a track mechanism for facilitating movement of the sliding top over the length of the base.

4. The lumbar spine pedicle screw guide according to claim **3**, wherein the track mechanism comprises:

a first protrusion on an outer surface of the base extending along the length thereof;

a first track on an inner surface of the sliding top for receiving the first protrusion therein;

at least one second protrusion on the inner surface of the sliding top; and

at least one second track on the outer surface of the base for receiving the second protrusion therein, the at least one second track extending the length of the base.

5. The lumbar spine pedicle screw guide according to claim **4**, wherein;

the at least one second track is disposed on an upper side portion of the base; and

the at least one second protrusion is correspondingly disposed on the inner surface of the sliding top.

6. The lumbar spine pedicle screw guide according to claim **1**, wherein said at least one calibration arm further comprises:

a plurality of calibration marks formed on the straight portion and the curved end; and

a groove within the straight portion, the guide further comprising a lock screw extending through the groove for securing the at least one calibration arm to the sliding top.

7. The lumbar spine pedicle screw guide according to claim **1**, wherein the pedicle access unit further comprises:

a mount selectively engaging the calibration arm at predetermined locations; and

a guide cylinder attached to the mount for directing the medical instruments and/or screw.

8. The lumbar spine pedicle screw guide according to claim **7**, wherein the guide cylinder is pivotally attached to the mount.

9. The lumbar spine pedicle screw guide according to claim **1**, further comprising a handle attached to the sliding top for moving the sliding top along the base.

10. The lumbar spine pedicle screw guide according to claim **1**, wherein the sliding top is movable to align the at least one calibration arm with a second target vertebra.

11. The lumbar spine pedicle screw guide according to claim **1**, wherein an angle for performing the pedicle cannulation can be selected based on placement of the pedicle access unit on the at least one calibration arm.

12. The lumbar spine pedicle screw guide according to claim **1**, wherein said at least one calibration arm consists of two calibration arms extending to opposite sides of said sliding top, each of the calibration arms having one of said pedicle access units attached thereto at selectively located positions.

* * * * *