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(54) Title: DEVICE FOR REMOVING BONE GRAFTS

(54) Titre: DISPOSITIF POUR PRELEVER DES COPEAUX D'OS

(57) Abstract

The invention relates to a device for removing bone grafts comprised of: A) a cutting tool (16) with a longitudinal axis (2), a cutting head (1) and a longitudinal shaft (8) attached to the cutting head (1) and concentrically disposed in relation to the longitudinal axis (2); B) driving means (14) provided with a handle (37) and C) a vacuum container (17) that can be connected to the shaft (8), wherein D) the cutting tool (16) has a continuos bore (10) extending in the direction of the longitudinal axis (2) and the cutting head (1) has at least one through hole (7) so that the bone grafts cut by the cutting head (1) can be conveyed through the bore (10) and E) the bone grafts can also be conveyed through the bore (10) from the cutting head (1) into the container (17) by means of the vacuum in said container (17) during cutting and removal of the bone grafts, wherein F) the cutting tool (16), the container (17) and the driving means (14) are connected to a device that can be freely moved manually by means of the handle (37).

(57) Abrégé

L'invention concerne un dispositif utilisé pour prélever des copeaux d'os, qui comprend: A) un outil de coupe (16) présentant un axe longitudinal (2), une tête de coupe (1) et une tige (8) longitudinale qui est raccordée à ladite tête de coupe (1) et placée concentriquement par rapport à l'axe longitudinal (2); B) des moyens d'entraînement (14) qui sont pourvus d'une poignée (37); et C) une enceinte (17) à vide pouvant communiquer avec la tige (8). Selon l'invention (D) l'outil de coupe (16) présente un alésage (10) traversant dans le sens de l'axe longitudinal (2), et la tête de coupe (1) est pourvue d'au moins une ouverture de passage (7), de telle sorte que les copeaux d'os enlevés par la tête de coupe (1) peuvent être transportés à travers l'alésage (10); E) même pendant le découpage de copeaux d'os, lesdits copeaux peuvent être transportés grâce au vide régnant dans l'enceinte (17), à travers l'alésage (10), de la tête de coupe (1) jusqu'à l'intérieur de l'enceinte; et F) l'outil de coupe (16), l'enceinte (17) et les moyens d'entraînement (14) sont assemblés en un dispositif pouvant être déplacé librement à la main, au moyen de la poignée (37).

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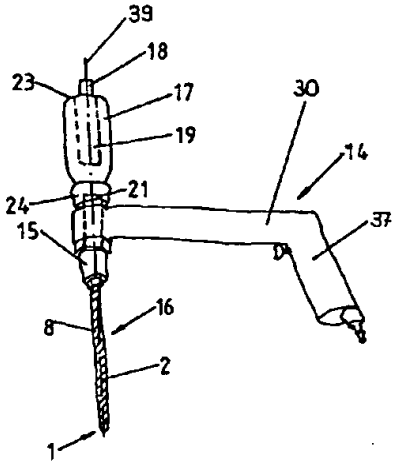
(54) Title: DEVICE FOR REMOVING BONE GRAFTS

(54) Bezeichnung: VORRICHTUNG ZUR GEWINNUNG VON KNOCHENSPÄNEN

(57) Abstract

The invention relates to a device for removing bone grafts comprised of: A) a cutting tool (16) with a longitudinal axis (2), a cutting head (1) and a longitudinal shaft (8) attached to the cutting head (1) and concentrically disposed in relation to the longitudinal axis (2); B) driving means (14) provided with a handle (37) and C) a vacuum container (17) that can be connected to the shaft (8), wherein D) the cutting tool (16) has a continuos bore (10) extending in the direction of the longitudinal axis (2) and the cutting head (1) has at least one through hole (7) so that the bone grafts cut by the cutting head (1) can be conveyed through the bore (10) and E) the bone grafts can also be conveyed through the bore (10) from the cutting head (1) into the container (17) by means of the vacuum in said container (17) during cutting and removal of the bone grafts, wherein F) the cutting tool (16), the container (17) and the driving means (14) are connected to a device that can be freely moved manually by means of the handle (37).



(57) Zusammenfassung

Vorrichtung zur Gewinnung von Knochenspänen, welche A) ein Schneidwerkzeug (16) mit einer Längsachse (2), einem Schneidkopf (1) und einem an den Schneidkopf (1) anschliessenden, konzentrisch zur Längsachse (2) angeordneten longitudinalen Schaft (8); B) Antriebsmittel (14), welche mit einem Handgriff (37) versehen sind; und C) einen unter Vakuum stehenden, mit dem Schaft (8) verbindbaren Behälter (17) umfasst; wobei D) das Schneidwerkzeug (16) eine in Richtung der Längsachse (2) durchgehende Bohrung (10) aufweist und der Schneidkopf (1) mit mindestens einer Durchgangsöffnung (7) versehen ist, so dass die vom Schneidkopf (1) spanabhebend abgetragenen Knochenspäne durch die Bohrung (10) förderbar sind; und E) auch während der spanabhebenden Gewinnung von Knochenspänen die Knochenspäne mittels des Vakuums im Behälter (17) durch die Bohrung (10) vom Schneidkopf (1) in den Behälter (17) förderbar sind, wobei F) Schneidwerkzeug (16), Behälter (17) und Antriebsmittel (14) zu einer mittels des Handgriffes (37) manuell frei bewegbaren Vorrichtung verbunden sind.

LEDIGLICH ZUR INFORMATION

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Description

Vorrichtung zur Gewinnung von Knochenspänen

Die Erfindung bezieht sich auf eine Vorrichtung zur Gewinnung von Knochenspänen gemäss dem Oberbegriff des Patentanspruchs 1.

Das Implantieren von körpereigenem Knochenmaterial bleibt die effizienteste Behandlungsmethode bei Nichtheilen eines gebrochenen Knochens, Pseudoarthrosis und zur Optimierung der Erfolgsrate bei Arthrodesis. Die Verwendung von körpereigenem Knochenmaterial ist sicherer und wirksamer als die Verwendung künstlich hergestellter Hydroxyapatit-Materialien oder körperfremder Knochenspäne, bedingt jedoch einen zusätzlichen Eingriff am Körper des Patienten. Dies kann durch ein begrenztes Eindringen und durch den Gebrauch einer zylindrischen Nadel, wie sie zur Entfernung von Knochenmaterial für Diagnosezwecke verwendet wird, minimiert werden. Die Technik ist jedoch kompliziert und gefährlich da keine genaue Kontrolle gewährleistet ist. Meist wird deshalb die Spongiosa durch einen grösseren Hautschnitt und aus einer grossen Öffnung am Beckenrand herausgemeisselt. Spezielle Knochenspan-Sammelinstrumente gestatten eine sichere und rasche Gewinnung von körpereigenen Knochenspänen durch einen kleinen Hauteinschnitt, was die Unannehmlichkeiten und Verletzungen des Patienten minimiert. Diese Vorrichtungen entfernen zuverlässig das Knochenmaterial und können mit einer Bohrmaschine angewendet werden, wodurch eine grössere Menge und eine bessere Kontrollmöglichkeit gewonnen werden sowie ein versehentliches Durchstossen durch die Kortikalis minimiert wird. Diese sichere und wirksame Technik ermöglicht, körpereigene Knochenspäne für Fusionen, Pseudoarthrosis und Knochenbrüche mit einer minimalen Verletzung des Spenders zu gewinnen. Die Entfernung der Knochenspäne am Körper des Patienten wird üblicherweise am Beckenknochen vorgenommen. Ebenfalls brauchbares Knochenmaterial lässt sich proximal an der Ulna oder distal am Radius gewinnen.

Eine Methode und eine Vorrichtung zur Gewinnung von Gewebe ist aus der US 5,403,317 BONUTTI bekannt. Diese bekannte Erfindung umfasst eine Vorrichtung zur perkutanen Gewebegewinnung und besteht aus einem flexiblen Bohrerschaft und Mitteln zum Antrieb des Schaftes. Zum Herausschneiden von Gewebefragmenten

aus dem Gewebe ist vorne am Schaft eine Schneidspitze angebracht. Die Gewebefragmente werden während des Schneidvorganges mittels eines Unterdruckes durch den Schaft zu einem Ort ausserhalb des Körpers gesaugt.

Nachteilig bei dieser bekannten Vorrichtung ist die Förderung der Knochenspäne durch einen mit einem Unterdruck beaufschlagten Schlauch von der Schneideinrichtung weg zu einem Filter oder anderen Abscheideeinrichtung. Die dadurch entstehenden langen Förderwege für die Knochenspäne bedingen einen grossen Unterdruck am vom Schneidkopf entfernten Ende der Förderleitung und bieten vor allem an Krümmungen der Förderleitung Möglichkeit zur unerwünschten Ablagerung von Knochenspänen innerhalb der Förderleitung.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung zu entwickeln, wo die Förderstrecke für die Knochenspäne zwischen dem Ort der Gewinnung und dem Sammelbehälter möglichst kurz ist und die Kochenspäne in einem direkt mit dem Bohrwerkzeug verbundenen Behälter gesammelt werden.

Die Erfindung löst die gestellte Aufgabe mit einer Vorrichtung zur Gewinnung von Knochenspänen, welche die Merkmale des Anspruchs 1 aufweist.

Weitere vorteilhafte Ausgestaltungen der Erfindung sind in den abhängigen Ansprüchen gekennzeichnet.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass die erfindungsgemässe Vorrichtung einen kompakten Aufbau aufweist, Schneidwerkzeug, Antriebsmittel und Sammelbehälter in einer manuell frei bewegbaren Einheit verbunden sind und durch die Anordnung des Sammelbehälters eine hohe Saugleistung der Vorrichtung ermöglicht wird.

Die erfindungsgemässe Vorrichtung umfasst einen hohlzylindrischen Schneidkopf, welcher verschieden gestaltete Bohrspitzen und Schneidkanten aufweisen kann, einen hohlzylindrischen Schaft mit Mitteln zum Einspannen des

Schaftes in eine Antriebsvorrichtung, und eine Antriebsvorrichtung, welche beispielsweise aus einer Universalbohrmaschine bestehen kann. Die hohlzylindrische Ausgestaltung des Schneidkopfes und des Schaftes ermöglicht das Absaugen der vom Schneidkopf abgetragenen Knochenspäne aus der Spongiosa durch die Bohrung im Innern der Hohlzylinder. Zum Sammeln der Kochenspäne ist an der Antriebsvorrichtung ein Behälter so angebracht, dass der hohlzylindrische Schaft in den Behälter mündet. Zum Absaugen der Knochenspäne ist am Behälter ein Stutzen für den Anschluss eines Vakuumschlauches angebracht. Durch das so angelegte Vakuum werden die Knochenspäne durch eine oder mehrere Durchgangsöffnungen im Schneidkopf in die Bohrung im Schaft gesaugt und von dort durch den gesamten Schaft hindurch in den Behälter gefördert. Damit die Knochenspäne nicht in den Vakuumschlauch geraten, ist im Behälter eine Abscheidevorrichtung zum Abscheiden der Knochenspäne aus dem Luftstrom angebracht. Dieser Abscheider kann als Filter, Sieb, Prallplatte oder Zyklon ausgeführt sein.

In einer bevorzugten Ausführungsform umfasst die erfindungsgemässe Vorrichtung einen bezüglich Torsion und/oder Biegung elastisch verformbaren Schaft. Diese Verformbarkeit lässt sich durch eine Ausführung des Schaftes als spiralförmig gewickeltes Metallblechband, als mit einer Drahtarmierung verstärkter Kunststoff- oder Gummischlauch oder auch als Metallrohr mit balgartiger Seitenwand herstellen. Zur Abdichtung der unter Vakuum stehenden Bohrung im Schaft des Werkzeuges wird vorzugsweise in diese Bohrung ein Gummi- oder Kunststoffschlauch eingezogen. Die elastische Verformbarkeit des Schaftes und ein nicht zu scharfkantig ausgebildeter Schneidkopf gestatten ein Ausräumen der Spongiosa zwischen der Kortikalis, ohne dadurch die härtere Kortikalis zu schneiden oder durch Letztere hindurchzubrechen.

Die Verbindung zwischen Schneidkopf und Schaft ist als lösbare oder feste Verbindung denkbar, wobei eine lösbare Verbindung einen kleineren Werkzeugsatz ermöglicht. Als lösbare Verbindung sind Schraubverbindungen, radiale Stiftschrauben oder radiale Stiftverbindungen möglich.

Die Bohrspitze des Schneidkopfes ist vorzugsweise als Sektor einer Kugelkalotte mit einer Schneidkante ausgeführt. Andere Ausführungsformen der Bohrspitze sind als Kegelsektoren mit Schneidkanten oder als hohlzylindrische Fräser mit stirnseitigen Schneidezähnen denkbar.

Eine spezielle Ausführungsform des Schneidkopfes besteht darin, dass die Bohrspitze des Schneidkopfes kugelkalottenförmig mit mindestens zwei koaxial und radial zur Längsachse sich in den Hohlraum erstreckenden Durchgangsöffnungen ausgebildet ist, wobei an den Kanten der Durchgangsöffnungen Schneidkanten zum Abtragen von Knochenspänen angebracht sind und die abgetragenen Knochenspäne durch die Durchgangsöffnungen in den Hohlraum des Schneidkopfes förderbar sind.

In einer bevorzugten Anwendungsform umfasst das Vakuum einen Druckbereich von ungefähr 0 bar bis 1 bar, vorzugsweise jedoch einen Druckbereich von 0,2 bar bis 0,8 bar.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine schematische Darstellung einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 2 eine perspektivische Darstellung des Schneidkopfes mit dem flexiblen Schaft einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 3 eine Ansicht des Schneidkopfes mit dem flexiblen Schaft einer Ausführungsform der erfindungsgemässen Vorrichtung; und

Fig. 4 eine schematische Darstellung einer weiteren Ausführungsform der erfindungsgemässen Vorrichtung.

In Fig. 1 ist eine bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung dargestellt. Das Schneidwerkzeug 16, welches zur Gewinnung der Knochenspäne dient, besteht aus einem Schneidkopf 1 mit einem sich entlang einer Längsachse 2 erstreckenden hohlzylindrischen Schaft 8. Dieser Schaft 8 ist in Einspannmitteln 15 einer als Antriebsmittel 14 dienenden Universalbohrmaschine 30 axial und rotativ fixiert. Die Universalbohrmaschine 30 ist mittels eines Handgriffes 37 als komplette Einheit mit Schneidwerkzeug 16 und Behälter 17 manuell frei bewegbar. Durch die Antriebsmittel 14 wird dem Schaft 8 mit dem Schneidkopf 1 eine Rotationsbewegung um die Längsachse 2 aufgeprägt, wodurch sich der Schneidkopf 1 in den Knochen bohrt und die zu sammelnden Knochenspäne abträgt. Der Schaft 8 ist vom Schneidkopf 1 bis zu seinem vom Schneidkopf 1 entfernten Ende 21 hohlzylindrisch ausgeführt, so dass die Knochenspäne entlang der gesamten Länge des Schaftes 8 förderbar sind. Ebenfalls an den Antriebsmitteln 14 angebracht ist ein Behälter 17 für die Sammlung der Knochenspäne. Der Behälter 17 ist koaxial zur Längsachse 2 mit seinem vorderen Ende 24 so an den Antriebsmitteln 14 lösbar befestigt, dass das vom Schneidkopf 1 entfernte Ende 21 des Schneidwerkzeuges 16 gegenüber der Umgebung luftdicht in den Behälter 17 mündet. Dieser gegenüber der Umgebung luftdichte Abschluss des Schneidwerkzeuges 16 in der Behälteröffnung lässt sich durch eine im wesentlichen spielfreie Lagerung des hinteren Endes 21 in der Behälteröffnung oder durch Einfügen einer Dichtung, beispielsweise einer O-Ringdichtung am hinteren Ende 21 oder in der Behälteröffnung erreichen. An seinem vom Schaft 8 entfernten Ende 23 ist der Behälter 17 mit einem Stutzen 18 versehen, woran sich ein Vakuumschlauch (nicht gezeichnet) anschliessen lässt. Durch das Vakuum im Schlauch wird der Behälter 17 ebenfalls evakuiert, wodurch im Innern des hohlzylindrischen Schaftes 8 ein Unterdruck entsteht und somit die vom Schneidkopf 1 abgetragenen Knochenspäne durch das Innere des Schaftes 8 gesaugt werden und in den Behälter 17 gelangen, wo sie dann in der Folge gesammelt werden können. Damit die Knochenspäne nicht durch das Vakuum mit in den Schlauch gerissen werden, ist im Behälter 17 eine Abscheidevorrichtung 19, welche in der bevorzugten Ausführungsform als Sieb ausgestaltet ist, so angebracht, dass die Knochenspäne nicht durch den Stutzen 18 austreten können.

Fig. 2 zeigt eine Ausführungsform des Schneidkopfes 1. Der Schneidkopf 1 ist als Hohlzylinder mit einer Längsachse 2 und einer Bohrspitze 20 ausgeführt und

umfasst einen vorderen an die Bohrspitze 20 anschliessenden Abschnitt 4 und einen hinteren von der Bohrspitze 20 entfernten Abschnitt 5. Der vordere Abschnitt 4 besteht aus einem Hohlzylinder mit einer als Kugelkalottensektor ausgebildeten Bohrspitze 20, wobei die im Querschnitt rechtwinklig zur Längsachse 2 betrachtete Seitenwand des vorderen Abschnitts 4 nur einen Kreisringsektor einschliesst, so dass eine radial zum hohlzylindrischen Teil und axial zur Bohrspitze 20 verlaufende Durchgangsöffnung 7 entsteht. Die Seitenwand des vorderen Abschnittes 4 ist von der Bohrspitze 20 bis zum hinteren Abschnitt 5 gegen die Durchgangsöffnung 7 hin als Schneidkante 3 ausgebildet. Wird der rotierende Schneidkopf 1 in den Knochen gebohrt, so werden durch die Schneidkanten 3 Knochenspäne abgetragen und gelangen durch die Durchgangsöffnung 7 in den Hohlraum 9 des Schneidkopfes 1 und werden von dort durch die Bohrung 10 im Schaft 8 durch das Vakuum abgesaugt.

In Fig. 3 ist das Werkzeug 16 mit Schneidkopf 1 und Schaft 8 dargestellt. Der Schaft 8 umfasst einen bezüglich Torsion und/oder Biegung elastisch verformbaren Teil 22 und einen mit Mitteln 13 zur Aufnahme eines Drehmomentes versehenen, vom Schneidkopf 1 entfernten Teil 11. Die Mittel 13 bestehen aus einem Abschnitt 25 mit Aussensechskant und einem daran anschliessenden zylindrischen Abschnitt 27 mit einer Nute 26. Die beiden Abschnitte 25 und 27 lassen sich in entsprechende Einspannmittel 15 (Fig. 1) an einem Antriebsmittel 14 (Fig. 1) einspannen, wobei der Schaft 8 mittels der Nute 26 axial und durch den Aussensechskant rotativ im Einspannmittel 15 (Fig. 1) lösbar fixierbar ist. Die Bohrung 10 im hohlzylindrischen Schaft 8 durchdringt den Schaft 8 in Richtung der Längsachse 2 vom Schneidkopf 1 bis zu dem vom Schneidkopf 1 entfernten Ende 21 des Schaftes 8, so dass die vom Schneidkopf 1 abgetragenen Knochenspäne entlang der Längsachse 2 durch das ganze Werkzeug 16 förderbar sind. Zur Fixation des Schneidkopfes 1 am Schaft 8 sind Feststellschrauben oder beispielsweise auch Federstifte zwischen Schaft 8 und Schneidkopf 1 denkbar. Der elastisch verformbare Teil 22 des Schaftes 8 ist aus einem spiralförmig gewickelten Metallstreifen gefertigt, wobei in der Bohrung 10 ein Gummi- oder Kunststoffschlauch 36 (Fig. 4) eingelegt ist, welcher gegenüber der Umgebung einen luftdichten Abschluss in der Bohrung im Schlauch 36 gewährleistet. Gegen das vom Schneidkopf 1 entfernte Ende 21 des Schaftes 8 ist dieser anschliessend an

die Mittel 11 zur Aufnahme eines Drehmomentes wieder als hohlzylindrischer Teil 28 ausgebildet, so dass eine ebenfalls gegenüber der Umgebung luftdichter Abschluss dieses Teils 28 bei der Einmündung in den Behälter 17 (Fig. 1) möglich ist.

In Fig. 4 ist eine weitere bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung dargestellt. Diese hier dargestellte Ausführungsform der erfindungsgemässen Vorrichtung unterscheidet sich von der in Fig. 1 dargestellten Ausführungsform nur darin, dass das Schneidwerkzeug 16 durch den koaxial zur Längsachse 2 angeordneten Behälter 17 durchgeht und die Mittel 13 zur Aufnahme eines durch die Universalbohrmaschine 30 abgegebenen Drehmomentes im Bereich des vom Schneidkopf 1 entfernten Behälterbodens 33 mit der Universalbohrmaschine 30 lösbar verbunden sind. Der Behälter 17 ist mit seinem Behälterboden 33 an der Universalbohrmaschine 30 lösbar befestigt. Anstelle eines Behälterdeckels ist ein Lagergehäuse 34 im Behälter 17 angebracht, worin das Werkzeug 16 bezüglich seiner Rotationsbewegung um die Längsachse 2 beispielsweise mittels Kugellager 35 gelagert ist. Auch bei dieser Ausführungsform lässt sich ein luftdichter Abschluss des Schneidwerkzeuges 16 im Lagergehäuse 34 gegenüber der Umgebung durch durch Einfügen einer Dichtung, beispielsweise einer O-Ringdichtung 40 zwischen Schneidwerkzeug 16 und Lagergehäuse 34 erreichen. Zudem ist der Stutzen 18 für den Anschluss eines Vakuumschlauches an der Seitenwand des Behälters 17 angebracht. Zur Abdichtung des flexiblen Schaftes 8 ist in dessen Bohrung 10 ein Gummi- oder Kunststoffschlauch 36 entlang der Längsachse 2 eingeführt. Die vom Schneidkopf 1 abgetragenen Knochenspäne werden durch das Vakuum durch die das Werkzeug 16 koaxial zur Längsachse 2 durchdringende Bohrung 10 bis zu dem vom Schneidkopf 1 entfernten Ende 21 des Werkzeuges 16 gefördert und dort durch Öffnungen 38 in den Einspannmitteln 15 in den Behälter 17 gesaugt. Damit die Knochenspäne nicht durch den Stutzen 18 mit in den Vakuumschlauch (nicht gezeichnet) gerissen werden, ist im Behälter 17 eine Abscheidevorrichtung 19, welche bevorzugt als Sieb ausgestaltet ist, angebracht.

Claims

Patentansprüche

1. Vorrichtung zur Gewinnung von Knochenspänen, welche
A) ein rotierbares, hohlzylindrisches Schneidwerkzeug (16) mit einer Längsachse (2), einem Schneidkopf (1) und einem an den Schneidkopf (1) anschliessenden, konzentrisch zur Längsachse (2) angeordneten longitudinalen Schaft (8);
B) Antriebsmittel (14), welche mit einem Handgriff (37) versehen sind und mittels welcher dem Schneidwerkzeug (16) mit dem Schneidkopf (1) eine Rotationsbewegung um die Längsachse (2) aufprägbar ist; und
C) einen unter Vakuum stehenden, mit dem Schaft (8) verbindbaren Behälter (17) mit einer Zentralachse (39) umfasst; wobei
D) das Schneidwerkzeug (16) eine in Richtung der Längsachse (2) durchgehende Bohrung (10) aufweist und der Schneidkopf (1) mit mindestens einer Durchgangsöffnung (7) versehen ist, so dass die vom Schneidkopf (1) spanabhebend abgetragenen Knochenspäne durch die Bohrung (10) förderbar sind; und
E) auch während der spanabhebenden Gewinnung von Knochenspänen die Knochenspäne mittels des Vakuums im Behälter (17) durch die Bohrung (10) vom Schneidkopf (1) in den Behälter (17) förderbar sind,
dadurch gekennzeichnet, dass
F) Schneidwerkzeug (16), Behälter (17) und Antriebsmittel (14) zu einer mittels des Handgriffes (37) manuell frei bewegbaren Vorrichtung verbunden sind.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das vom Schneidkopf (1) entfernte Ende (21) des Schneidwerkzeuges (16) in den Behälter (17) mündet.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, dass der Behälter (17) am Antriebsmittel (14) lösbar angebracht ist.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der Behälter (17) so am Antriebsmittel (14) lösbar angebracht ist, dass die Zentralachse (39) konzentrisch zur Längsachse (2) verläuft.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass der Behälter (17) relativ zur Längsachse (2) stillsteht und das vom Schneidkopf

(1) entfernte Ende (21) des rotierenden hohlzylindrischen Schneidwerkzeuges (16) in den Behälter (17) mündet.

6. Vorrichtung nach einem der Ansprüche 2 bis 5, dadurch gekennzeichnet, dass das vom Schneidkopf (1) entfernte Ende (21) des rotierenden hohlzylindrischen Schneidwerkzeuges (16) so in den Behälter (17) mündet, dass der Übergang zwischen Schneidwerkzeug (16) und Behälter (17) gegenüber der Umgebung luftdicht abgeschlossen ist.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass das vom das vom Schneidkopf (1) entfernte Ende (21) des rotierenden hohlzylindrischen Schneidwerkzeuges (16) im wesentlichen spielfrei in den Behälter (17) mündet.

8. Vorrichung nach Anspruch 6, dadurch gekennzeichnet, dass das vom Schneidkopf (1) entfernte Ende (21) des rotierenden hohlzylindrischen Schneidwerkzeuges (16) eine Dichtung umfasst und der Behälter (17) eine Behälteröffnung umfasst, so dass die Dichtung den ringförmigen Spalt zwischen dem Ende (21) des Schneidwerkzeuges (16) und der Behälteröffnung abdichtet und damit der Übergang zwischen Schneidwerkzeug (16) und Behälter (17) gegenüber der Umgebung luftdicht abgeschlossen ist.

9. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass der Behälter (17) ein Lagergehäuse (34) umfasst, worin das Schneidwerkzeug (16) konzentrisch zur Längsachse (2) und um diese rotierbar gelagert ist.

10. Vorrichtung nach Anspruch 9, dadurch gekennzeichnet, dass das Lagergehäuse (34) ein Kugellager (35) umfasst, worin das Schneidwerkzeug (16) konzentrisch zur Längsachse (2) und um diese rotierbar gelagert ist.

11. Vorrichtung nach Anspruch 9 oder 10, dadurch gekennzeichnet, dass das Lagergehäuse (34) eine Dichtung umfasst, wodurch die Lagerung des Schneidwerkzeuges (16) im Lagergehäuse (34) gegenüber der Umgebung luftdicht abgeschlossen ist.

12. Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, dass die Dichtung eine O-Ringdichtung (40) ist.

13. Vorrichtung nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass am Behälter (17) ein Stutzen (18) für den Anschluss eines Vakuumschlauches angebracht ist.

14. Vorrichtung nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, dass der Behälter (17) eine Abscheidevorrichtung (19) zur Abscheidung der Knochenspäne aus dem Luftstrom umfasst.

15. Vorrichtung nach Anspruch 14, dadurch gekennzeichnet, dass die Abscheidevorrichtung (19) aus einem Filter besteht.

16. Vorrichtung nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass der Schaft (8) auf einem an den Schneidkopf (1) anschliessenden Teil (22) bezüglich Torsion und/oder Biegung elastisch ist.

17. Vorrichtung nach Anspruch 16, dadurch gekennzeichnet, dass der Schaft (8) aus einem spiralförmig gewickelten Metallband gefertigt ist.

18. Vorrichtung nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, dass in der Bohrung (10) des Schaftes (8) entlang der Längsachse (2) zusätzlich ein Kunststoff- oder Gummischlauch eingeführt ist.

19. Vorrichtung nach Anspruch 16 oder 18, dadurch gekennzeichnet, dass der Schaft (8) aus einem Metallrohr mit balgartiger Wand besteht.

20. Vorrichtung nach einem der Ansprüche 1 bis 19, dadurch gekennzeichnet, dass der Schneidkopf (1) hohlzylindrisch gestaltet ist und einen sich entlang der Längsachse (2) erstreckenden Hohlraum (9), einen mit einer Bohrspitze (20) und mit mindestens einer Schneidkante (3) versehenen vorderen Abschnitt (4), einen hohlzylindrischen hinteren Abschnitt (5) und mindestens eine im vorderen Abschnitt (4) die Aussenwand (29) des Schneidkopfes (1) radial

durchdringende Durchgangsöffnung (7) zur Förderung der durch die mindestens eine Schneidkante (3) abgetragenen Knochenspäne in den Hohlraum (9) des Schneidkopfes (1) umfasst.

21. Vorrichtung nach Anspruch 20, dadurch gekennzeichnet, dass die Bohrspitze (20) des Schneidkopfes (1) als Kugelkalottensektor ausgebildet ist.

22. Vorrichtung nach Anspruch 20, dadurch gekennzeichnet, dass die Bohrspitze (20) des Schneidkopfes (1) kugelkalottenförmig mit mindestens zwei koaxial und radial zur Längsachse (2) sich in den Hohlraum (9) erstreckenden Durchgangsöffnungen (7) ausgebildet ist, wobei an den Kanten der Durchgangsöffnungen (7) Schneidkanten (3) zum Abtragen von Knochenspänen angebracht sind und die abgetragenen Knochenspäne durch die Durchgangsöffnungen (7) in den Hohlraum (9) des Schneidkopfes (1) förderbar sind.

23. Vorrichtung nach einem der Ansprüche 1 bis 22, dadurch gekennzeichnet, dass die Antriebsmittel (14) aus einer Universalbohrmaschine (30) bestehen.

24. Vorrichtung nach einem der Ansprüche 1 bis 23, dadurch gekennzeichnet, dass der Schaft (8) durchgehend hohlzylindrisch ausgeführt ist, Mittel (13) zur Aufnahme eines Drehmomentes, welches eine Rotation des Schaftes (8) um die Längsachse (2) verursacht, aufweist und an seinem am Schneidkopf (1) anschliessbaren Ende (12) so an den hinteren Abschnitt (5) anschliessbar ist, dass die Bohrung (10) des hohlzylindrischen Schaftes (8) mit dem Hohlraum (9) fluchtend ausrichtbar ist und vom Schaft (8) das Drehmoment auf den Schneidkopf (1) übertragbar ist.

25. Vorrichtung nach Anspruch 24, dadurch gekennzeichnet, dass die Antriebsmittel (14) Einspannmittel (15) zur rotativen und axialen Fixierung der Mittel (13) am Schaft (8) umfassen.

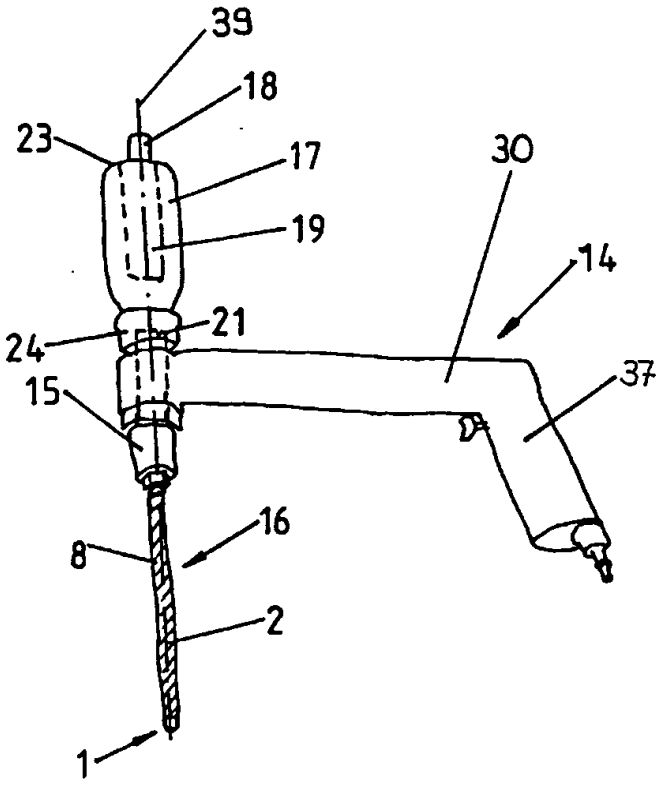

Fig. 1

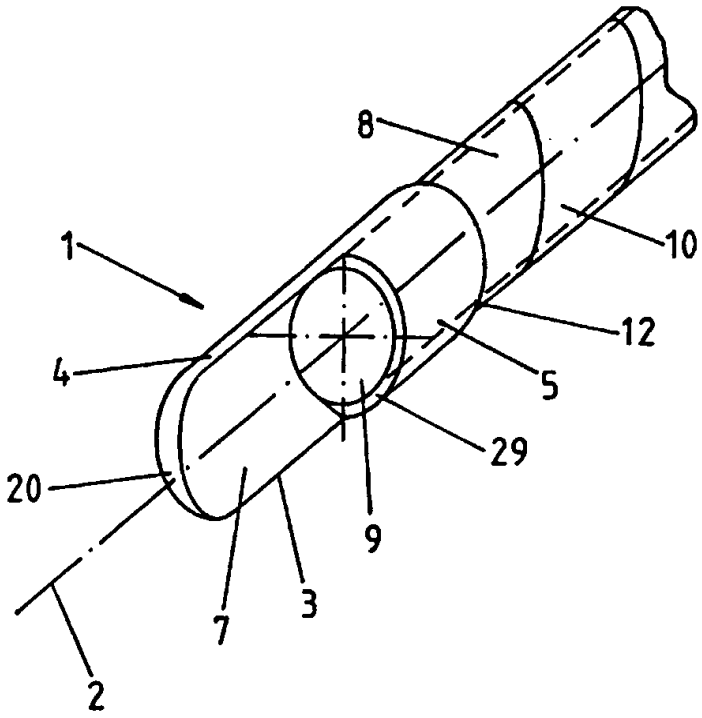

Fig. 2

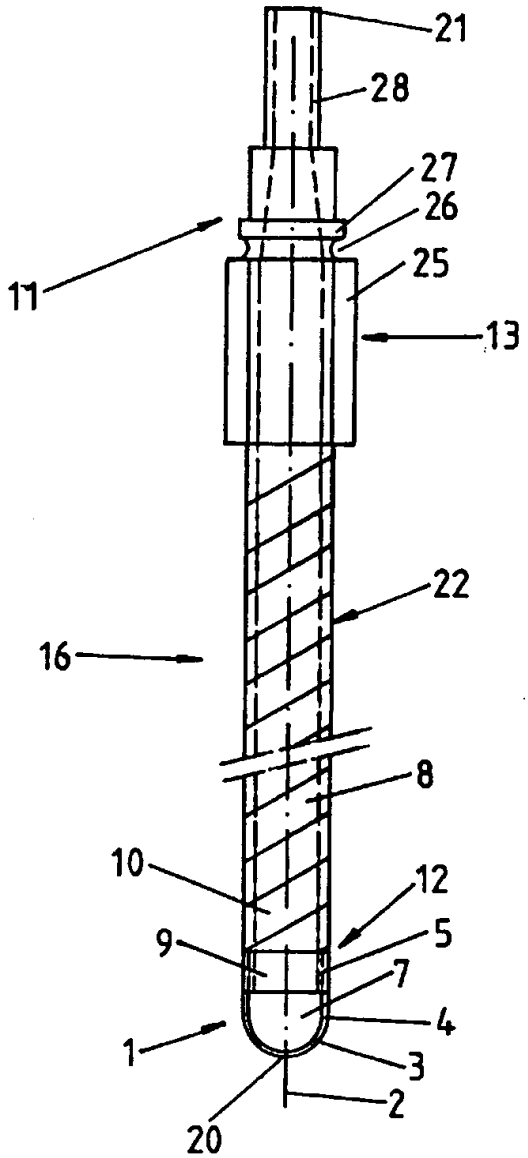

Fig. 3

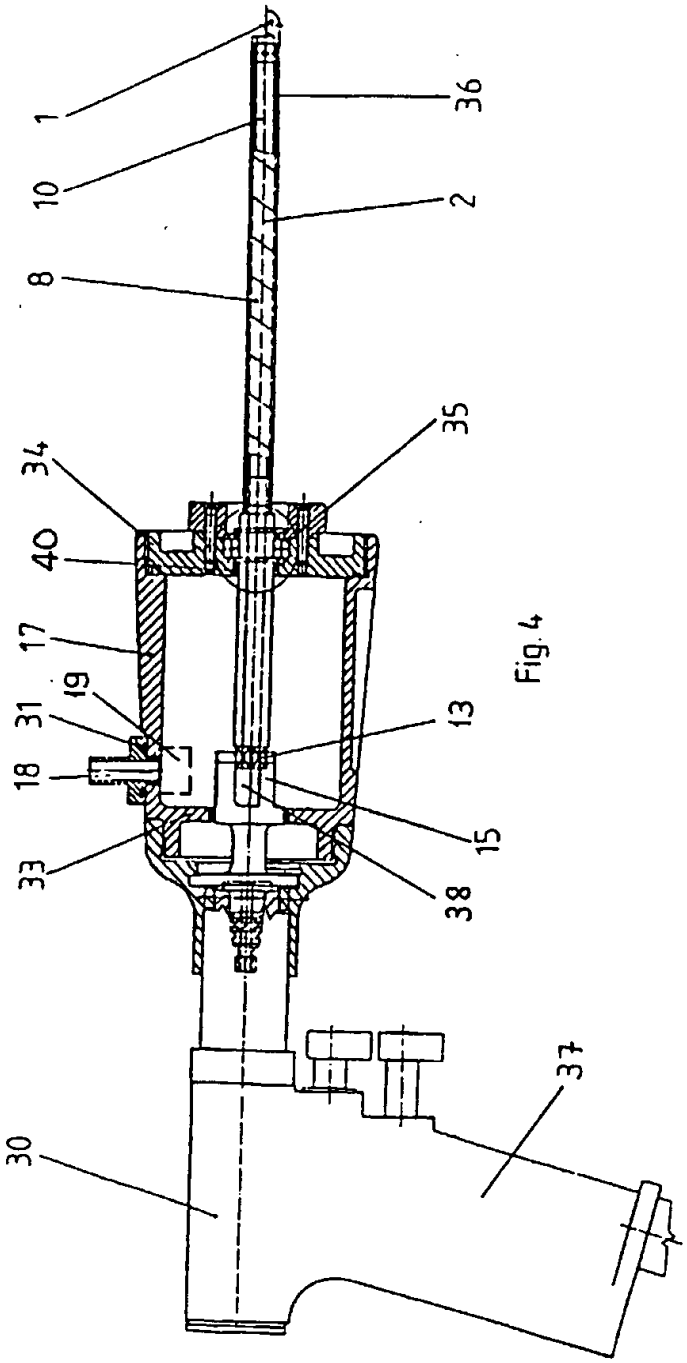

Fig. 4

INTERNATIONAL SEARCH REPORT

Interna l Application No
PCT/CH 00/00046

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/16

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 403 317 A (P.M.BONUTTI) 4 April 1995 (1995-04-04) cited in the application abstract; figures 1,3,12 column 3, line 6 - line 8 column 5, line 38 - line 62	1,13-16, 19,20, 23-25
Y	US 5 569 284 A (W.P.YOUNG ET AL.) 29 October 1996 (1996-10-29) abstract; figures 1,7,9 column 5, line 59 -column 6, line 12	1,13-16, 19,20, 23-25
A	WO 97 16118 A (BIOMEDICAL ENTERPRISES) 9 May 1997 (1997-05-09) abstract; figure 3B	2,4,5,7, 9

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
19 April 2000	02/05/2000

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	Nice, P

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INTERNATIONAL SEARCH REPORT

Internat l Application No
PCT/CH 00/00046

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 4 646 738 A (A.F.TROTT) 3 March 1987 (1987-03-03) column 7, line 21 -column 8, line 2 column 8, line 36 - line 58; figures 3,9	16,17, 20,24
A	WO 96 39956 A (AUST & TAYLOR MEDICAL) 19 December 1996 (1996-12-19) abstract page 7, line 1 - line 11 page 14, line 3 - line 6 page 20, line 12 - line 17	16-18
A	WO 97 38635 A (DISK WHISK) 23 October 1997 (1997-10-23) page 4, line 5 - line 13 page 6, line 5 - line 16 page 7, line 26 - line 30 figures 3,18	21,22
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A	US 5 556 399 A (R.J.HUEBNER) 17 September 1996 (1996-09-17) abstract; figure 1	20-23

2

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No
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INTERNATIONALER RECHERCHENBERICHT

Internat. Ite Aktenzeichen
PCT/CH 00/00046

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61B17/16

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61B

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	US 5 403 317 A (P.M.BONUTTI) 4. April 1995 (1995-04-04) in der Anmeldung erwähnt Zusammenfassung; Abbildungen 1,3,12 Spalte 3, Zeile 6 - Zeile 8 Spalte 5, Zeile 38 - Zeile 62	1,13-16, 19,20, 23-25
Y	US 5 569 284 A (W.P.YOUNG ET AL.) 29. Oktober 1996 (1996-10-29) Zusammenfassung; Abbildungen 1,7,9 Spalte 5, Zeile 59 -Spalte 6, Zeile 12	1,13-16, 19,20, 23-25
A	WO 97 16118 A (BIOMEDICAL ENTERPRISES) 9. Mai 1997 (1997-05-09) Zusammenfassung; Abbildung 3B	2,4,5,7, 9

-/—

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der Internationalen Recherche	Absendedatum des Internationalen Recherchenberichts
19. April 2000	02/05/2000

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, P

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Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

INTERNATIONALER RECHERCHENBERICHT

Internat. Ite Aktenzeichen
PCT/CH 00/00046

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 4 646 738 A (A.F.TROTT) 3. März 1987 (1987-03-03) Spalte 7, Zeile 21 -Spalte 8, Zeile 2 Spalte 8, Zeile 36 - Zeile 58; Abbildungen 3,9	16,17, 20,24
A	WO 96 39956 A (AUST & TAYLOR MEDICAL) 19. Dezember 1996 (1996-12-19) Zusammenfassung Seite 7, Zeile 1 - Zeile 11 Seite 14, Zeile 3 - Zeile 6 Seite 20, Zeile 12 - Zeile 17	16-18
A	WO 97 38635 A (DISK WHISK) 23. Oktober 1997 (1997-10-23) Seite 4, Zeile 5 - Zeile 13 Seite 6, Zeile 5 - Zeile 16 Seite 7, Zeile 26 - Zeile 30 Abbildungen 3,18	21,22
A	WO 97 39685 A (SPINETECH) 30. Oktober 1997 (1997-10-30) Zusammenfassung; Abbildungen 1,2	20-22
A	US 5 556 399 A (R.J.HUEBNER) 17. September 1996 (1996-09-17) Zusammenfassung; Abbildung 1	20-23

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Seite 2 von 2

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internat es Aktenzeichen
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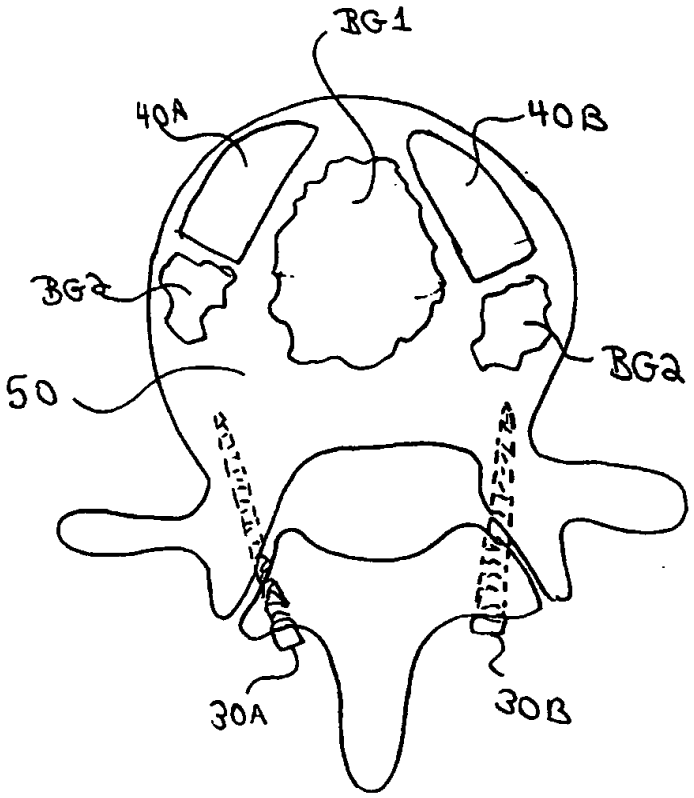
(54) Title: FACET SCREW AND BONE ALLOGRAFT INTERVERTEBRAL SUPPORT AND FUSION SYSTEM



(57) Abstract: An intervertebral support assembly, comprising a pair of bone allografts (40A and 40B) positioned between two adjacent vertebrae, the bone allografts being positioned towards the anterior portion of the adjacent vertebrae; and a pair of facet screws (30A and 30B), each facet screw securing together a facet joint between the two adjacent vertebrae. A method of providing support between two adjacent vertebrae, comprising positioning a pair of bone allografts (40A and 40B) between the two adjacent vertebrae at a location towards the front of the adjacent vertebrae; and securing together facet joints between the two adjacent vertebrae with a pair of facet screws (30A and 30B).

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FACET SCREW & BONE ALLOGRAFT INTERVERTEBRAL SUPPORT AND FUSION SYSTEM

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of, and claims the benefit of priority from U.S. application no. 60/172,849, filed on 12/10/99, the full disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

The present invention relates to intervertebral support systems, and to systems for promoting intervertebral bone fusion.

BACKGROUND OF THE INVENTION

A variety of support assemblies currently exist which may be surgically implanted into a patient's intervertebral space so as to provide support between two (or more) adjacent vertebrae. Surgical implantation of such systems is typically used to provide support along the spinal column in cases where a portion of the patient's intervertebral anatomy has become diseased or destroyed. In addition, such support systems are also commonly used following a diskectomy, wherein the patient's intervertebral disk is surgically removed.

A drawback of these existing support systems is that they tend to be somewhat large and bulky, especially when these systems operate to provide support across a large portion of the patient's vertebral region. Being large and bulky, surgical implantation of these systems into a patient's vertebral region often creates a substantial amount of trauma to the patient.

Moreover, the installment of such large, bulky support systems into a patient's intervertebral space typically also requires a large amount of tissue to first be removed from the patient's intervertebral space so as to make way for the device.

Most commonly, existing support systems typically operate by inhibiting (normal) movement between the adjacent vertebrae, thereby holding these vertebrae at fixed positions relative to one another, with the mechanical body of the supporting structure providing the needed support along the patient's spinal column. Such supporting systems are typically made of stainless steel or titanium, and are designed to permanently remain within the patient's body.

SUMMARY OF THE INVENTION

The present invention provides a novel system of intervertebral support using a pair of bone allografts and a pair of facet screws.

An advantage of the present system is that, by inhibiting motion between two adjacent vertebrae, it facilitates natural bone fusion between these vertebrae. An advantage of the present invention's use of bone allografts (positioned between the vertebrae) is that these allografts will eventually be resorbed into the patient's body as bone growth between the immobilized vertebrae progresses. In contrast, existing mechanical (e.g.: metallic) intervertebral support structures simply remain as large permanent foreign structures within the patient's body. In preferred aspects, motion between the two adjacent vertebrae is specifically inhibited by the facet screws, as will be explained.

The present system advantageously provides intervertebral support at three locations in particular, with these three locations together forming a triangle. Specifically, each of the facet screws provides support at the facet joints (which are disposed at two symmetrically spaced apart locations at the posterior or rear of the vertebral column). The bone allografts are preferably positioned to provide support at an anterior (i.e. front), central location in the vertebral column. An advantage of the present three point (i.e.: triangular) support system is that support is provided in three perpendicular directions, (thereby providing support with respect to forward-backward bending, side-to-side bending and torsion of the spine). Furthermore, the present three point (i.e.: triangular) support system provides support at three separate locations which are spaced apart over a relatively large section of the patient's spinal column, providing enhanced stability. Specifically, the three sides of the present support triangle correspond to the locations of the two facet joints and the inter vertebral disc.

An important advantage of the present system is that it can be assembled in a minimally invasive percutaneous (preferably cannulated) surgical approach. In contrast, existing systems which provide support across a wide area of the patient's vertebrae typically comprise a single large integrated structure which substantially fills the patient's intervertebral space, and which is typically installed during a major invasive open surgical procedure. A further advantage of the present assembly is that since it comprises four separate components, (two bone allografts and two facet screws), these four components can be installed sequentially, with each of the components being installed through a cannula. In

contrast, existing intervertebral support systems typically comprise a single large assembly which cannot be installed through a cannula.

In preferred aspects, the two bone allografts are positioned at an angle to one another. An advantage of having the bone allografts disposed angled to one another is that they provide support in perpendicular directions (i.e.: along two axes which are angled to one another). Specifically, in a preferred case using long, narrow shaped bone allografts, the bone allografts are preferably positioned with their long central longitudinal axes disposed at an angle to one another.

Since the present pair of bone allografts are positioned at an angle to one another, tall, narrow bone allografts can be used. Advantages of using a tall, narrow bone allograft include its fabrication requiring less bone material than would be used in conventionally manufactured allografts (which tend to be both flatter and wider, or large in diameter and length, e.g.: cylindrical). In addition, the present narrow bone allografts are more easily inserted into the patient through a (narrower) cannulated passageway.

In preferred aspects, two cannulae are used for positioning the pair of bone allografts, with the cannulae positioned at opposite posterolateral angles to one another. One cannula is used to position the first bone allograft and one cannula is used to position the second bone allograft. In this aspect, the angle between the bone allografts preferably corresponds to the angle between the cannulae. Accordingly, each of the bone allografts can be inserted directly into the patient's intervertebral space in a relatively straight path through the cannula(e) and into the patient's intervertebral space. As such, the present pair of bone allografts are easily positioned at a preferred angle to one another when initially deployed in a percutaneous posterolateral approach procedure. Moreover, in preferred aspects, the bone allografts can be inserted into the intervertebral space and then rotated by approximately 90° to achieve vertebral distraction, tensioning the annulus and opening the foramen, thereby decompressing the nerve root.

As stated above, in a preferred aspect of the present invention, both the bone allografts and the facet screws are positioned in the patient's spinal region through a posterolateral minimally invasive approach, which may optionally include a cannulated approach.

Prior to installing the present bone allografts and facet screws, a portion (or all) of the patient's intervertebral disk may be removed (i.e.: a "diskectomy" may be performed). Thereafter, the opposite vertebral endplates of the adjacent vertebrae may

optionally be decorticated, which may produce a natural healing (bone fusion) response, if desired.

Thereafter, and in accordance with the present invention, the pair of bone allografts are positioned in the patient's intervertebral space. Preferably the bone allografts are inserted through posterolaterally introduced cannulae. In preferred aspects, two cannulae are used, with one positioning each bone allograft; however, the use of a single cannula to place the two bone allografts one after another (in opposite posterolateral approaches) is also contemplated. Additionally, the two bone allografts could be placed through one cannula positioned from only one posterolateral direction. Advantageously, each of the pair of bone allografts can be positioned (i.e.: inserted into the intervertebral space) through a separate cannula with the posterolateral angle at which the cannulae are disposed corresponding to the angle between the bone allografts.

Preferably, after the bone allografts have been positioned between the adjacent vertebrae, the bone allografts will support the vertebrae, causing the vertebrae to move into a natural lordotic angle limiting facet joint movement such that it becomes easier to insert the facet screws.

The present facet screws are used to secure a patient's facet joints together, thus preventing relative movement therebetween. An advantage of using facet screws is that they provide stabilization to the spine, but are not as surgically time consuming to install as, for example, pedicle screws. Another advantage of the present system is that, by immobilizing adjacent facet joints, it provides stability for vertebral arthrodesis between the adjacent vertebrae.

In accordance with the present invention, therefore, a system is provided to position a facet screw to secure a patient's opposite adjacent first and second facet joints together, and to promote fusion therebetween. Each of the facet screws may preferably be positioned such that it passes through, and locks together, the superior articular process of one vertebrae with the inferior articular process of an adjacent vertebrae. Preferably, the threads of the facet screw extend all the way into the pedicle, thus providing increased anchoring strength. This embodiment is called the transfacet approach. Other approaches for facet screw placement are also contemplated (i.e. the translaminar approach) within the scope of the present invention.

Accordingly, each of the facet screws provides support at an opposite posterior (rear) side of the patient's vertebral column. Together with the bone allografts, which

provide support at the anterior (front center) of the vertebral column, the present system of two bone allografts and two facet screws, provides a "triangular" support structure.

In an optional preferred aspect of the invention, autologous bone graft material is harvested from the patient and is delivered percutaneously into the patient at a location adjacent to the bone allografts. Specifically, the autologous bone graft material may be positioned both behind the allografts (i.e.: within the V-shape formed by the two allografts) and to the rear of the bone allografts (i.e.: behind the allografts in their posterolateral direction of approach). In preferred aspects, the autologous bone graft material may be harvested from the patient's iliac crest. Such harvesting of bone graft material directly from the patient's iliac crest is especially advantageous when the minimally invasive approach used passes through the patient's iliac crest, with bone material being removed from the iliac crest to provide cannulated access to the patient's intervertebral space.

In preferred aspects, the present bone allografts are dimensioned with a height of 0.20 to 0.75 inches, a width of 0.20 to 0.75 inches, and a length of 0.60 to 1.20 inches. In one particular preferred aspect, the present bone allografts are dimensioned with a height of about 0.40 inches, a width of about 0.25 inches, and a length of about 0.80 inches.

In preferred aspects, the height to width ratio of the allografts is about 1.2 to 2.0. In more preferred aspects, the height to width ratio of the allografts is about 1.4 to 1.8. In more preferred aspects, the height to width ratio of the allografts is about 1.6.

In preferred aspects, the bone allografts are positioned between adjacent vertebrae by an inserter. Optionally, a two pronged inserter may be used with each of the bone allografts held between the prongs of the inserter. In preferred aspects, the bone allografts may be formed with lateral gooves in which the prongs of the inserter are received.

In optional preferred aspects, the bone allografts may be formed with a curved front edge such that they can be positioned near the outer (front) perimeter of the intervertebral space, thereby advantageously resting on the hard cortical bone at the perimeter of the vertebrae. Most preferably, each of the bone allografts are formed such that their curved front end is the hardest portion of the bone allograft, thereby providing greatest support around the curved front end of the allograft.

In optional aspects, the positioning of the bone allografts may also involve distraction of the vertebrae, which may be performed by the inserter itself, by the shape of the bone allograft itself, or by additional tools (which may also be received through the cannula(e).

In accordance with the present invention, the two facet screws are also positioned in a percutaneous posterolateral approach (which may optionally be cannulated).

In preferred aspects, the cannulae (through which both the bone allografts and the facet screws are advanced) are positioned with the assistance of a surgical guideframe.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top view of the present support system showing first and second facet joints held together by facet screws, and showing placement of first and second bone allografts.

Fig. 2 is a side view of the present support system, as positioned between two adjacent vertebrae.

Fig. 3 is an illustration of placement of a pair of bone allografts with the assistance of a polar coordinate surgical guideframe.

Fig. 4 is an illustration of placement of a pair of facet screws with the assistance of a rectangular coordinate surgical guideframe.

Fig. 5 is a front perspective view of one of the bone allografts.

Fig. 6 is a top plan view of a bone allograft and an inserter.

Fig. 7 is a rear view of a bone allograft.

Fig. 8 corresponds to Fig. 1, but shows the additional placement of autologous bone graft material in the patient's intervertebral space.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention comprises an intervertebral support system and a method of installing an intervertebral support system.

In preferred aspects, the present invention comprises an intervertebral support assembly, comprising, a pair of bone allografts positioned between two adjacent vertebrae, with the bone allografts being positioned towards the front of the adjacent vertebrae; and a pair of facet screws, each facet screw securing together a facet joint between the two adjacent vertebrae.

Referring to Figs. 1 and 2, the present invention is shown as follows. A pair of bone allografts 40A and 40B are provided. Bone allografts 40A and 40B are preferably positioned between adjacent vertebrae 50 and 52. Most preferably, bone allografts 40A and 40B are positioned at an anterior location (i.e.: towards the front of adjacent vertebrae 50 and

52). In addition, bone allografts 40A and 40B are preferably positioned near the curved outer perimeter (front, and or sides) of the intervertebral space, as shown.

As can be seen in Fig. 1, bone allografts 40A and 40B may preferably be positioned at an angle ALPHA to one another. In preferred aspects, angle ALPHA is approximately 30° to 160°. Most preferably, angle ALPHA is approximately 90° to 120°.

As can be seen in Figs. 1 and 2, each bone allograft 40A / 40B has a length L, a width W and a height H, as shown. By positioning bone allografts 40A and 40B at angle ALPHA to one another, support is provided both in an anterior-posterior (i.e.: front-to-back) and in a lateral (i.e.: side-to-side) direction. The angling of bone allografts 40A and 40B to one another is especially advantageous when providing support when bone allografts 40A / 40B are dimensioned to be narrow (i.e.: have a small W value), and also when they are tall and narrow (i.e.: have a large H value as well).

In preferred aspects, bone allografts 40A and 40B have a preferred length L from 0.60 to 1.20 inches, a preferred width W from 0.20 to 0.75 inches, and a preferred height H from 0.20 to 0.75 inches.

In an optional aspect, shown in Fig. 8, autologous bone graft material BG is positioned between and to the rear of bone allografts 40A and 40B (i.e.: BG1) and is also positioned behind (in a posterolateral approach) each of bone allografts 40A and 40B (i.e.: BG2). The positioning of autologous bone graft material BG offers the advantage of promoting intervertebral bone fusion.

In optional preferred aspects, bone allografts 40A and 40B may comprise bone block systems as set forth in copending U.S. Regular Patent application, 09/ 320,081, filed May 26, 1999, and Provisional Patent application, 60/120,663, filed Feb. 19, 1999, and incorporated herein by reference in their entirety for all purposes. For example, placement of bone allografts 40A and 40B may be accomplished using any of the inserters, or insertion techniques as set forth in these applications.

Moreover, bone allografts 40A and 40B may be stored in saline prior to use in accordance with the systems set forth in copending U.S. Regular Patent application, 09/687,611, filed Oct. 11, 2000, and Provisional Patent application, 60/226,660, filed August 21, 2000, and incorporated herein by reference in their entirety for all purposes.

As can also be seen, facet screws 30A and 30B are used to secure together first facet joints (10A and 10B) and second facet joints (20A and 20B). As illustrated, facet screws 30 are positioned in a transfacet manner disposed in a posterior approach with respect to the patient, however, other approaches such as a translaminar approach are also

contemplated within the scope of the present invention. In the present transfacet approach of Fig. 1, first facet joint 10 preferably comprises a patient's inferior articular process and second facet joint 20 comprises a patient's superior articular process. When tightened into position, facet screws 30A and 30B will immobilize first facet joint 10 and second facet joint 20 together.

Facet screws 30A and 30B can be any form of commercially available facet screws but may also include facet screws positioned in accordance with the novel system set forth in copending U.S. Regular Patent application 09/549,807, filed Apr. 14, 2000, and incorporated herein by reference, in which a system for ablating the opposing faces of the facet joints (so as to induce bone growth therebetween) is also set forth.

The present system also sets forth a preferred method of installing the present assembly. In a preferred aspect, the present invention comprises a method of providing support between two adjacent vertebrae 50 and 52, comprising positioning a pair of bone allografts 40A and 40B between the two adjacent vertebrae 50 and 52 at a location towards the front of the adjacent vertebrae; and securing together facet joints 10A and 10B between the two adjacent vertebrae 50 and 52 with a pair of facet screws 30A and 30B.

In preferred aspects, placement of each of bone allografts 40A and 40B and facet screws 30A and 30B is accomplished in a cannulated approach, as follows.

Referring to Fig. 3, placement of bone allografts 40A and 40B with a polar coordinate surgical guideframe is seen. An example of such a polar coordinate surgical guideframe 60 is set forth in copending U.S. Provisional Patent application 60/213,730, filed June 22, 2000, and incorporated herein by reference in its entirety. In this aspect of the invention, cannulae 62 and 64 are positioned at posterolateral angles to patient P, as shown. Preferably, each of cannulae 62 and 64 is moved along curved member 65 in curved direction D1 to a position such that cannulae 62 and 64 are positioned at (or near) angle ALPHA to one another. Therefore, when bone allografts 40A and 40B are advanced in a straight path through respective cannulae 62 and 64, bone allografts 40A and 40B will be positioned at preferred angle ALPHA to one another.

In optional preferred aspects, the positioning of autologous bone graft material BG between and to the rear of bone allografts 40A and 40B (i.e.: BG1) and / or positioned behind (in a posterolateral approach) each of bone allografts 40A and 40B (i.e.: BG2) is carried out be passing bone graft material BG through cannulae 60 and 62 after bone allografts 40A and 40B have been positioned.

As shown in Figs. 5, bone allograft 40 preferably has a curved front end 41 such that, when positioned between vertebrae 50 and 52, it can be positioned close, very close or adjacent to, the curved outer perimeter of the vertebrae, as shown in Fig. 1. Bone allograft 40 may optionally have lateral (i.e.: side) grooves 42 extending therealong. As shown in Fig. 6 and 7, grooves 42 may be used for holding bone allograft 40 between the prongs of a two prong inserter 45 which may be used to advance bone allograft 40 into position. In optional preferred aspects, advance bone allograft 40 is advanced into the patient's intervertebral space on its side (with dimension H being parallel to vertebrae 50 and 52). Thereafter, inserter 45 may be rotated by about 90° such that bone blocks 40 are positioned as shown in Fig. 1. An advantage of this is that bone allografts 40A and 40B may each be inserted prior to full distraction (with tall, narrow bone allografts 40A and 40B initially inserted on their sides, thereby fitting easier into the patient's intervertebral space prior to distraction of the vertebrae. In optional preferred aspects, the actual rotation of allografts 40A and 40B assists in distraction of the vertebrae 50 and 52 as the tall, narrow allografts are stood upright.

Placement of facet screws 30A and 30B may then be carried out after placement of bone allografts 40A and 40B. (The present invention, however, is not so limited, i.e.: the facet screws may be positioned prior to positioning the bone allografts). Most preferably, the placement of facet screws 30A and 30B is carried out using the same guideframe as was used to position the bone allografts. For illustration purposes, however, Fig. 4 shows the positioning of facet screws 30A and 30B accomplished with a rectangular coordinate surgical guideframe 70. An example of such a rectangular coordinate surgical guideframe is set forth in copending U.S. Patent Application 09/326,739, filed June 4, 1999, and U.S. Provisional Patent Applications 60/120,663, filed Feb. 19, 1999 and 60/129,702, filed Apr. 16, 1999, all incorporated herein by reference in their entirety. Cannula 70 is preferably positionable back and forth along cross member 74, and is rotatable in direction R. In a preferred aspect, as illustrated, cannula 72 is angled to facilitate the positioning of one of facet screws 30 therethrough in a transfacet approach.

In optional aspects, the positioning of cannulae 60 and 62 (or 72) can be accomplished in accordance with the novel image intensifier (C-arm reticle) systems as set forth in copending U.S. Patent Applications 09/326,740, filed June 4, 1999, and 09/696,923, filed Oct. 25, 2000, and U.S. Provisional Patent Application 60/120,663, filed Feb. 19, 1999, all incorporated herein by reference in their entirety.

In optional preferred aspects, bone allografts 40 are fabricated from an outer portion of a donor patient's femur bone with curved front end 41 comprising an outer surface

of the femur bone. When fabricated in this manner, curved front end 41 will comprise the hardest (cortical) portion of the allograft. Placing curved front end 41 at or near the curved outer perimeter (i.e.: near the side, front) of the vertebrae 50 and 52 will thus result in positioning the preferably hardest part of allograft 40 (i.e.: curved front end 41) on the hardest (cortical) portion (ie. the outer edges) of the vertebrae 50 and 52.

While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, a variety changes, adaptations, and modifications will be obvious to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

WHAT IS CLAIMED IS:

1. 1. An intervertebral support assembly, comprising:

a pair of bone allografts positioned between two adjacent vertebrae, the bone allografts being positioned towards the anterior portion of the adjacent vertebrae; and

a pair of facet screws, each facet screw securing together a facet joint between the two adjacent vertebrae.

2. The intervertebral support system of claim 1, wherein the bone allografts are positioned at an angle to one another.

3. The intervertebral support system of claim 2, wherein the angle is 30° to 160°

4. The intervertebral support system of claim 2, wherein the angle is approximately 90° to 120°.

5. The intervertebral support system of claim 1, wherein the bone allografts are formed from a femur bone.

6. The intervertebral support system of claim 1, wherein the bone allografts have curved front ends.

7. The intervertebral support system of claim, wherein the curved front end of the bone comprises an outer surface of a femur bone.

8. The intervertebral support system of claim, wherein the bone allografts have lateral grooves disposed therealong.

9. The intervertebral support system of claim, wherein the bone allografts have height to width ratios of about 1.2 to 2.0.

10. The intervertebral support system of claim, wherein the bone allografts have height to width ratios of about 1.4 to 1.8.

11. The intervertebral support system of claim, wherein the bone allografts have height to width ratios of about 1.6.

12. The intervertebral support system of claim 1, wherein each facet screw is positioned in a transfacet approach.

13. The intervertebral support system of claim 1, wherein each facet screw is positioned in a translaminar approach.

14. The intervertebral support system of claim 1, further comprising:
autologous bone graft material positioned between and to the rear of the bone allografts.

15. The intervertebral support system of claim 14, wherein the autologous bone graft material is harvested from an iliac crest.

16. The intervertebral support system of claim 1, further comprising:
autologous bone graft material positioned posterolaterally behind the bone allografts.

17. The intervertebral support system of claim 16, wherein the autologous bone graft material is harvested from an iliac crest.

18. A method of providing support between two adjacent vertebrae, comprising:
positioning a pair of bone allografts between the two adjacent vertebrae at a location towards the anterior portion of the adjacent vertebrae; and
securing together facet joints between the two adjacent vertebrae with a pair of facet screws.

19. The method of claim 18, wherein each of the bone allografts are positioned adjacent to a curved outer perimeter of the two adjacent vertebrae.

20. The method of claim 18, wherein the bone allografts are positioned at an angle to one another.

21. The method of claim 20, wherein the angle is 30° to 160°.

22. The method of claim 20, wherein the angle is approximately 90° to 120°.

23. The method of claim 18, further comprising:
positioning autologous bone graft material posterolaterally behind the bone allografts.

24. The method of claim 18, further comprising:
positioning autologous bone graft material positioned between and to the rear of the bone allografts.

25. The intervertebral support system of claim 18, further comprising:
harvesting autologous bone graft material from an iliac crest.

26. The method of claim 18, wherein each of the bone allografts are advanced into position between the two adjacent vertebrae through a percutaneous cannula.

27. The method of claim 26, wherein the percutaneous cannula is disposed in a posterolateral approach.

28. The method of claim 26, wherein the percutaneous cannula is positioned by a surgical guideframe.

29. The method of claim 18, wherein each of the bone allografts are rotated by about 90° after insertion into the patient's intervertebral space.

30. The method of claim 18, wherein a first bone allograft is advanced into position between the two adjacent vertebrae through a first percutaneous cannula and the second bone allograft is advanced into position between the two adjacent vertebrae through a second percutaneous cannula.

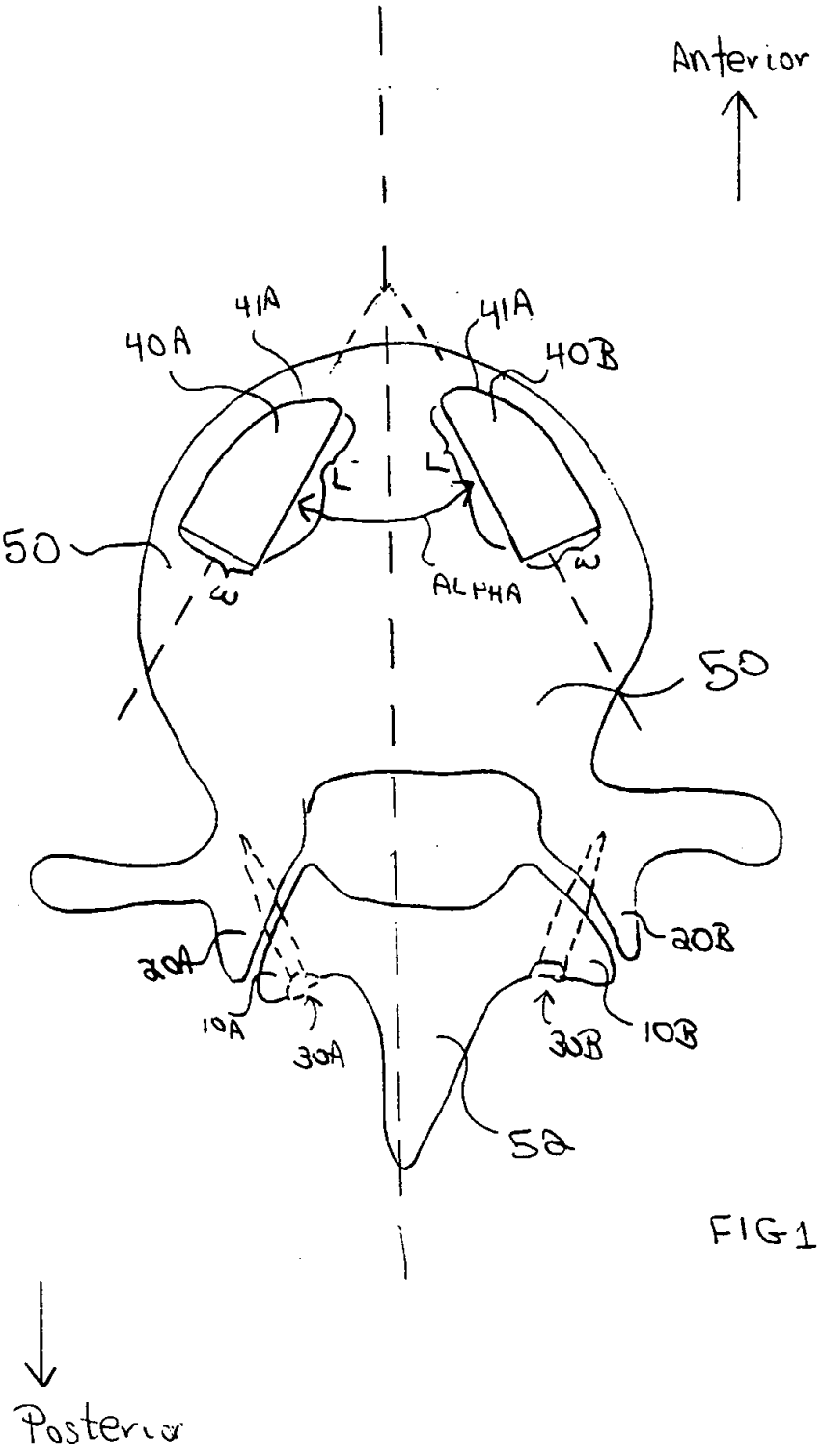
31. The method of claim 30, wherein the first and second percutaneous cannulae are disposed in opposite posterolateral approaches.

32. The method of claim 18, wherein the facet screws are advanced into contact with the facet joints through a percutaneous cannula.

33. The method of claim 32, wherein the percutaneous cannula is positioned by a surgical guideframe.

34. The method of claim 18, wherein each facet screw is positioned in a transfacet approach.

35. The method of claim 18, wherein each facet screw is positioned in a translaminar approach.


Anterior
41A
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20A
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30A
30B
10B
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Posterior

FIG-1

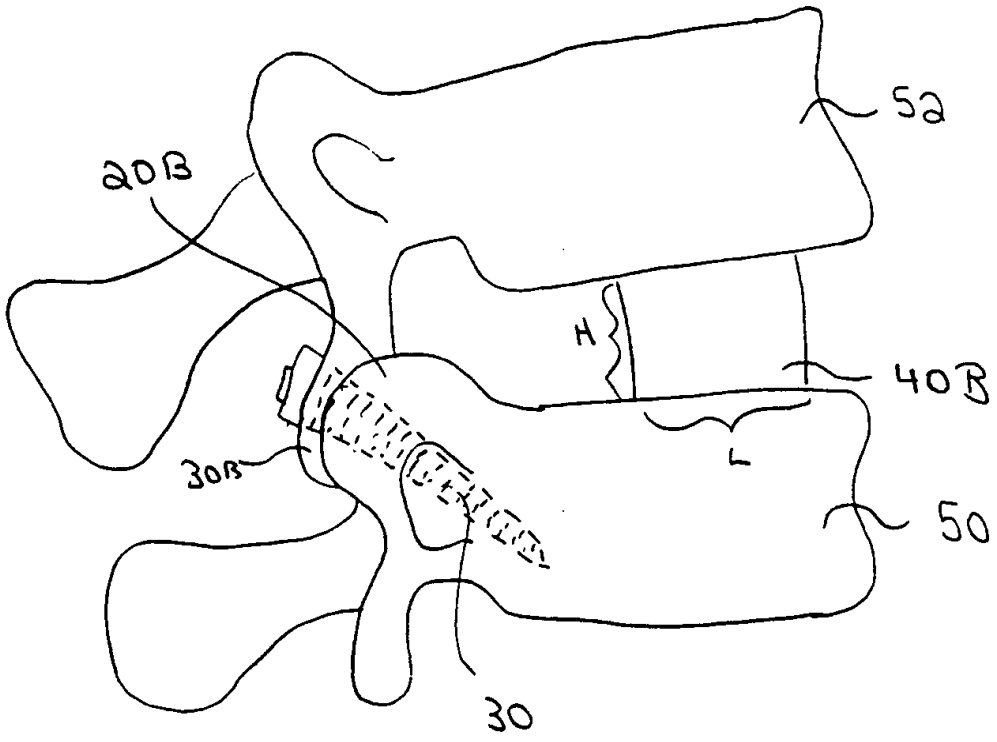


FIG 2

FIG3

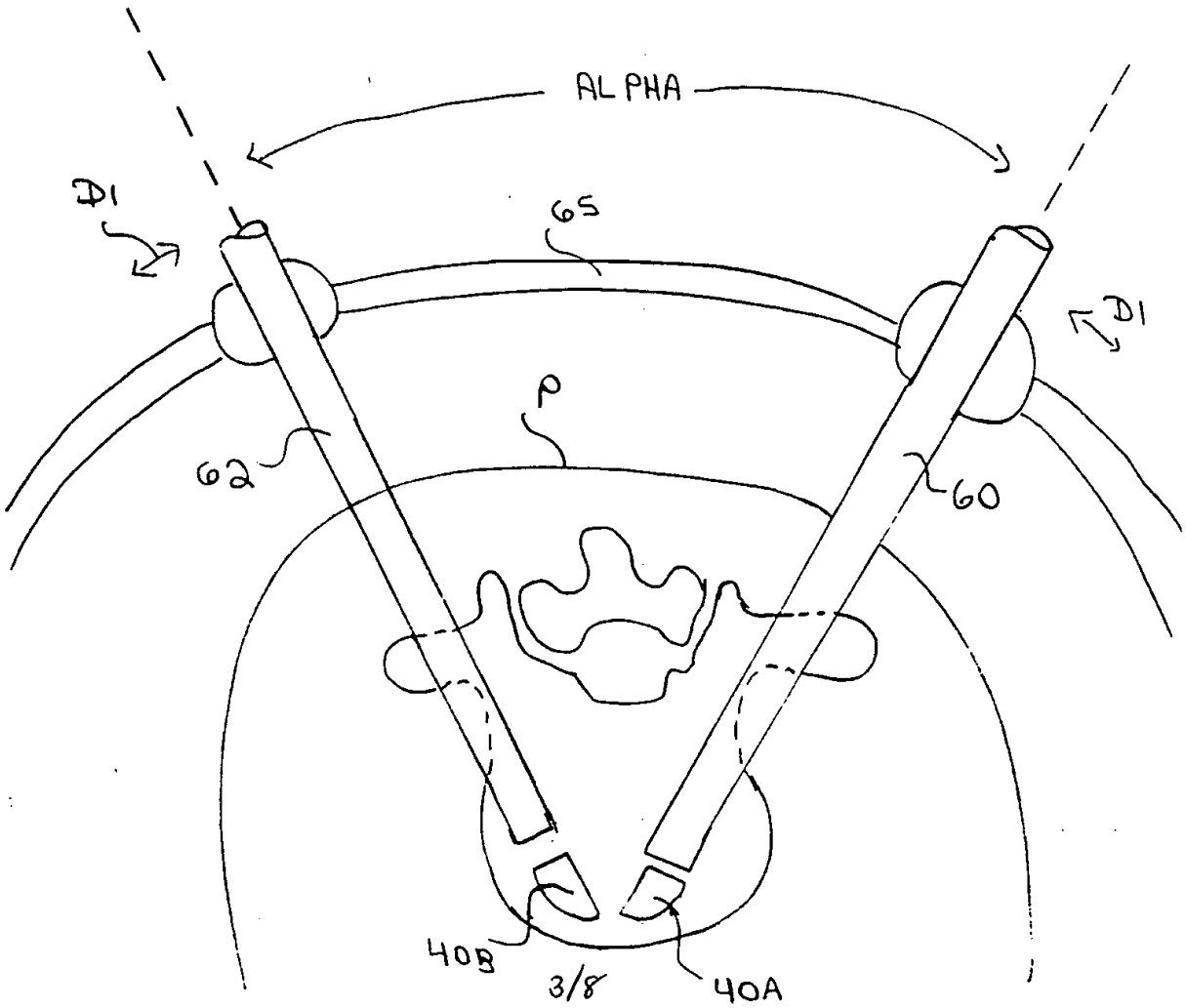
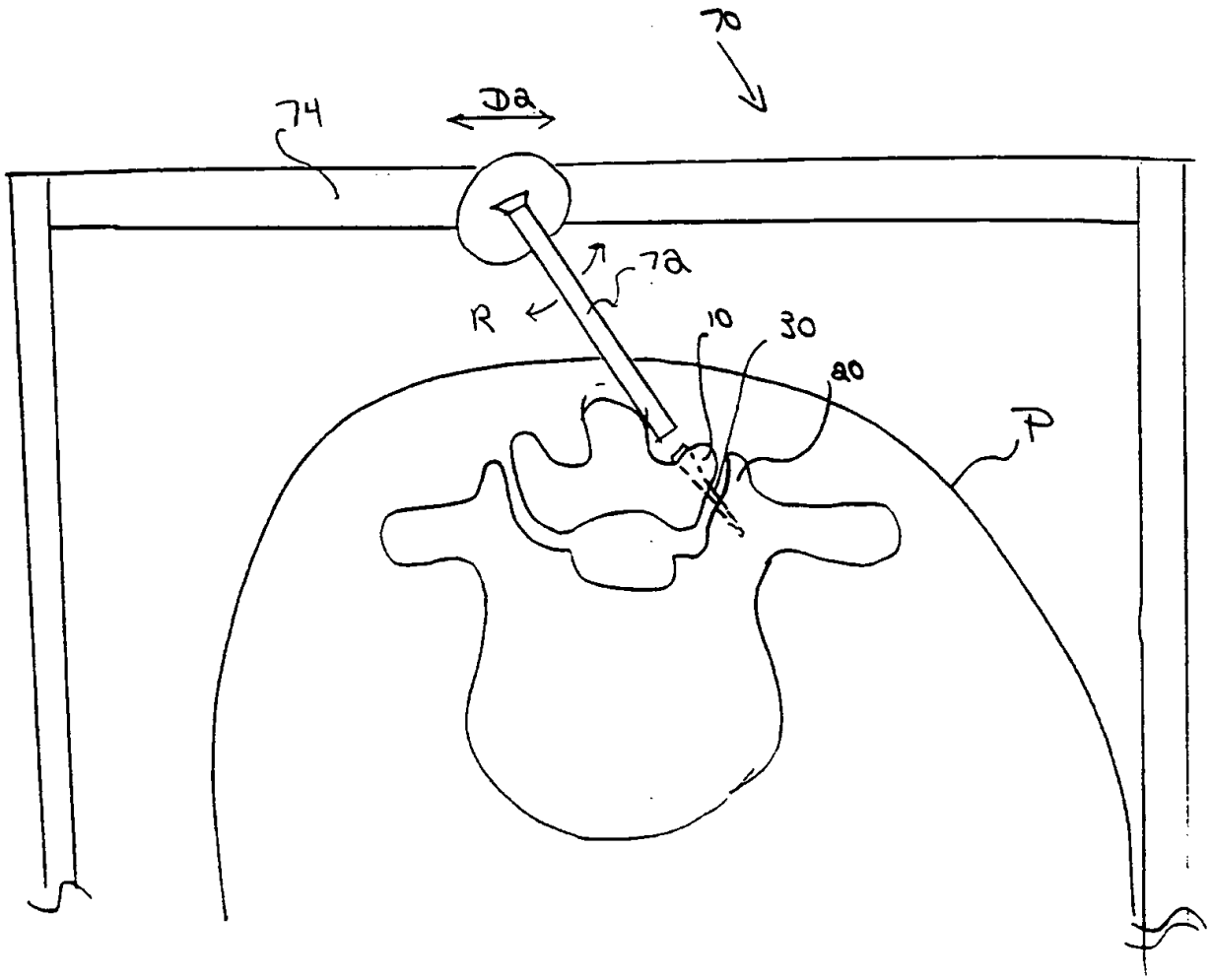


FIG 4



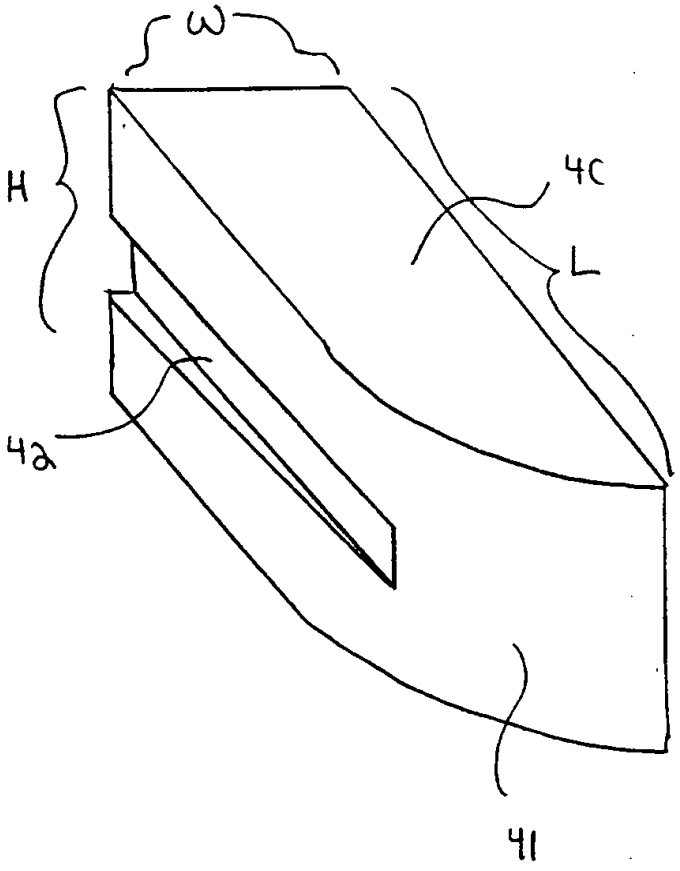
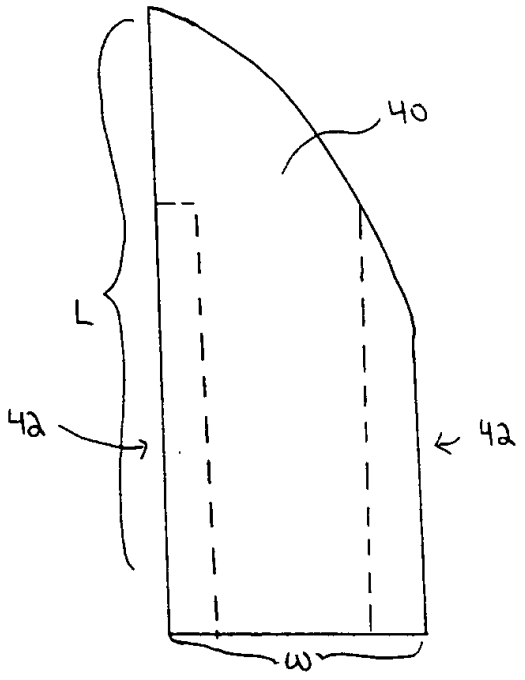


FIG 5



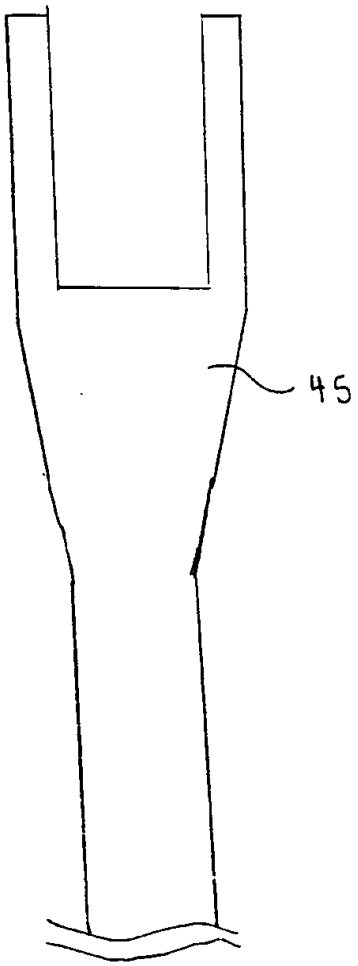


FIG 6

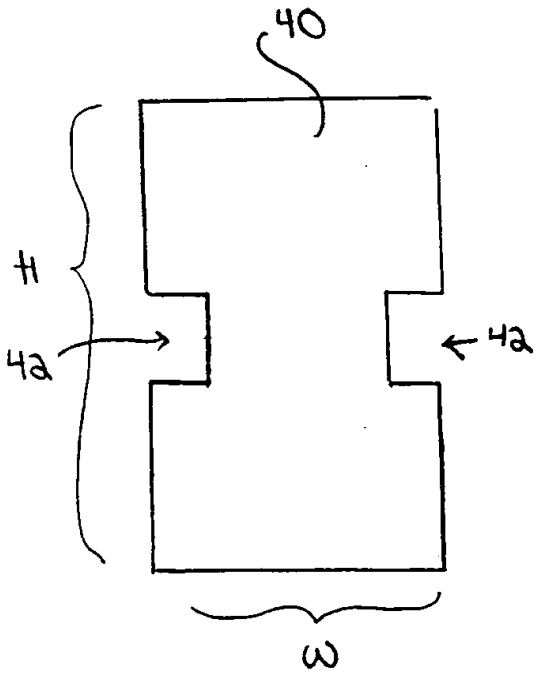


FIG 7

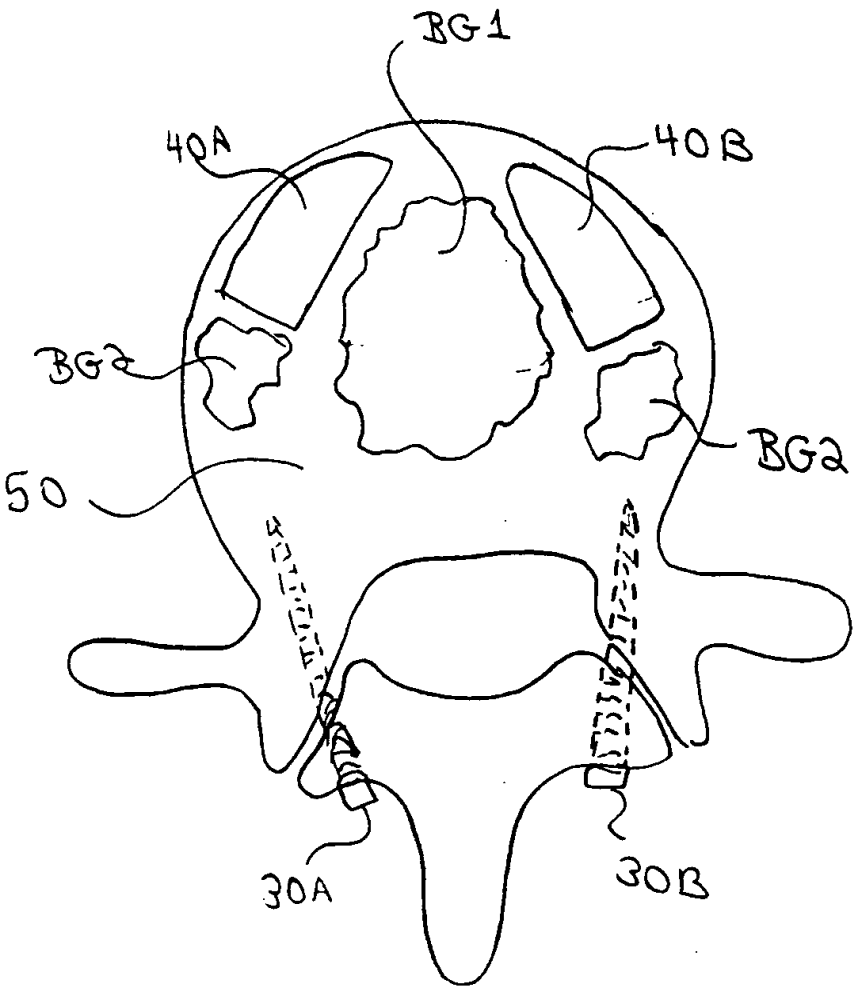


FIG 8

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/44, 5/00
US CL :623/17.16; 606/87

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.16; 606/87

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 6,045,580 A (SCARBOROUGH et al.) 04 April 2000, see entire document.	1-35

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
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"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		

Date of the actual completion of the international search 25 MARCH 2001	Date of mailing of the international search report 26 APR 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVID J ISABELLA Telephone No. (703) 308-3060

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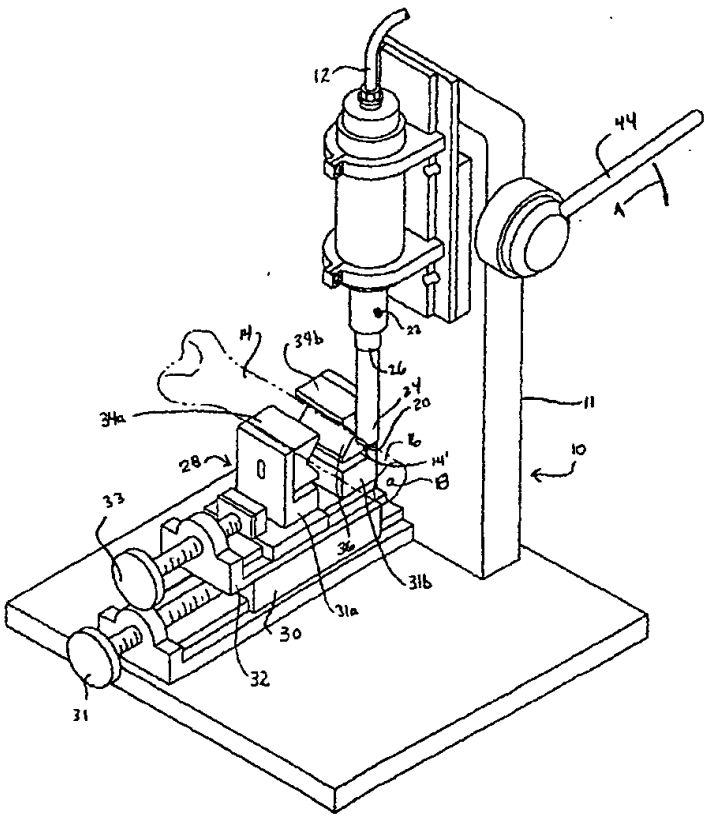
[Continued on next page]

(54) Title: METHODS FOR MANUFACTURING SKELETAL IMPLANTS



(57) Abstract: Instrumentation for manufacturing a bone dowel from human or animal cadaveric bone and instrumentation for evaluating the suitability of the bone and/or dowel for implant use after each step of the manufacturing process is provided. Such instrumentation for manufacturing a bone dowel includes a blanking or coring apparatus, a milling apparatus, a threading apparatus and a tapping apparatus. A gauge is provided to inspect and determine the suitability of the bone dowel at each step of the manufacturing process. By inspecting the dowel being manufactured after each step of the manufacturing process, time and effort which is needlessly wasted during completion of the manufacturing of dowels which are unsuitable for implant use (due to unsuitable bone and/or inaccurate machining of bone) can be avoided. Instrumentation for more accurately positioning bone and the partially manufactured dowel into the instrumentation for machining the dowel is also provided. Such instrumentation includes a gauge for positioning a piece of bone in relation to the apparatus, and mounting blocks for securing the partially manufactured dowel in relation to the milling apparatus.

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

METHODS FOR MANUFACTURING SKELETAL IMPLANTS

This application claims priority from United States provisional application Serial No. 60/173,646, filed December 30, 1999, which is incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates generally to methods and instrumentation for manufacturing an implant, and more particularly to methods and instrumentation for manufacturing and inspecting an intervertebral implant formed from cadaveric human or animal bone.

2. Background to Related Art

Intervertebral implants which are formed from cadaveric human or animal bone ("bone") are well known in the art. Intervertebral implants formed of bone having a threaded dowel configuration, i.e., cylindrical, are also well known. The manufacturing or machining of a threaded intervertebral bone dowel is an involved process which includes at least a drilling or coring step, a milling step, a tapping step and a threading step. Due to the anatomical limitations of bone, each of the manufacturing steps must be precisely performed to produce a dowel having the requisite dimensions suitable for implant use. Typically, the entire manufacturing process is performed before the dowel is evaluated or inspected for suitability for implant use. Thus, where donor bone is not suitable for dowel manufacture or the donor bone has been improperly machined, much time and effort is needlessly wasted in performing additional manufacturing

steps on a dowel which will never be useable as an implant.

Accordingly, a continuing need exists for methods and instrumentation for precisely manufacturing a bone dowel from a bone and for quickly identifying unsuitable bone early in the machining process to avoid undue waste of time and effort.

SUMMARY:

In accordance with the present disclosure, instrumentation for manufacturing a bone dowel from human or animal cadaveric bone and instrumentation for evaluating the suitability of the bone and/or dowel for implant use after each step of the manufacturing process is provided. Such instrumentation for manufacturing a bone dowel includes a blanking or coring apparatus, a milling apparatus, a threading apparatus and a tapping apparatus. A series of gauges are provided to inspect and determine the suitability of the bone dowel at each step of the manufacturing process. By inspecting the dowel being manufactured after each step of the manufacturing process, time and effort which is needlessly wasted during completion of the manufacturing of dowels which are unsuitable for implant use (due to unsuitable bone and/or inaccurate machining of bone) can be avoided.

Instrumentation for more accurately positioning bone and the partially manufactured dowel into the instrumentation for machining the dowel is also provided. Such instrumentation includes a gauge for positioning a piece of bone in relation to the coring apparatus, and mounting blocks for securing the partially manufactured dowel in relation to the milling, threading and tapping apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS:

Preferred embodiments of the presently disclosed instrumentation for manufacturing and evaluating intervertebral implants are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective of one preferred embodiment of the presently disclosed blanking or coring apparatus;

FIG. 1A is a perspective view of the presently disclosed Shimp gauge;

FIG. 2 is a perspective view of a bone dowel formed by the coring apparatus shown in FIG. 1;

FIG. 3 is a perspective view with parts separated of a holding block of the presently disclosed dowel milling apparatus;

FIG. 4 is a perspective view of the holding block shown in FIG. 3 in the assembled condition;

FIG. 5 is a side view of the holding block shown in FIG. 3;

FIG. 6 is a perspective view of one preferred embodiment of the presently disclosed milling apparatus;

FIG. 7 is a perspective view of the bone dowel formed by the milling apparatus shown in FIG. 6;

FIG. 8 is a perspective view of the slot milling bit of the milling apparatus shown in FIG. 6;

FIG. 9 is a perspective view of the support blocks of the second adjustment vise of the coring apparatus shown in FIG. 1;

FIG. 10 is a side view of the support block shown in FIG. 9;

FIG. 11 is a backside view of the support block shown in FIG. 9;

FIGS. 12a-12c are perspective, front and side views of one embodiment of the presently disclosed wall thickness GO/NO GO gauge;

FIG. 13 is a perspective view of one embodiment of the presently disclosed slot width

GO/NO GO gauge;

FIG. 14 is a perspective view of one embodiment of the presently disclosed outer diameter and length gauge;

FIG. 15 is a perspective view of one embodiment of the presently disclosed pilot hole gauge;

FIG. 16 is a perspective view with parts separated of one embodiment of the presently disclosed drilling holding block;

FIG. 17 is a perspective view of the bone dowel after the pilot hole has been drilled and tapped;

FIG. 18 is a perspective of the holding block shown in FIG. 16 in the assembled condition;

FIG. 19 is a perspective view of one embodiment of the presently disclosed tapping holding block;

FIG. 20 is a perspective view of the presently disclosed dowel threading tool;

FIG. 21 is a perspective view of a presently disclosed dowel thread gauge; and

FIG. 22 is a perspective view of a threaded bone dowel after the outer surface has been threaded using the dowel threading tool shown in FIG. 20.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The embodiment of the methods and apparatus disclosed herein are discussed in terms of skeletal implantation and related instrumentation. It is contemplated that the present methods and apparatus for manufacturing implants find application in spinal implantation procedures whereby a fusion implant is placed into a receiving bed formed in an intervertebral space.

In one particular embodiment in accordance with the principles of the present disclosure, a procedure is described for machining and inspecting fusion implants including threaded cortical dowels. It is contemplated that the procedure may include processes such as coring a dowel, milling a dowel, tapping a dowel and threading a dowel. These processes are described in greater detail below.

Referring now in detail to the drawings wherein like reference numerals identify similar or like components throughout the several views, FIG. 1 illustrates aspects of a process for coring a bone dowel using a dowel coring apparatus 10.

CORING OF A DOWEL:

A pneumatic dowel blanking or coring apparatus 10 is prepared and set up for operation prior to the coring process by connecting an air supply line 12 of dowel coring apparatus 10 to an air supply. The dowel coring apparatus 10 includes a drill press 11. Typically, an air pressure of 100 psi and above is utilized to drive a dowel cutter 24, although coring apparatus using lesser pressures may also be used. Dowel coring apparatus 10 is also attached to a water supply (not shown) for irrigation.

A bone shaft 14 is selected for producing the threaded cortical dowels. Bone shaft 14 is preferably a long bone shaft, i.e., the shaft of a femur, ulna, radius, tibia or fibula, although other bone may also be used. A cortical shaft portion 16 of bone shaft 14 includes a medullary canal 18 which is examined to determine the appropriate size dowel cutter to be used. The dowel cutter includes a hollow cylindrical bit which must be greater in diameter than the medullary canal of bone shaft 14. It is contemplated that dowel cutter sizes such as, for example, 6mm, 8mm, 10mm, 12mm,14mm, 16mm, 18mm, etc., may be used.

After the appropriate size dowel cutter 24 is selected, it is secured to dowel coring

apparatus 10. Dowel cutter 24 is secured to shaft 26 of dowel coring apparatus 10 in a known manner and includes an annular serrated edge 14. Dowel cutter 24 is configured to penetrate bone shaft 14 to blank a dowel.

Bone shaft 14 is placed into a vise assembly 28 of dowel coring apparatus 10 so that a targeted portion of shaft 14 may be blanked to produce the dowel. A first adjustment vise 30 positions bone shaft 14 along at least one axis so that canal 18 is centered with dowel cutter 24. First adjustment vise 30 is manipulated by knob 31 to adjust positioning of bone shaft 14 relative to dowel cutter 24.

A second adjustment vise 32 secures and stabilizes bone shaft 14 in position for coring. Second adjustment vise 32 includes support blocks 31a and 31b and inserts 34a and 34b. One insert is supported on each support block. Each support block is rotatably secured to vise 32 and each insert is vertically adjustable in relation to a respective support block to facilitate securement of the irregular shape of bone shaft portion 16 within vise 32. Second adjustment vise 32 is manipulated by rotating knob 33 to advance insert 34a towards insert 34b to clamp shaft portion 16 therebetween. It is contemplated that the components of the first and second adjustment vises may be movable by motorized means. Referring to FIGS. 9-11, inserts 34a and 34b have angled cavities 36 configured to receive bone shaft 14. It is contemplated that angled cavities 36 may have alternate angular configurations or may comprise other geometric configurations such as, for example, elliptical, parabolic, etc.

As illustrated in FIG. 1A, a shimp gauge 38 can be employed for properly aligning dowel cutter 24 with bone shaft 14. Shimp gauge 38 includes flexible walls 39a and 39b which are positioned on opposite sides of and snap onto dowel cutter 24. Gauge 38 includes a cross hair 40 for aligning dowel cutter 24 with the center of the medullary canal 18 of bone shaft 14. More

specifically, with gauge 38 positioned about dowel cutter 24, knob 31 can be turned to adjust the position of bone shaft 14 with respect to dowel cutter 24. Bone shaft 14 should be positioned such that cross hair 40 is aligned with and positioned in front of the medullary canal at bone shaft 14. A window cavity 42 is formed about cross hair 40 and allows for a visual determination of the adequacy of thickness of cortical shaft portion 16, i.e., the cortical thickness of bone shaft 14 should cover the space between cross hair 40 and the edge 42' of window 42. To assist in visualization of canal 18 during subsequent cuts, it is suggested to remove bone shaft 14 from vise assembly 28 and saw off the previously cut end of cortical shaft portion 16.

Referring back to FIG. 1, during operation, the air and water supplies connected to dowel coring apparatus 10 are activated. As a safety feature, the air and water supplies are activated only after dowel cutter 24 is installed. A handle 44 of dowel coring apparatus 10 is manipulated, such as, for example, by gradually being pulled down in the direction indicated by arrow "A", until dowel cutter 24, which is rotating, passes through bone shaft 14. Handle 44 is thereafter released. It is contemplated that manipulation of handle 44 should be performed slowly because cutting too fast may result in off-center drilling, resulting in possible damage to the bone dowel. It is further contemplated that the components of the dowel coring apparatus may be movable by motorized means.

Referring to FIG. 2, a bone dowel 46 is produced and is disposed within dowel cutter 24. Bone dowel 46, which comprises a cylindrical bone blank having a throughbore defined by medullary canal 18, may be removed from dowel cutter 24 by hand or by the use of compressed air.

Referring to FIGS. 12A-12C, an in process check of the sidewall thickness of bone dowel 46 is performed to determine the adequacy thereof. Bone dowel 46 is rinsed in water to remove

loose bone particles from its exterior and medullary canal 18. The cortical sidewall thickness of bone dowel 46 is checked using a gauge, such as the universal Wall Thickness Go/No Go gauge 48. Using a gauge end 50, which is suitably marked, e.g., "wall", medullary canal 18 of bone dowel 46 is positioned about post 52 such that the thinnest portion of the bone wall defined between medullary canal 18 and the outer circumference of bone dowel 46 is permitted to freely fall between gauge post 52 and sidewall 54 of gauge 48. Bone dowel 46 should not be forced or pushed between gauge post 52 and sidewall 54, as a false measurement for adequacy of the bone dowel may be taken. If the dowel falls to the bottom of post 52, the bone wall is too thin, and the bone dowel is rejected. This adequacy procedure is repeated for the opposite side of canal 18. If the bone dowel wall is unacceptable, i.e., rejected, bone shaft 14 should be rechecked for centering and/or a different size, i.e., larger, dowel cutter should be used. It is contemplated that reassessment of the suitability of the donor for bone dowel production may be reconsidered. If bone dowel 46 is acceptable, proceed in the manufacturing method.

Referring again to FIGS. 12A-12C, an in process check of cortical face wall thickness may be checked using the universal Wall Thickness Go/No Go gauge 48. Using gauge end 56, which is suitably marked, e.g., "Face", medullary canal 18 of bone dowel 46 is positioned onto post 58 with one end of dowel 46 positioned against face wall 60 of gauge 48 at its thinnest point. Bone dowel 46 is permitted to freely fall between gauge post 58 and face wall 60. For the reasons discussed above, bone dowel 46 should not be forced or pushed between gauge post 58 and face wall 60. If bone dowel 46 falls to the bottom of post 58, it is rejected, i.e., the wall thickness is insufficient for dowel use. If the face wall thickness of bone dowel 46 is unacceptable, bone dowel 46 is rejected and placement of bone shaft 14 in dowel coring apparatus 10 should be checked. If the bone dowel is rejected, the suitability of the donor bone

for bone dowel production may be reconsidered. If bone dowel 46 is acceptable, proceed in the manufacturing method.

Referring to FIG. 14, an in process check of the outside diameter and length of bone dowel 46 is performed to determine the adequacy thereof. Bone dowel 46 is placed in an appropriate outside diameter and length Go/No Go gauge 62. Bone dowel 46 is inserted into the No Go end 64 of gauge 62. If bone dowel 46 is acceptable (does not fit in No-Go end 64) proceed to check bone dowel 46 in the Go end 66 of gauge 62 by inserting bone dowel 46 into the Go end 66 of gauge 62 so that a slot of bone dowel 46 mates on a gauge boss 68 and medullary canal 18 is visible in window 70. If bone dowel 46 fits in the Go end 66 of gauge 62, the outside diameter is acceptable. If the outside diameter is acceptable, the length of bone dowel 46 can be checked by viewing length marker 72 to determine if the length falls within an acceptable range. If the length is acceptable, bone dowel 46 is acceptable. If bone dowel 46 fails, bone dowel 46 is rejected and dowel coring apparatus 10 should be checked. If the diameter of bone dowel 46 is acceptable, but the length is too long, bone dowel 46 is cut to a proper length and rechecked. If the length of bone dowel 46 is too short, bone dowel 46 is rejected.

The results of the above mentioned in-process checking procedures may be recorded on an attached log or the like.

MILLING OF SLOT AND FACE

Referring to FIGS. 3-8, a dowel milling apparatus 74 is prepared and set up for operation during the manufacturing process by connecting an air supply 75 to dowel milling apparatus 74 (FIG. 6). Typically, a pressure of 100 psi and above is utilized, although milling apparatus requiring lower air pressures may also be used. A water supply (not shown) is connected to

dowel milling apparatus 74 for irrigation.

Referring to FIGS. 6 and 8, a face and slot milling bit 76 is secured to dowel milling apparatus 74. As a safety feature, air supply 75 should not be connected to apparatus 74 until the bit is secured to the dowel milling apparatus 74. Moreover, the water supply should only be turned on when using dowel milling apparatus 74.

Referring to FIGS. 3-5, bone dowel 46 is inserted into an appropriately sized holding block 78. Bone dowel 46 is positioned in holding block 78 such that canal 18 is visible through block window 80 and the slot is milled approximately perpendicular to canal 18. The depth of bone dowel 46 as seated in block 78 is set with use of a guide 82 attached to block 78, as shown in FIG. 5. Set screws 84 are tightened so that block 78 holds bone dowel 46 securely in place. Up to three bone dowels can be placed into holding block 78 at one time. It is contemplated that holding block 78 may be alternately configured to hold a single or multiple number of bone dowels.

Referring back to FIG. 6, holding block 78 is inserted into a pre-centered vise 86 positioned on dowel milling apparatus 74 and vise 86 is secured.

Dowel milling apparatus 74 is activated by activating the water and air supplies. A handle 88 is manipulated to feed block 78 throughface and slot milling bit 76 in the forward and reverse directions. It is contemplated that bone dowel 46 should only pass through face and slot milling bit 76 forwards and reverse once. It is further contemplated that bone dowel 46 should not have reverse movement until face and slot milling bit 76 is completely clear of the last bone dowel in block 78. It is envisioned that prior to stopping dowel milling apparatus 74, face and slot milling bit 76 is clear of bone dowel 46. Dowel milling apparatus 74 is deactivated and holding block 78 is removed from vise 86.

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Referring to FIG. 7, after the milling step described above, bone dowel 46 has a milled slot 90 and smooth face 91. Slot 90 is oriented substantially perpendicular to medullary canal 18. Bone dowel 46 may be removed from block 78.

Referring to FIG. 13, an in process check of the slot width is performed using the universal Slot Width Go/No Go Gauge 102. Go side 104 of gauge 102 is inserted into slot 90 of bone dowel 46 so that it extends through the entire length of slot 90. If gauge 102 extends through the entire slot, it is acceptable. If it does not extend through the entire slot, bone dowel 46 is rejected. If bone dowel 46 is acceptable, proceed to check a No Go side 106 in the same manner. No Go side 106 should not fit into slot 90. Thus, if it does, slot 90 is too wide and bone dowel 46 is rejected. If No Go side 106 does not fit into slot 90, it is acceptable. If slot 90 is rejected, milling apparatus 74 should be checked. If bone dowel 46 is acceptable, proceed in the manufacturing process as follows.

Referring to FIG. 16, bone dowel 46 is placed in a holding block 92 for drilling and tapping an insertion tool engaging bore 95. Bone dowel 46 is positioned with milled slot 90 on top. Up to three bone dowels can be placed into holding block 92 at one time. It is contemplated that holding block 92 may be alternately configured to hold a single or multiple number of bone dowels. Referring to FIG. 17, holding block 92 includes a drill centering device 93 having a guide bore 97 to facilitate proper positioning of a pilot hole drill bit 94 for drilling hole 95 in bone dowel 46.

Drill centering device 93 includes a drill guide 96 which defines guide bore 97 and cooperates with pilot hole drill bit 94 for drilling pilot hole 95. Pilot hole drill bit 94 is secured to an electric drill or the like. Manual activation of pilot hole drill bit 94 is also contemplated.

Pilot hole drill bit 94 is inserted through guide bore 97 to drill pilot hole 95. Drill bit 94

is rotated clockwise until drill bit 94 is observed through a holding block window (not shown) inside canal 18 of bone dowel 46 and drill bit 94 turns freely. Pilot hole drill bit 94 is removed by rotating drill bit 94 counter clockwise. Pilot hole drill bit 94 should not be advanced such as to engage the opposite wall of canal 18.

Referring to FIG. 15, an in process check of pilot hole 95 of bone dowel 46 is performed to determine the adequacy of the inner diameter thereof. To accomplish this, pilot hole 95 is visually checked to ensure that it is approximately centered and that it passes into canal 18. Next, the inner diameter of pilot hole 95 is checked with Pilot Hole Pin Gauge 97. To accomplish this, end 98 of gauge 97 is inserted into pilot hole 95. Insertion should not be forced. If end 98 extends though pilot hole 95 and into canal 18, the diameter of pilot hole 95 is too large and bone dowel 46 is not acceptable. If pilot hole 95 does not extend into canal 18, it can be drilled through using a hand held tool and rechecked for proper inner diameter, as discussed above.

Referring to FIG. 19, pilot hole 95 is now threaded. To accomplish this, a tap centering device 101 is secured to mounting block 92. Tap centering device 101 is similar to drill centering device 93 except that guide bore 97' is larger than guide bore 97 to allow passage of tap 99. A tap 99 is inserted through guide bore 97' of device 101 to thread pilot hole 95 of bone dowel 46. Tap 99 is removed after this is accomplished by manually twisting tap 99 counter clockwise from guide bore 97'. It is contemplated that tap 99 may be operated by motorized means. It is further contemplated that tap 99 should not be inserted so far as to engage the opposite wall of canal 18.

Bone dowel 46 can now be removed from holding block 92. Bone dowel 46 is rinsed in water to remove loose bone particles from its exterior and medullary canal 18. Referring to FIG.

18, bone dowel 46 now includes internally threaded pilot hole 95. Referring again to FIG. 15, an end 100 of gauge 97 may be used to check the adequacy of the threads of pilot hole 95.

An in-process check of the cortical face wall thickness of bone dowel 46 may be conducted using the universal wall thickness Go/No Go gauge 48, similar to that described above with regard to FIGS. 12a-12c. If the face wall thickness of bone dowel 46 is unacceptable, reject bone dowel 46 and recheck slot and face milling bit 76 and placement in holding block 78. Also reassess the suitability of the donor bone being used for dowel production. If acceptable, proceed in the manufacturing process.

THREADING

Referring to FIGS. 20 and 21, bone dowel 46 can now be externally threaded. A threading tool 108 is prepared and set up for operation during the manufacturing process. A water supply (not shown) is connected to threading tool 108 for irrigation. It is contemplated that the water supply should be activated only when threading tool 108 is in use. It is further contemplated that threading tool 108 may be configured for a variety of different size bone dowels, such as, for example, 14mm, 16mm, 18mm, 20mm, etc. Bone dowel 46 is positioned onto a loading shelf 110 within threading tool 108 through a window 112 formed in tool 108. Threading tool 108 includes a plurality of circumferentially spaced inserts 114 having teeth for engaging and threading the exterior cylindrical surface of bone dowel 46. A driver 116 engages the slotted end of bone dowel 46 to drive bone dowel 46 through threading tool 108 to form the threads on the exterior of bone dowel 46. Bone dowel 46 is placed onto driver 116 such that a tang 118 located at an end of driver 116 engages slot 90 of bone dowel 46.

Tang 118 is configured to engage slot 90 of bone dowel 46 to manually advance bone dowel 46 through tool 108 by turning a handle 120 clockwise. When bone dowel 46 has passed

entirely through threading tool 108, it will discharge from tool 108 into a cradle or the like (not shown) positioned at one end of tool 108. Bone dowel 46 should not be backed through threads 114 of tool 108 once it has passed through initially, nor should bone dowel 46 be run through twice. Referring to FIG. 21, bone dowel 46 now includes external threads 122..

Referring to FIG. 22, an in process check of threads 122 of bone dowel 46 is performed to determine the adequacy thereof. To accomplish this, dowel threads 122 are checked using thread check gauge 124 which includes verifying threads 126. Verifying threads 126 are aligned with dowel threads 122 and threads 122 of bone dowel 46 are visually checked for gaps, unevenness, and improper fit. If gauge 124 fits threads 122 without gaps and unevenness, threads 122 are acceptable. If threads 122 are unacceptable, bone dowel 46 is rejected and threading tool 108 is inspected for quality and adjusted. If threads 122 are acceptable, proceed in the manufacturing process as follows:

An in-process check of the outside diameter and length of bone dowel 46 may be conducted using outside diameter and length gauge 62, similar to that described above with regard to FIG. 14. After completion of the above method, each acceptable bone dowel 46 is sterility tested, measured and packaged for use.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the double sided gauges shown in FIGS. 14-17 can be formed as two separate gauges. The gauges may also be provided in a kit for forming bone dowels having any desired dimensions. Moreover, the coring and milling apparatus can be electrically, hydraulically, or pneumatically actuated apparatus. Therefore, the above description should not be construed as limiting but exemplifications of the various embodiments. One skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

CLAIMS:

1. A method for manufacturing a bone dowel from a bone shaft defining a medullary canal, the method comprising the following steps:

a) coring a cylindrical dowel from the bone shaft such that the medullary canal of the bone shaft forms a throughbore in the dowel having an axis which is transverse to the longitudinal axis of the dowel;

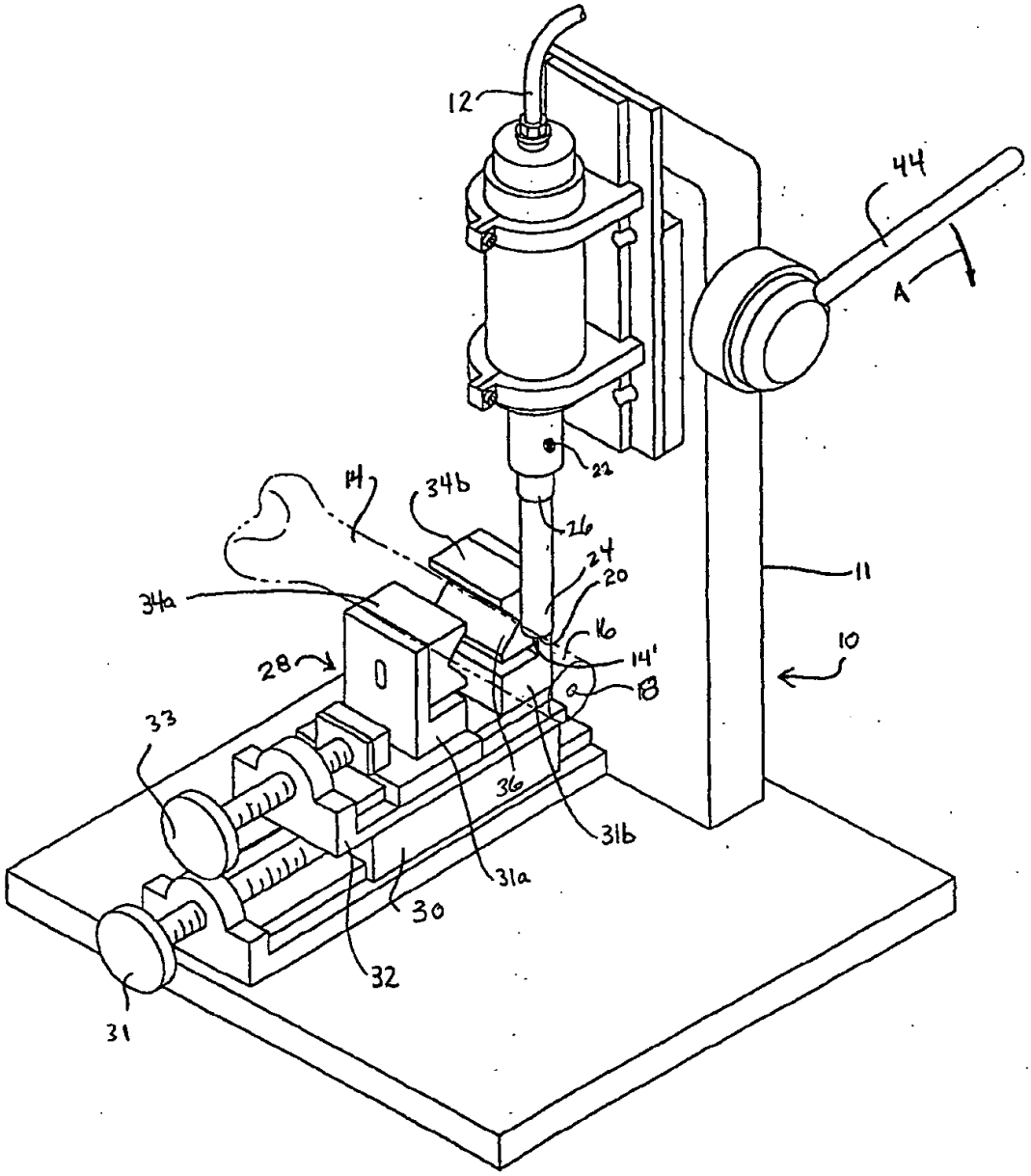
b) performing an in-process inspection of wall thickness of the dowel;

c) rejecting the dowel if the dowel wall thickness does not have at least predetermined dimensions suitable for implant use; and

d) forwarding the dowel for further machining if the dowel has dimensions greater than the predetermined dimensions suitable for implant use.

2. A method according to Claim 1, wherein the step of performing an in-process inspection of the wall thickness of the dowel includes inspecting the sidewall thickness of the dowel.

3. A method according to Claim 1 wherein the step of performing an in-process inspection of the wall thickness of the dowel includes inspecting the thickness of the top and bottom walls of the dowel.


12
44
A
14
34b
22
26
24
20
11
34a
16
10
28
14'
18
33
36
31b
31a
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32
31

FIG. 1

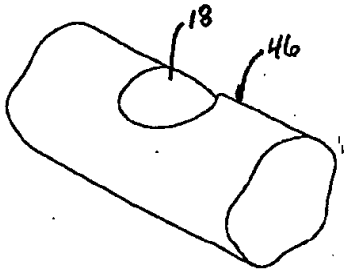

18
46

FIG. 2

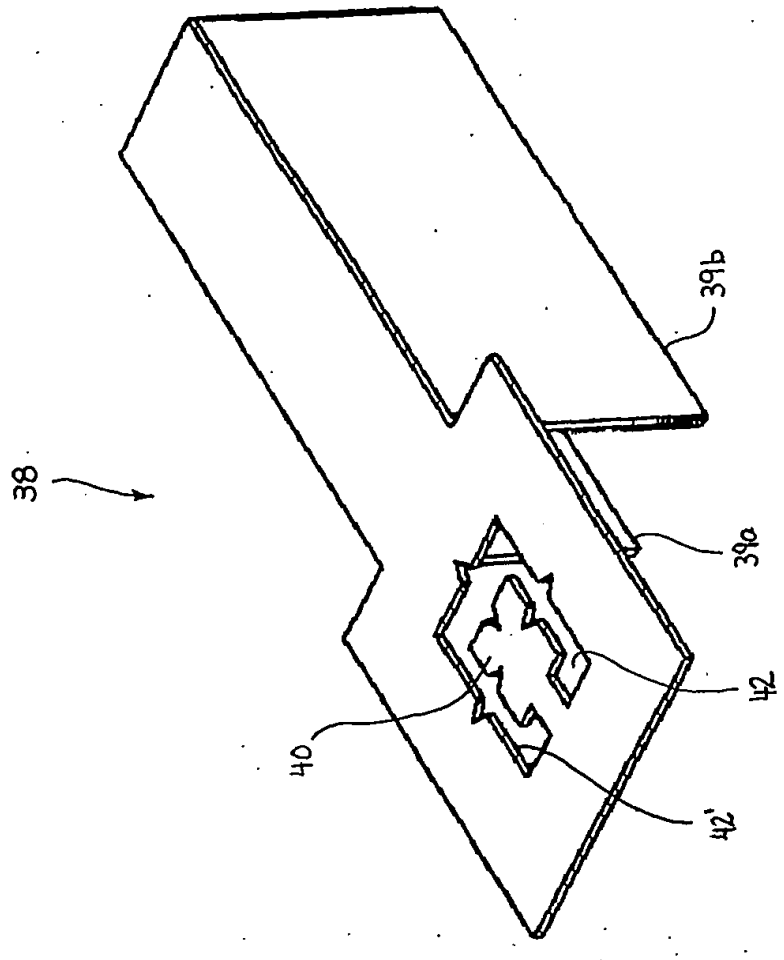


FIG. 1A

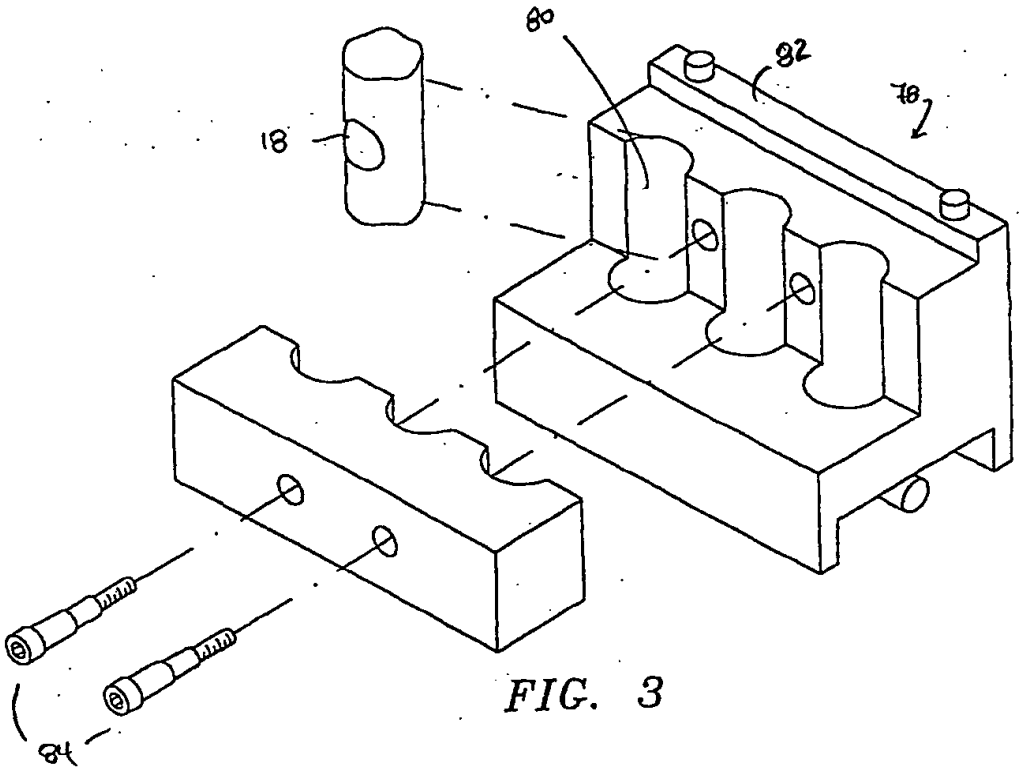


FIG. 3

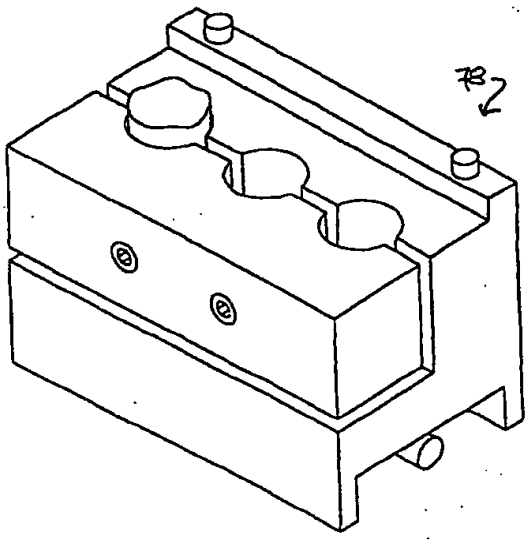


FIG. 4

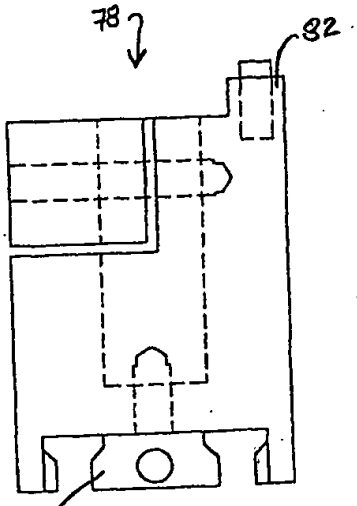


FIG. 5

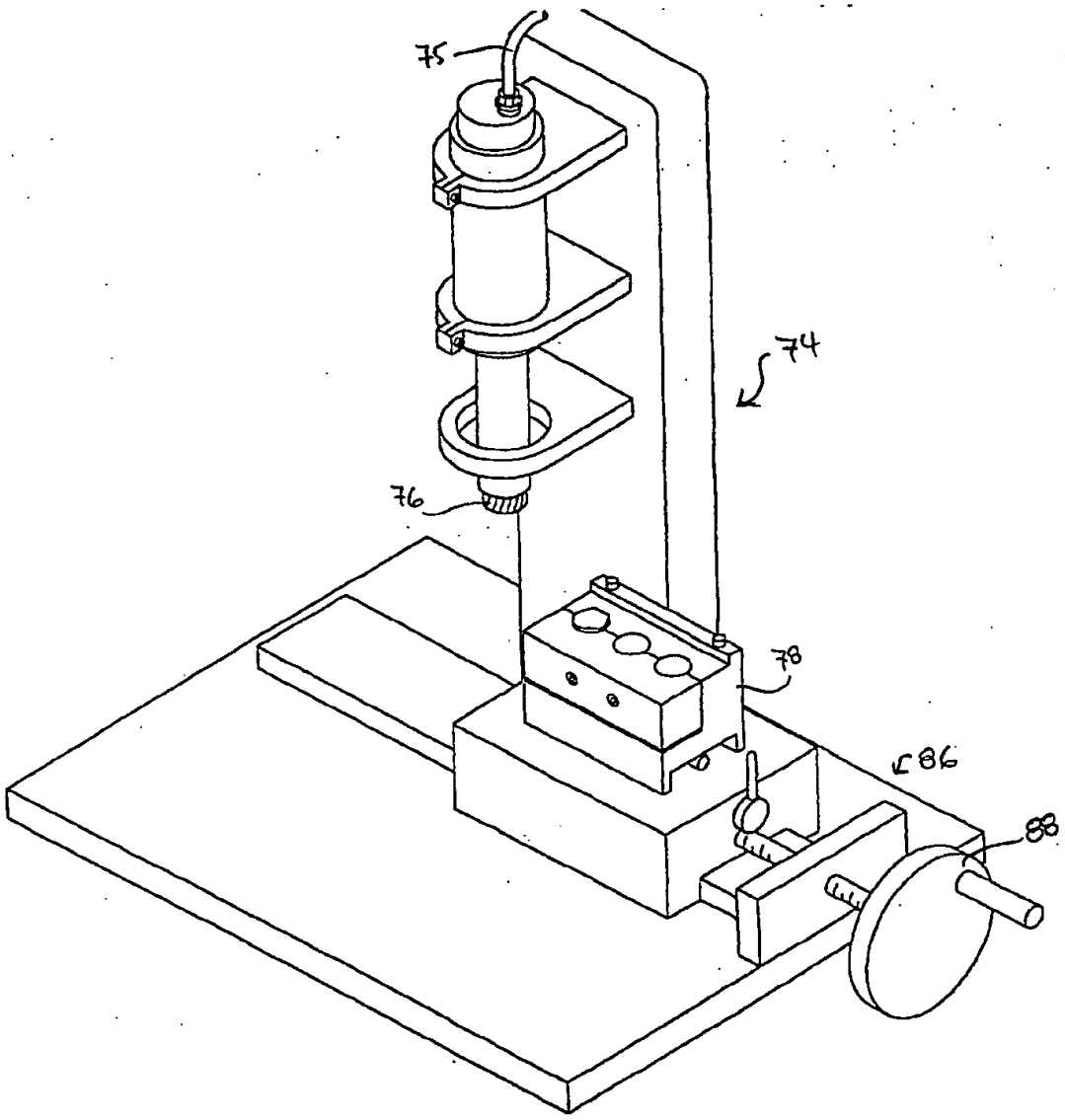


FIG. 6

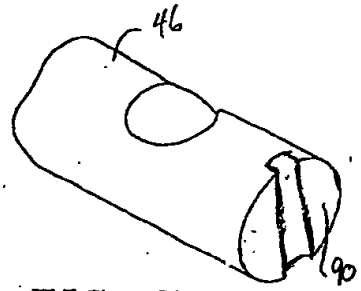


FIG. 7

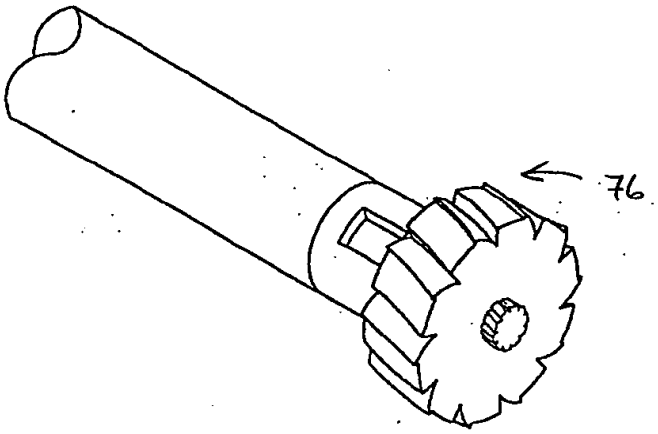


FIG. 8

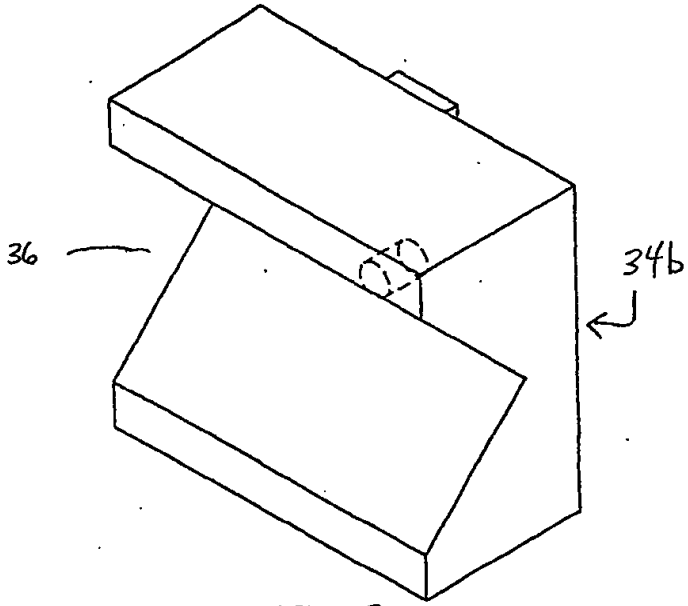


FIG. 9

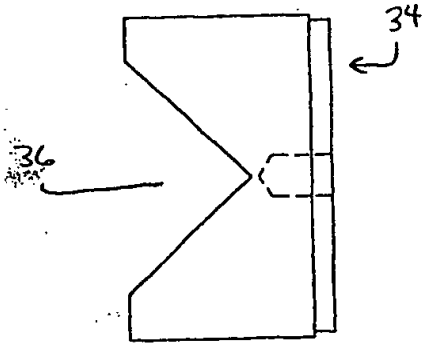


FIG. 10

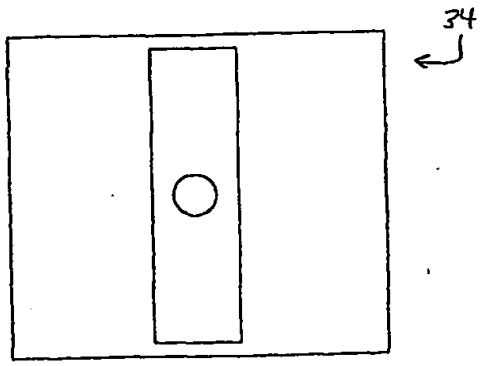


FIG. 11

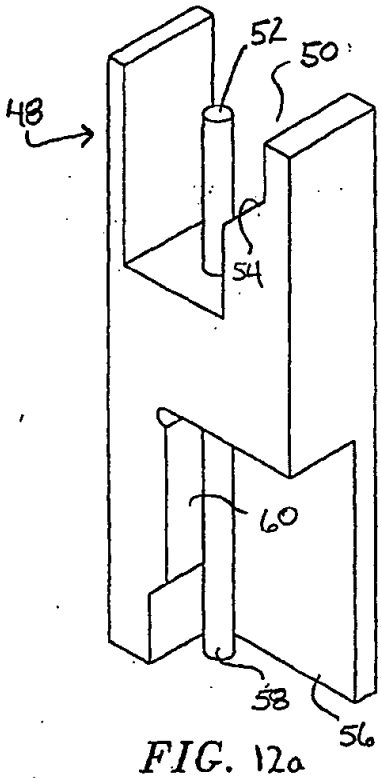


FIG. 12a

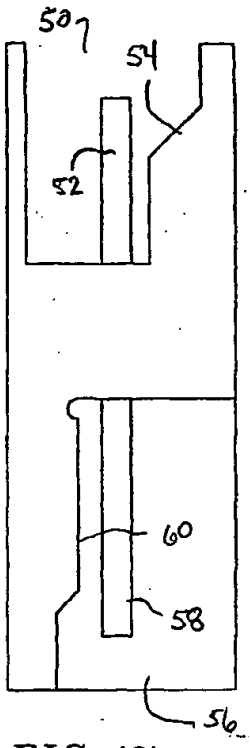


FIG. 12b

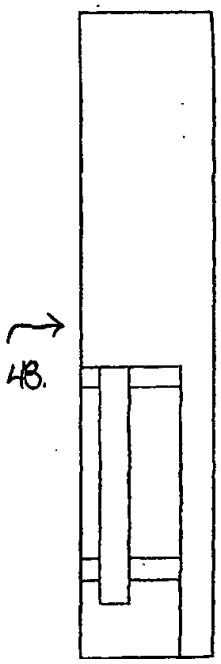


FIG. 12c

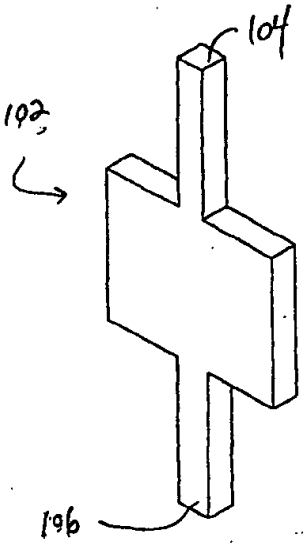


FIG. 13

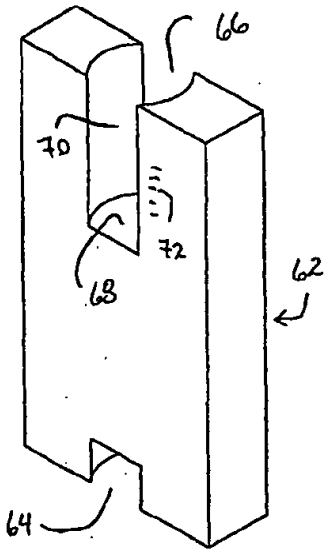


FIG. 14

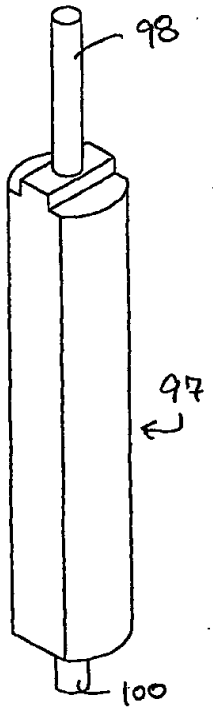


FIG. 15

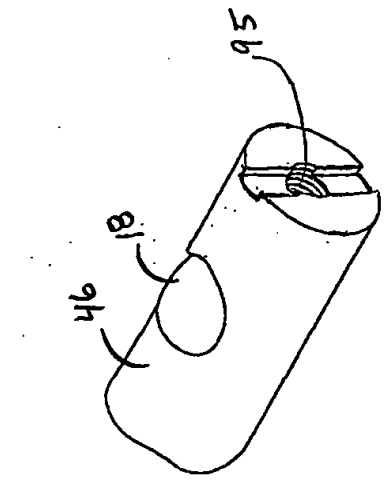


FIG. 17

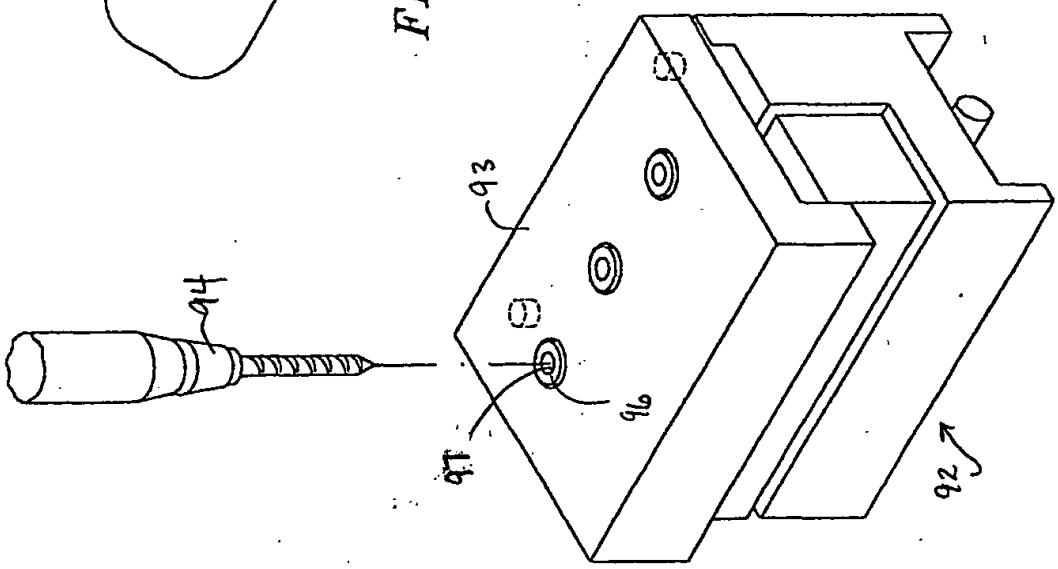


FIG. 18

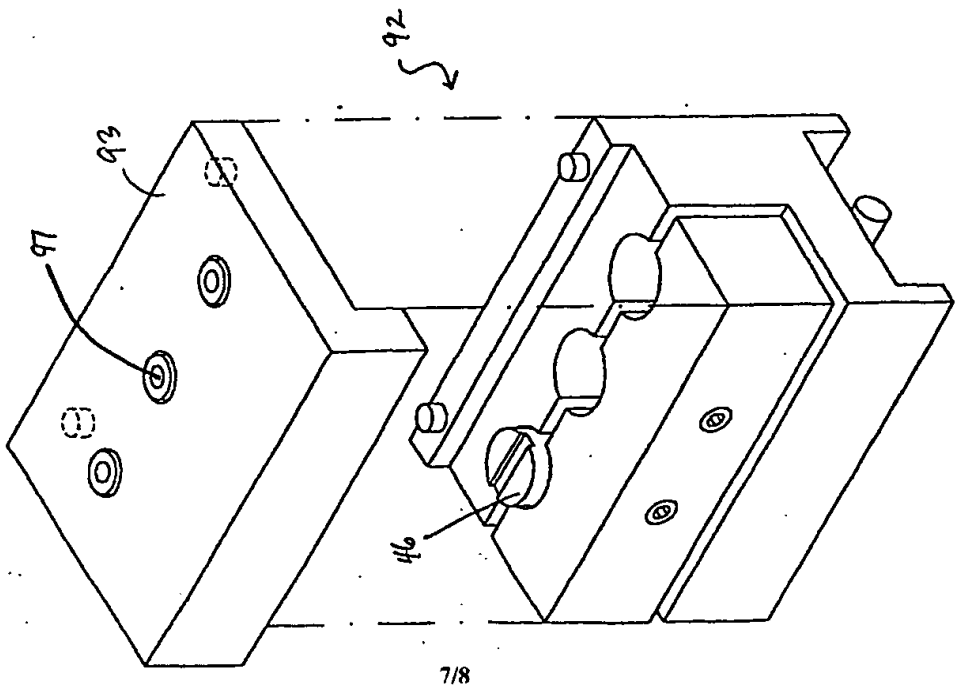
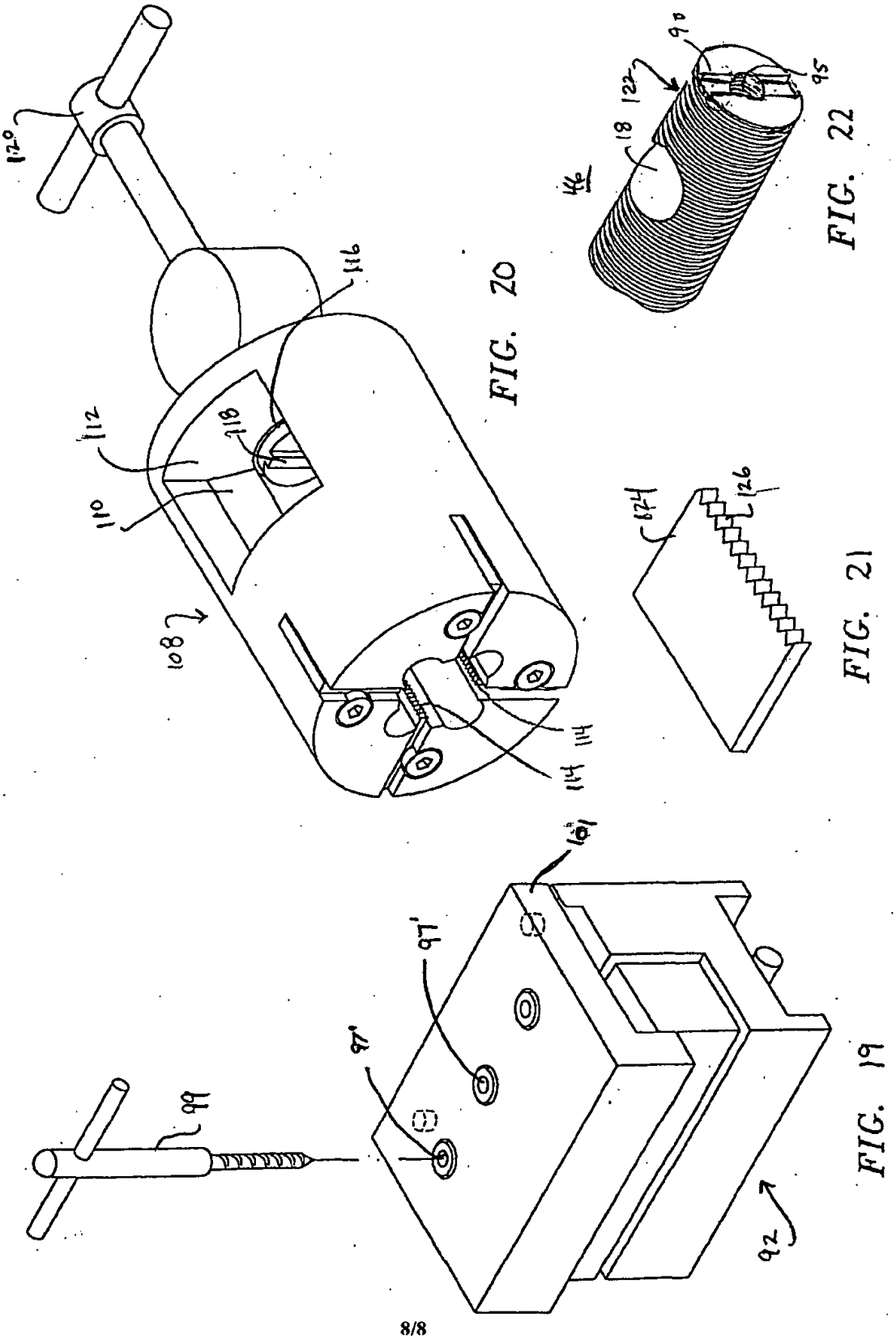


FIG. 16


120
116
112
118
110
108
111
114
FIG. 20
90
122
18
95
46
FIG. 22
124
126
FIG. 21
101
97'
97'
99
92
FIG. 19

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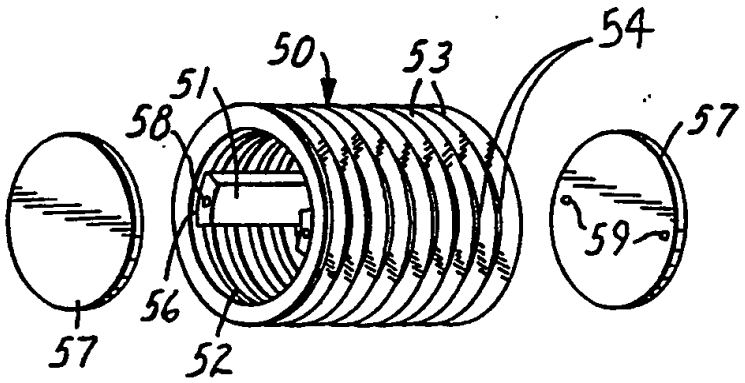

(57) Abstract

A fusion cage (10) having an external thread (12) can be surgically inserted into a threaded bore extending laterally between the adjacent bony structures such as two vertebrae (94, 95) with the thread (12) penetrating into cancellous bone of each of the vertebrae (94, 95). The fusion cage (10) is easily screwed into place by hand without damage to the bony structures (94, 95). Cage (10) is then packed with a bone-growth-inducing substance such as cancellous bone. When a pair of such cages (10) are implanted between adjacent vertebrae (94, 95), patients have been able to sit without pain by the second or third day, much earlier than has been possible in prior spinal fusions except those involving steel plates and screws. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread (12) of the fusion cage (10) forms a permanent interconnection between the two bony structures (94, 95).

* See back of page

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SURGICAL METHOD AND APPARATUS FOR FUSING ADJACENT BONE STRUCTURES

CROSS-REFERENCE TO RELATED APPLICATION

This is a division and continuation-in-part of our copending application S.N. 07/259,031, filed October 17, 1988.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

Description of Related Art

Subsequent to injury, diseases or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the vertebral motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks

of pain reduction, maintenance of intervertebral height, and immobility of the vertebrae. When fusion bone is first placed, it is soft and moveable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the vertebrae quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the vertebrae, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the vertebrae. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion and absorption of bone with potential further collapse. The pain may also become progressively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are may methods for intervertebral fusion. The most successful have achieved a success rate of about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B.R. Wiltberger in a paper published in Clinical Orthopedics, Vol 35, pp 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might

loosen, with a renewed danger of expulsion. See also a 2-page brochure from Neurological Survey Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure:

> "is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate bone-to-bone fusion.... The implanted structure is in the form of a perforated cylindrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it.
>
> "The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated

cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments" (col. 2, lines 26-55).

U.S. Pat. No. 2,537,070 (Longfellow) shows in Fig. 2 a "reinforce 7" that is much like Bagby's fusion basket.

Vich, J. Neurosurg., Vol 63, pp 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft.

"Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertical cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose" (p. 750).

Vich's Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding. Vich also says:

"When grafts with a diameter of 14 mm were used, we sometimes threaded the receiving bed with a die-stock of 13 mm to facilitate the insertion" (p. 751).

An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or appliance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to the vertebrae, such as, dorsal spinous processes or laminas. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower at its most posterior portion. Ventral to this cavity, the stout ligamentous disc annulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

In U.S. Pat. No. 4,743,256 (Brantigan) pairs of plugs are implanted as struts spanning and maintaining the disc space between adjacent vertebrae. While bone plugs were previously used in the same way, Brantigan employs "rigid plugs of structural material having porous surfaces to facilitate ingrowth of bone tissue" (col. 2, lines 66-68), inserting these into "grooves bridging the cancellous bone of one vertebral body to the cancellous bone of the subjacent vertebral body ..." (col. 2, lines 1-6). "The plugs are preferably made of an inert metal substrate such as stainless steel ... having a porous coating of metal particles ..." (col. 3, lines 8-14). The plug of Fig. 12 "has bone piercing tangs or points 31" (col. 5, line 61).

SUMMARY OF THE INVENTION

The present invention provides a method for implanting a fusion cage in order to fuse adjacent bony structures, which method is safer, surer, easier and faster as compared to the implantation of bone dowels or Brantigan's rigid plug or Bagby's fusion basket or Longfellow's "reinforce." Briefly, the novel implantation method involves the following steps:

(a) forming between said bony structures a lateral bore with a female thread that penetrates into their cancellous regions,

(b) forming a hollow cylindrical fusion cage to have an external, substantially continuous helical thread (preferably a V-thread) that is

perforated in the valley between adjacent turns and can mate with said female thread,

(c) screwing the cage into said thread bore, and

(d) packing the cage with bone-inducing substance.

The female thread formed in step (a) preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread or other male-thread fusion cage preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

Parent U.S. patent application S.N. 07/259,031 indicates that the V-thread fusion cage preferably is made of implantable-grade stainless steel and that titanium is also useful. Currently, titanium is preferred, it having been shown to be more compatible to bone.

Parent U.S. patent application S.N. 07/259,031 also teaches that the V-thread fusion cage preferably is fitted with end caps. The end caps

preferably are X-ray transparent to permit post-operative checks on the status of the developing bone. X-ray transparent end caps can be stamped from a flexible sheet of thermoplastic resin such as "Delrin" acetal resin or polypropylene and may have a small opening for an instrument by which they can be put into place.

A threaded bore into which a hollow cylindrical fusion cage can be surgically implanted to fuse adjacent bony structures can be prepared by the steps of:

(a) drilling a pilot hole laterally between said bone structures,

(b) inserting a pilot rod into the pilot hole,

(c) fitting a hollow drill over the pilot rod,

(d) with the hollow drill, enlarging the pilot hole to form a bore that penetrates into the cortical bone of each of said bony structures, and

(e) tapping a female thread into the wall of said bore with the crown of the thread penetrating into the cancellous portion of each of said bony structures.

When using a male-thread fusion cage between adjacent vertebrae to promote bone ingrowth, the fusion cage should be implanted in pairs on opposite sides of the disc space. After placement of the first cage, there is an impressive, instant stabilization of the previously unstable vertebral segment. The second cage is then screwed into its tapped hole, thus rendering the space completely immobile. Each cage is

held in place by its male-thread, biting into female threads that were formed in step (e). Gravity, muscle pull and elastic recoil of the spread (or stretched) outer disc annulus together exert force against each of the fusion cages. Thus the fusion cages are held in place by compression forces between the adjacent vertebrae.

Because the cancellous bone of the vertebral bodies has internal strength similar to wet balsa wood and a hard shell similar to about a 1.5 mm veneer of white oak, it is difficult to drill parallel bores without the drill bits wandering into a common center, unless a drill guide or jig is provided. This problem is met by the following method of forming and threading a bore between adjacent vertebrae, which method involves the following steps:

(a) cutting away ligaments to expose the site,

(b) spreading the vertebrae apart,

(c) nibbling away as much of each lamina as is necessary to access the site,

(d) drilling a pilot hole laterally between said vertebrae, each of sufficiently small diameter to be self-seeking of the center of the disc space,

(e) inserting a pilot rod into the pilot hole,

(f) sliding over the pilot rod a hollow lamina drill to cut the spinous process and to score the lamina,

(g) drilling to remove the lamina within the score,

(h) fitting into the resulting arcuate opening in the lamina a C-retractor which has a split cylindrical sleeve of the same diameter as the lamina drill, a handle extending from one end toward the upper end of the spine, and spikes at its outer end,

(i) forcing at least one of the spikes into each of said adjacent vertebrae to anchor the C-retractor,

(j) reinserting the pilot rod to rest on the bottom of the pilot hole,

(k) sliding a hollow vertebral drill over the pilot rod and inside the sleeve of the C-retractor,

(l) forming with the hollow drill a bore that penetrates into the cortical bone of each of said vertebrae,

(m) removing the hollow drill, the pilot rod, and the cut bone, and

(n) using the C-retractor as a guide, tapping a female thread, the crown of which extends into the cancellous bone of each of the vertebrae.

As indicated in the drawing, said pilot rod and the shafts of said hollow lamina drill and tap having markings to show the depths to which they penetrate into the bore.

When male-thread fusion cages are to be positioned between adjacent vertebrae, the sides that are to face laterally preferably are closed to prevent disc tissue from growing into the cages, because this could interfere with bone growth between the

vertebrae. By leaving the lateral sides closed, the fusion cages have greater structural strength, thus permitting the perforations adjacent the vertebrae to be larger. When leaving the lateral quadrants closed, we have achieved 70% perforation of the area of the top and bottom quadrants (as projected onto the inner face of a cylinder) while maintaining good compressive strength.

End caps can help to prevent disc tissue from growing into the cages, and for this reason, any openings in the end caps should be small.

A large majority of patients requiring intervertebral fusions have narrowing of the disc space, typically 10 mm or less in the lower back. Because minimal penetration into the end plates of the vertebrae is required (about 3mm for each), three major diameters of the fusion cage thread should suffice for most patients, namely, 14, 16 and 18 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion cage preferably does not exceed 25 mm but is at least 20 mm in length to give sufficient contact as well as a good platform when implanted in pairs.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument.

Other instruments that have been developed for use in the implantation of the novel fusion cage include tapping instruments for forming helical

threads in a bore in recipient bone. A first novel tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slideably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using this first novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three, because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

Said first novel tapping instrument and a novel wrench are illustrated in the drawing, together with other instruments that can be used to implant male-thread fusion cages surgically.

THE DRAWINGS

In the drawing, all figures of which are schematic,

Fig. 1 is an exploded isometric view of a first V-thread fusion cage of the parent U.S. Patent Application S.N. 07/259,031 and two perforated end caps;

Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion cages of said U.S. Patent Application S.N. 07/259,031;

Fig. 3 is an isometric view of a first tapping instrument (partly cut away to reveal details of construction) for forming female threads in bores into which male-thread fusion cage is to be inserted;

Fig. 4 is an isometric view of a wrench for screwing a male-thread fusion cage into a threaded bore;

Fig. 5 is an exploded isometric view of a third male-thread fusion cage of said U.S. Patent Application S.N. 07/259,031;

Fig. 6 is a plan view of a pilot drill that can be used in preparation for forming a threaded bore laterally between two vertebrae into which a male-thread fusion cage can be surgically implanted;

Fig. 7 is a plan view of a pilot rod that also can be used in preparation for forming said threaded bore;

Fig. 8 is a plan view of a hollow lamina drill that can be used in conjunction with the pilot rod of Fig. 7;

Fig. 9 is an isometric view showing the use of a C-retractor in preparation for the surgical implantation of a pair of male-thread fusion cages between two vertebrae;

Fig. 10 is a plan view of a hollow vertebral drill that also can be used with the pilot rod of Fig. 7; and

Fig. 11 is a plan view of a second tapping instrument that can be used in conjunction with the C-retractor of Fig. 9 to tap a female thread in the bore formed by the hollow vertebral drill of Fig. 10.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The fusion cage 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally space holes 11 in the axial direction, each hold being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion cage to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion cage by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to Fig. 2, a series of fusion cages can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion cages each of which has perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion cage identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion cages in Figs. 1 and 2 could be made from a model by the lost wax process.

The tapping instrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end. Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown)

to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 31 to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to compete the tapping.

The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion cage to permit the fusion cage to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion cage.

Fig. 5 shows a third male-thread fusion cage 50 that has formed from a solid steel cylinder by drilling an axial bore 51 and then broaching out a pair of cylindrical channels 52 that extend to a diameter only a little smaller than the external surface of said cylinder. A V-thread 53 has then been machined in that external surface, thus creating perforations 54 in the valley between adjacent turns of the thread, each perforation extending completely across one of the channels 52. Each end of each land between the channels has been machined to have a recess 56 to enable an end cap 57 to fit flush with the end of the fusion cage. At each recess 56, each land has been formed with a small bore 58 into which one of a pair of projections 59 from the end cap 57 fits snugly to hold the end cap in place.

In Fig. 6, a pilot drill 60 has a T-handle 62 at one end of a shaft 63 and at the other end a collar 64 holding a bit 66. A set screw 68 in the collar permits the protruding length of the bit to be adjusted, and the larger diameter of the collar acts as a stop. Typically, the bit 66 extends 25 mm beyond the collar 64.

In Fig. 7, a pilot rod 70 has a cylindrical shaft 71, at one end of which is a cylindrical boss 72 that is 30 mm in length and slidably fits into a bore formed by the pilot drill 110 of Fig. 11. The boss 72 has two scribe marks 73 that indicate the depth in cm of the bore. At its other end, the shaft 71 is formed with a flat 75 that has scribe marks 76 marked to indicate 0, 1, 2 and 3 cm for purposes explained below.

Shown in Fig. 8 is a hollow lamina drill 80 which has a cutting edge 82 and a central bore 83 that slidably fits over the shaft 71 of the pilot rod 70. An anodized aluminum handle 84 permits a surgeon to drive the lamina drill by hand.

Shown in Fig. 9 is a C-retractor 90 which has a cylindrical sleeve 91 that is formed with an opening 92 across about one-fourth of its circumference over its full length. Extending from one end of the sleeve opposite to said opening 92 is a malleable handle 93 by which the cylindrical sleeve 91 can be fitted through the arcuate laminotomy (formed by the lamina drill 80) down to the vertebrae 94 and 95. At the other end of the sleeve 91 are four spikes 96 in two pairs, one pair on either side of a line that is 180° from the center of said opening 92. When the sleeve of the C-retractor 90 is concentric with a pilot bore that has been drilled laterally into the disc 97 between the two vertebrae 94 and 95, one pair of the spikes can be set into the dorsal surfaces of each vertebra after careful orientation to be concentric with the pilot rod 70 while it is seated in the pilot bore. As also shown in Fig. 9, one purpose of the sleeve 91 of the C-retractor 90 is to keep tools from contacting the dura 98 and the spinal nerve 99.

Shown in Fig. 10 is a hollow vertebral drill 100, the shaft 101 of which is formed with a central bore (not shown) that slidably fits over the shaft 71 of the pilot rod 70 while the C-retractor 90 is in place. At one end of the hollow drill are scalloped cutting edges 105, and at the other is a hard rubber handle 103 that permits a surgeon to drive the

vertebral drill by hand. Scribe marks 107 indicate 0, 1, 2 and 3 cm. The 0 mark is at the top of the cylindrical sleeve 91 of the C-retractor when the vertebral drill is first put into place, and it and the other marks sequentially disappear behind the cylindrical sleeve as the vertebral drilling progresses. At the same time the scribe marks 76 on the flat 75 of the shaft 71 of the pilot rod 70, appear behind the handle 103 of the vertebral drill. While the surgeon watches the disappearance of the scribe marks 107 on the vertebral drill, a surgical assistant holds the pilot rod at the proper attitude and monitors the progress of the drilling by watching the appearance of the scribe marks 76 on the pilot rod. The greater inside diameter of the C-retractor 90 compared to that of the scalloped cutting edges 105 affords to the surgeon the opportunity to make slight lateral corrections as the drilling progresses.

Shown in Fig. 11 is a second tapping instrument 110, the tap 112 of which slidably fits into the cylindrical sleeve 91 of the C-retractor 90. At the other end of its shaft 113 is a T-handle 114 by which a surgeon drives the tap until it reaches the depth of the bore.

Implanting the Fusion Cage of Fig. 1

In order to implant the fusion cage 10 between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminas of each side, namely standard laminotomies. The neural tissues, dural sac and nerves, are

retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x-ray. The height of the disc space is measured on the x-ray so that the proper sizes of drills, tap, and fusion cage may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about 25 mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion cage of the invention with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the

threaded intradiscal bore to its full depth. After removing the wrench, the cage is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion cage by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion cages and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion cages will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the vertical spine.

Example 1

The fusion cage of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

diameter of starting cylinder	16 mm
length of cylinder	25 mm
diameter of each small hole 11	3 mm
diameter of circle on which holes 11 are centered	11.5 mm
diameter of central hole	11 mm
pitch of V-thread 12	2.5 mm/turn

angle at crown of thread 12	60°
fillet radius in valley of thread 12	0.4 mm
axial width of perforation 13	1.6 mm
circumferential breadth of perfs. 13	2.8 mm
when projected onto interior of a cylinder, % of area perforated	25%

Example 2

The fusion cage of Fig.1 1 has been machined from a stainless-steel cylinder to have the same dimensions as that of Example 1 except that the diameter of the circle on which holes 11 were centered was increased to 12 mm. This results in 70% perforation in each of the areas of the top and bottom quadrants.

To test the compressive strength, a pine block was drilled to the outside diameter of the thread of the fusion cage, and a 1/4-inch section was cut away to leave two pieces, between which the fusion cage was placed with its perforations facing two pieces. A force of 808 pounds was applied before the fusion cage began to deform into an oval shape, thus indicating that it has much more than adequate compressive strength to withstand any forces to which it might be put when implanted between a person's vertebrae.

Example 3

A fusion cage, identical to that of Example 2 except that the cage was made from titanium, was tested in the same way for compressive strength. It resisted 850 pounds before beginning to deform.

Surgical Experience

The fusion cage of Example 2 has been surgically implanted in pairs between adjacent vertebrae of each of three persons. In each case after placement of the first cage, there was an impressive, instant stabilization of the previously unstable vertebral segment. Upon threading the second cage into its tapped hole, the segment became completely immobile.

Each of those three patients was able to tolerate sitting without low back pain by the second or third post-surgical day. This unexpectedly early comfort expressed by each of these three patients signified good, immediate stability to the previously painfully unstable spinal segment.

The first patient, on a routine visit at two months postoperative, had an almost full range of painless motion (bending, twisting) of the lumbar spine. The second patient, at 18 days postoperative, made an unscheduled visit to ask permission to go biking and reported a greater than 90% relief of all back and leg pains. The third patient showed approximately 1/3 range of normal painless motion of the lumbar spine on the sixth postoperative day.

What is claimed is:

1. Surgical method of fusing adjacent bony structures, said method comprising the steps of:

(a) forming between said bony structures a lateral bore with a female thread that penetrates into their cancellous regions,

(b) forming a hollow cylindrical fusion cage to have an external, substantially continuous helical thread that is perforated in the valley between adjacent turns and can mate with said female thread,

(c) screwing the cage into said threaded bore, and

(d) packing the cage with bone-inducing substance.

2. Method as defined in claim 1 wherein said threaded bore extends into the disc space between adjacent vertebrae, and prior to step (a) is the added step of spreading said vertebrae apart.

3. Method as defined in claim 2 wherein a second threaded bore is formed to extend into the opposite side of said disc space and parallel to said threaded bore, and steps (b), (c) and (d) are repeated to implant an identical fusion cage in said second threaded bore.

4. Method as defined in claim 1 wherein said female thread is formed in step (a) by hand tapping.

5. Method for surgically preparing two adjacent bony structures for implanting a hollow cylindrical fusion cage that has an external, substantially continuous helical thread and is perforated in the valley between adjacent turns of the thread, said method comprising the steps of:

(a) drilling a pilot hole laterally between said bony structures,

(b) inserting a pilot rod into the pilot hold,

(c) fitting a hollow drill over the pilot rod,

(d) with the hollow drill, enlarging said pilot hole to form a bore that penetrates into the cortical bone of each of said bony structures, and

(e) tapping a female thread into the wall of said bore, the crown of which penetrates into the cancellous portion of each of said bony structures, which female thread can mate with the helical thread of the fusion cage.

6. Method as defined in claim 5 wherein said bore extends laterally into the disc space between adjacent vertebrae.

7. Method as defined in claim 6 wherein steps (a) through (e) are repeated to form a second threaded bore parallel to the first, one on each side of the disc space.

8. Method as defined in claim 7 wherein each said female thread is formed in step (e) by hand tapping.

9. Method as defined in claim 5 and further comprising subsequent to step (e) the steps of:

(f) screwing the fusion cage into said threaded bore, and

(g) then filling the cage with bone-inducing substance.

10. Method as defined n claim 9 wherein the bone-inducing substance is cancellous bone chips.

11. Method for surgically preparing two adjacent vertebrae for implanting a hollow cylindrical fusion cage that has an external, substantially continuous helical thread and is perforated in the valley between adjacent turns of the thread, said method comprising the steps of:

(a) cutting away ligaments to expose the site,

(b) spreading the vertebrae apart,

(c) nibbling away as much of the lamina as is necessary to access the site,

(d) drilling a pilot hole laterally between said vertebrae, each of sufficiently small diameter to be self-seeking of the center of the disc space,

(e) inserting a pilot rod into the pilot hole,

(f) sliding over the pilot rod a hollow lamina drill to cut the spinous process and to score the lamina,

(g) drilling to remove the lamina within the score,

(h) fitting into the resulting arcuate opening in the lamina a C-retractor which has a split cylindrical sleeve of the same diameter as the lamina drill and a handle extending from one end toward the upper end of the spine,

(i) reinserting the pilot rod to reset on the bottom of the pilot hole,

(j) sliding a hollow vertebral drill over the pilot rod and inside the sleeve of the C-retractor.

(k) forming with the hollow drill a bore that penetrates into the cortical bone of each of said vertebrae,

(l) removing the hollow drill, the pilot rod, and the cut bone, and

(m) using the C-retractor as a guide, tapping a female thread, the crown of which extends into the cancellous bone of each of the vertebrae.

12. Method as defined in claim 11 and comprising the added step of maneuvering aside the dura and nerve with said split cylindrical sleeve of the C-retractor.

13. Method as defined in claim 12 wherein the C-retractor is formed with spikes extending axially from one end of said cylindrical sleeve, said method comprising the added step of forcing at least one of said spikes into each of said adjacent vertebrae to anchor the C-retractor.

14. A tapping instrument for forming a female thread in a bore into bone, said tapping instrument comprising:

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge at the leading edge of the external thread so that a female thread is formed in said bore upon rotation of the hollow shaft,

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with said scallop and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

15. A tapping instrument as defined in claim 14 and symmetrically formed with three scallops and cutting edges.

16. A tapping instrument as defined in claim 14 wherein said one end of the pilot rod has external threads which, when the threaded pilot rod is turned, carry detritus to be deposited through the scallops into the reservoir.

17. A C-retractor comprising a cylindrical sleeve that is split to form an opening across a small fraction of its circumference over its full length, a malleable handle extending from one end of the sleeve opposite to said opening, and spikes protruding axially from the other end of the sleeve.

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18. A C-retractor as defined in claim 17 and having four of said spikes in two pairs with one pair on either side of a line that is 180° from the center of said opening.

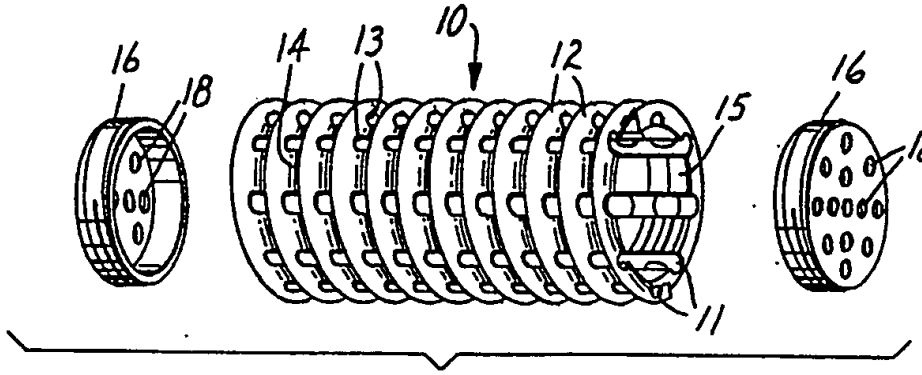

FIG. 1

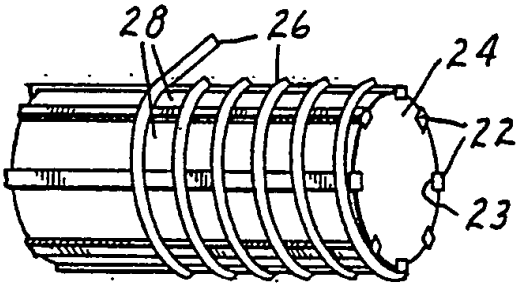

FIG. 2

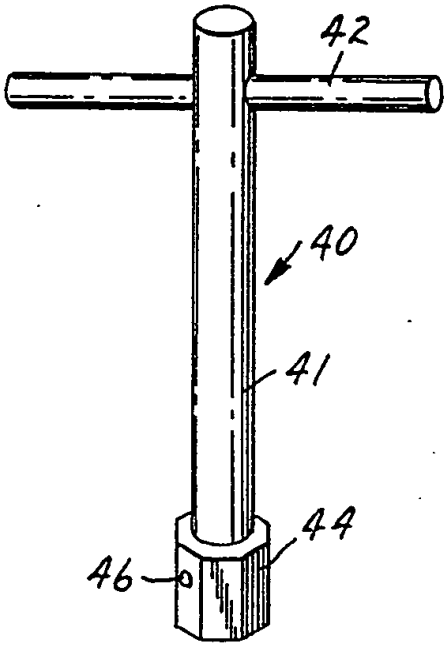

FIG. 4

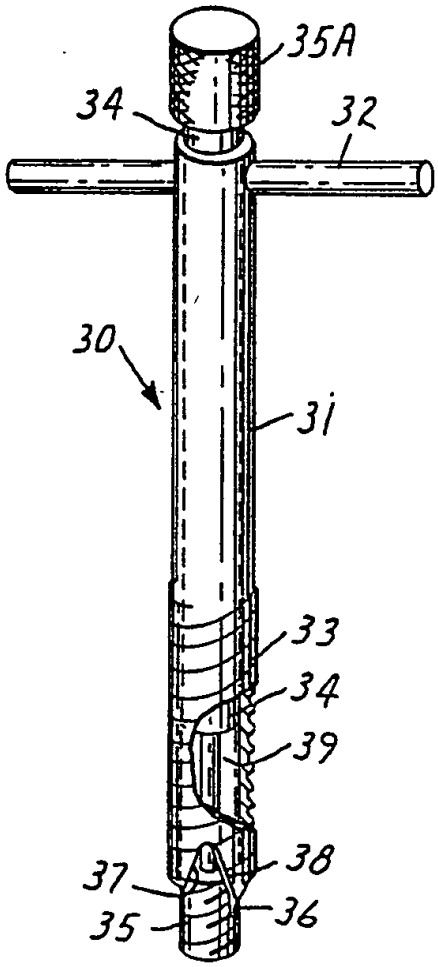

FIG. 3

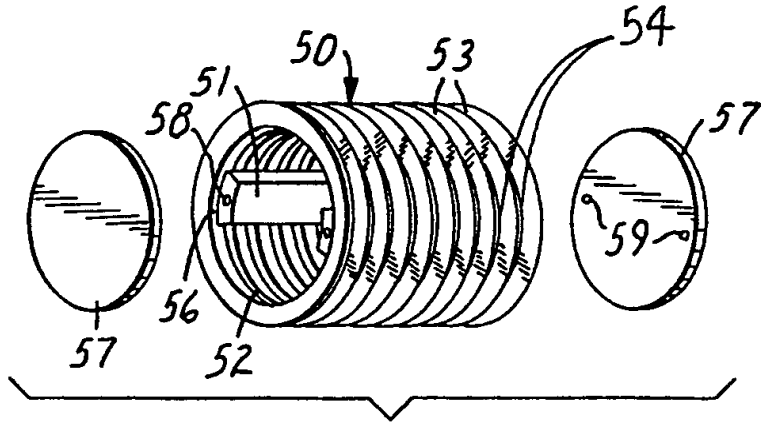

FIG.5

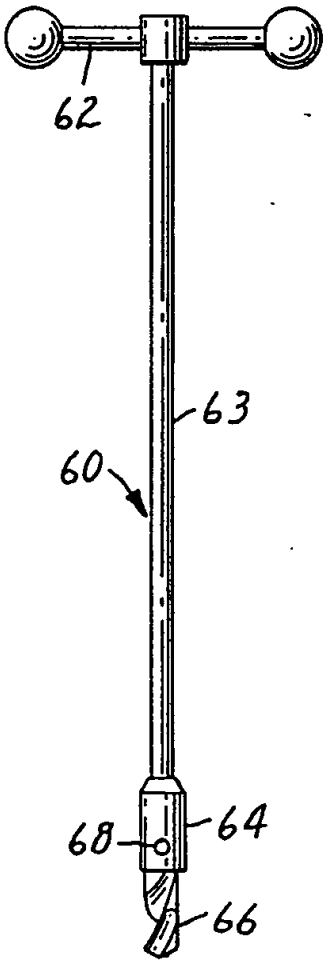

FIG.6

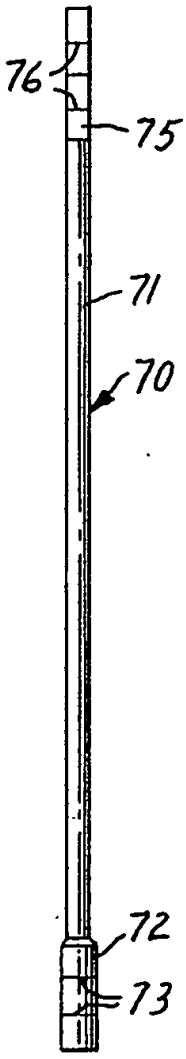

FIG.7

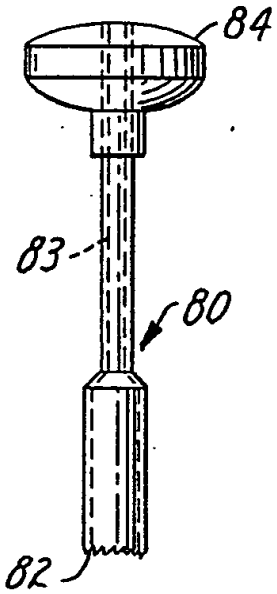

FIG.8

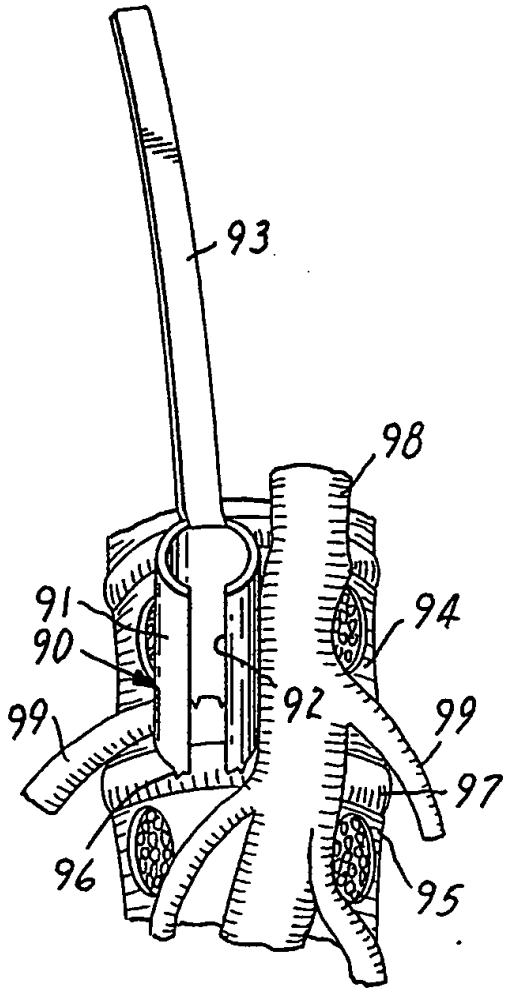

FIG. 9

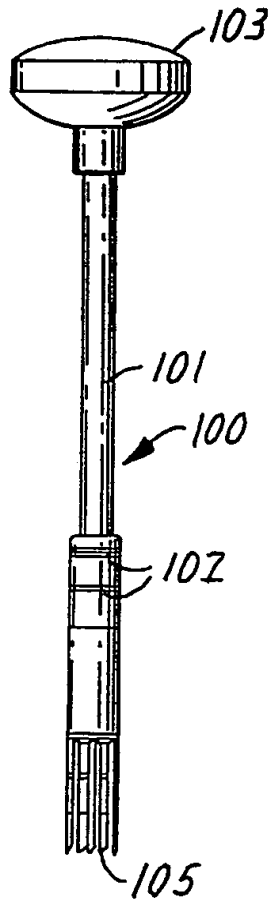

FIG.10

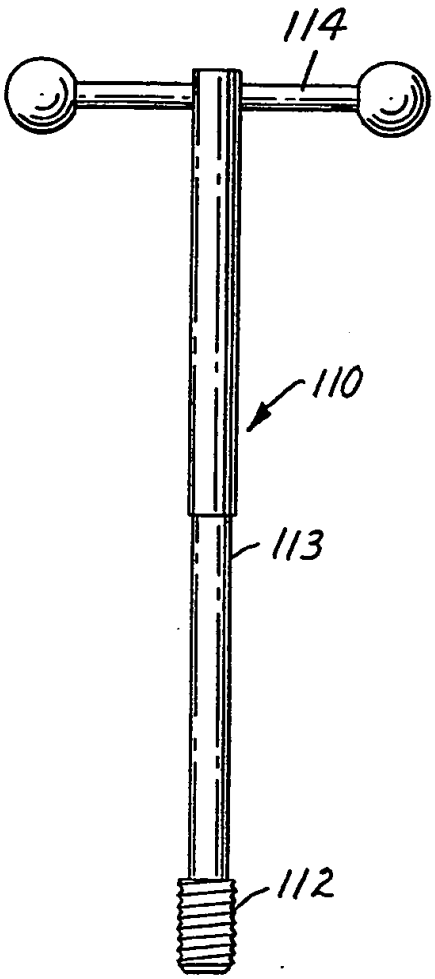

FIG.11

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/05318

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC [5]: A61F 2/44
US: 606/61,79,99;623;17

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	606/61,86,79,80,81,96,99,108 623/16-22

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US,A RE 31865 (ROUX) 16 April 1985	1-13
A	US,A 4492226 (BELYKH ET AL) 8 January 1985	
A	US,A 4599086 (DOTY) 8 July 1986	
A	US,A 4522200 (STEDNITZ) 11 June 1985	
A	US,A 4677972 (TORNIER) 7 July 1987	1-13
A	US,A 3783860 (BURSTEIN ET AL) 8 January 1974	
A	US,A 4059115 (JUMASHEV ET AL) 22 November 1987	14-16
A	US,A 4657550 (DAHER) 14 April 1987	
A	US,A 4501269 (BAGBY) 26 February 1985	
A	US,A 3848601 (MA ET AL) 19 November 1974	

* Special categories of cited documents: [15]

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
24 January 1991	08 MAR 1991
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	for KERRY OWENS

Form PCT/ISA/210 (second sheet) (May 1986)

DC 2-13-91

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
A	US, A 3651807 (HUGGINS) 28 March 1972 see figure 1	17,18
A	US, A 4585437 (SIMMS) 29 April 1986 see figure 1	17,18
A,P	US, A 4878915 (BRANTIGAN) 7 November 1989	1-16

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	DE, A 3505567 (VICH) 5 June 1986	
A	FR, A 2295729 (MAHAY + CIE) 23 July 1976	1-13
X Y	US, A 4802468 (DOWLAN) 7 February 1989 see figure 3	14 15
Y	US, A 4649918 (PEGG ET AL) 17 March 1987 see column 2, lines 47-50	15

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

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

1. ☐ Claim numbers . because they relate to subject matter [1] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . 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 [1], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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 of the international application.

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

3. ☐ 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 claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

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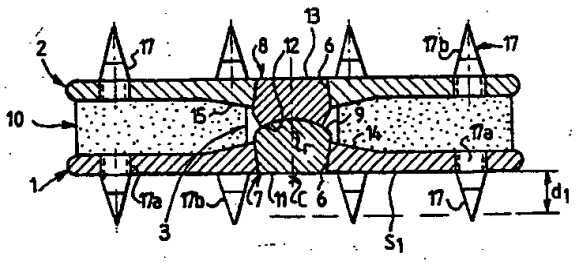
(54) Title: INTERVERTEBRAL DISK PROSTHESIS

(54) Titre: PROTHESE DISCALE INTERVERTEBRALE

(57) Abstract

Prosthesis comprising two plates (1, 2) secured to the corresponding vertebrae (L4, L5), and a ball joint linking the plates to one another, its centre of rotation (C), in an anterior-posterior plane (OX, OY) being offset rearwards in the posterior part of the plates. The ball joint with reference to a transversal plane (OX, OZ) is located substantially in the middle of the plates, and with reference to a vertical plane (OY, OZ) is located under the plate (1) of the lower vertebra (L5). The prosthesis also includes an elastic intercalary cushioning ring (10) having an opening (10a) for the passage of the joint (3) and being lodged in the space delimited between the plates and around the joint. This positioning of the centre of curvature (C) prevents straining of the articular apophyses during movements of the vertebrae, while the elastic ring (1) matches the prosthesis to the physiological lordosis of the vertebral column, cushioning the multiple stresses occurring during these movements.



(57) Abrégé

Cette prothèse comprend deux plaques (1, 2) fixées aux vertèbres correspondantes (L4, L5), et une rotule (3) d'articulation des plaques l'une sur l'autre, son centre de rotation (C), dans un plan antéro-postérieur (OX, OY) est décalé vers l'arrière dans la partie postérieure des plaques, dans un plan transversal (OX, OZ) est situé sensiblement au milieu des plaques, et dans un plan vertical (OY, OZ) est situé sous la plaque (1) de la vertèbre inférieure (L5); cette prothèse comporte de plus un anneau intercalaire d'amortissement (10), en une matière souple, percé d'une ouverture (10a) de passage de la rotule (3) et logé dans l'espace délimité entre les plaques et autour de la rotule. Ce positionnement du centre de courbure (C) évite de contraindre les apophyses articulaires lors des mouvements des corps vertébraux, tandis que l'anneau souple (10) adapte la prothèse à la lordose physiologique du rachis lombaire et permet l'amortissement des contraintes multiples lors des mouvements.

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Codes utilisés pour identifier les Etats parties au PCT, sur les pages de couverture des brochures publiant des demandes internationales en vertu du PCT.

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"Prothèse discale intervertébrale"

La présente invention a pour objet une prothèse discale intervertébrale.

Comme on le sait, un disque intervertébral se présente sous la forme d'une lentille biconvexe attachée par ses faces aux surfaces articulaires des corps vertébraux. Il est constitué d'une partie périphérique dure (annulus), formée de lamelles fibreuses concentriques, et d'une partie centrale (nucleus pulposus), gélatineuse et molle, constitué de minces faisceaux fibreux séparés par des espaces remplis d'un tissu muqueux. Un disque intervertébral est un élément déformable permettant tous les mouvements relatifs possibles (6 degrés de liberté) mais qui limite les amplitudes de ces derniers, notamment en torsion, en association avec les ligaments intervertébraux et les butoirs osseux. Le disque intervertébral est une structure viscoélastique d'amortissement, qui participe à la résistance et à la stabilité du rachis verticalisé en état de pesanteur.

Un disque intervertébral peut subir des altérations pour diverses raisons, notamment vieillissement et dégénérescence, pouvant provoquer des hernies discales.

La dégénérescence discale correspond à une destruction fonctionnelle puis anatomique du disque, qui semble résulter de l'effet des contraintes mécaniques sur un disque aux structures en voie de désorganisation. La dégénérescence discale modifie le comportement mécanique du disque et aboutit à une diminution de hauteur de l'espace intersomatique, laquelle entraîne une perturbation de l'ensemble fonctionnel disque-articulaires. Il en résulte une instabilité susceptible de provoquer des conséquences cliniques gênantes, notamment des lombalgies. Ainsi l'instabilité segmentaire entraîne un fonctionnement anormal des articulaires, induisant une réaction arthrosi-

que, source de douleurs et de processus ostéophytiques.

On a donc proposé de remplacer le disque déficient par un disque artificiel, dont de nombreux types de réalisations ont été envisagés. Ainsi certaines prothèses comportent des articulations ne supprimant aucun degré de liberté, alors que d'autres au contraire négligent totalement certains mouvements et n'autorisent au maximum qu'un degré de liberté. Les auteurs des premières prothèses considèrent que le disque artificiel ne doit en aucune manière imposer un mouvement, que la stabilité de l'unité fonctionnelle est assurée par la rétention des freins ligamentaires restants et qu'une articulation non contrainte garantit une liaison os/prothèse durable.

Les auteurs du second type de prothèse estiment physiologiquement inutiles certains degrés de liberté, et rétablissent un degré de liberté considéré comme essentiel. Ainsi on connaît une prothèse formant charnière n'autorisant la rotation qu'autour d'un axe transversal.

Les prothèses articulées peuvent être extrêmement variées et comporter notamment des matériaux présentant une certaine souplesse, ou bien mettre en oeuvre des moyens mécaniques tels que des ressorts.

Toutefois ces réalisations connues ne donnent pas entière satisfaction, par exemple parce que les frottements au niveau de l'articulation restent trop élevés (prothèse décrite dans le brevet FR 2 659 226), ou parce que l'on observe une instabilité de la prothèse en rotation. De plus, la prothèse décrite dans le brevet précité ne permet qu'une inclinaison et une flexion extension limitée à 10 degrés dans tous les plans, valeur faible en regard de la mobilité naturelle d'une vertèbre.

Il est encore actuellement relativement difficile de cerner les indications de l'arthroplastie discale, qui

est proposée notamment pour le traitement des lombalgies et sciatalgies par instabilité, des lombo-sciatiques post-disectomie , et des spondylolisthésis de grade I.

En fait, le but de l'implant constitué par la prothèse discale visée par l'invention est triple :

a) Etre dimensionné pour pouvoir restaurer une hauteur normale de l'espace intersomatique. En effet, la dégénérescence discale, modifiant le comportement mécanique du disque et aboutissant à une diminution de hauteur de l'espace intersomatique, entraîne une perturbation de l'ensemble fonctionnel disque-articulaires. Cette diminution de hauteur provoque une surcharge mécanique sur les facettes articulaires, arthrogène et source possible de lombalgie. Elle peut entraîner un déplacement vers le haut et en avant de l'articulaire supérieur de la vertèbre inférieure, aboutissant à un rétrécissement du trou de conjugaison, cause possible de sciatalgie.

b) Autoriser une mobilité physiologique entre les deux vertèbres instrumentées.

L'instabilité peut être consécutive à la dégénérescence discale ou induite par la chirurgie. Les limites entre mobilité normale et anormale ne sont pas encore définies avec précision. L'instabilité segmentaire entraîne un fonctionnement anormal des articulaires, induisant comme déjà indiqué une réaction arthrosique.

c) Posséder une stabilité intrinsèque et autoriser un mouvement intersomatique.

L'arthroplastie s'adresse à des cas où jusqu'à présent une arthrodèse est indiquée. Elle peut être une alternative intéressante à cette intervention, non dénuée de conséquences sur les étages adjacents. En effet, toutes les arthrodèses lombaires entraînent dans les segments

adjacents une augmentation des contraintes et un déplacement des centres de rotation, pouvant conduire à une hypermobilité.

Le suivi à long terme des zones adjacentes aux arthrodèses montre un pincement discal constant à partir de la quinzième année, et surtout un glissement ou un déplacement angulaire dont la fréquence augmente avec le recul. On peut aussi observer une arthrose importante, une hernie discale ou une spondylolyse acquise de cette néocharnière.

La prothèse discale visée par l'invention comprend deux plaques équipées de moyens de fixation aux vertèbres correspondantes, ainsi qu'un dispositif d'articulation des plaques l'une sur l'autre.

Conformément à l'invention, le dispositif d'articulation est une rotule dont le centre de rotation, dans un plan antéro-postérieur est décalé vers l'arrière dans la partie postérieure des plaques et du corps vertébral, dans un plan transversal est situé sensiblement au milieu des plaques et du corps vertébral, et dans un plan vertical est situé sous la plaque de la vertèbre inférieure ; cette prothèse comporte de plus un anneau intercalaire d'amortissement, réalisé en une matière souple, percé d'une ouverture de passage de la rotule et dimensionné pour se loger dans l'espace délimité entre les plaques et autour de la rotule en épousant sensiblement le contour des plaques.

Le positionnement du centre de courbure de la rotule tel que défini selon l'invention présente l'avantage d'éviter de contraindre les apophyses articulaires, comme dans les vertèbres naturelles, ce qui n'avait pas été jusqu'à présent obtenu avec les prothèses connues.

De plus la prothèse selon l'invention possède tout

à la fois la résistance mécanique nécessaire et des frottements réduits au niveau de l'articulation, grâce au dimensionnement approprié du système à rotule. En effet le centre de rotation n'est ni trop éloigné de l'articulation, ni trop proche de celle-ci, et permet ainsi de reproduire une mobilité proche de la mobilité naturelle.

D'autres particularités et avantages de l'invention apparaîtront au cours de la description qui va suivre, faite en référence aux dessins annexés qui en illustrent une forme de réalisation à titre d'exemple non limitatif.

La figure 1 est une vue en perspective éclatée d'une paire de vertèbres équipées des éléments constitutifs d'une prothèse discale selon une forme de réalisation de l'invention.

La figure 2 est une vue de dessus de la plaque inférieure de la prothèse discale de la Fig.1.

La figure 3 est une vue en coupe longitudinale suivant 3/3 de la Fig.2 de la prothèse selon l'invention dans une position où les deux plaques sont parallèles.

La figure 4 est une vue en élévation de la prothèse des Fig.1 à 3 dans une position où les deux plaques sont inclinées l'une par rapport à l'autre.

La figure 5 est une vue en coupe longitudinale suivant 5-5 de la Fig.6 d'une seconde forme de réalisation de l'invention.

La figure 6 est une vue de dessus de la prothèse de la Fig.5.

La figure 7 est une vue en élévation longitudinale de la prothèse des Fig.5 et 6 avec ses plaques parallèles.

La figure 8 est une vue similaire à la Fig.7 avec les plaques formant un angle entre elles.

Les figures 9, 10, 11 et 12 sont des vues en pers-

pective de quatre variantes d'exécution de la prothèse selon l'invention.

On voit à la Fig.1 deux vertèbres adjacentes, par exemple les vertèbres lombaires L5 et L4, pouvant être reliées par une prothèse discale. Cette prothèse comprend deux plaques 1 et 2, fixées respectivement à la vertèbre inférieure L5 et à la vertèbre supérieure L4, une articulation à rotule 3 des deux plaques 1 et 2 l'une sur l'autre, et un anneau souple 10 d'amortissement intercalé entre les deux plaques 1 et 2 et traversé par la rotule 3.

Les plaques 1, 2 sont similaires, ont des dimensions sensiblement égales à celles des vertèbres L5, L4 (ces vertèbres pouvant être situées à d'autres étages que L5-L4, y compris des étages non lombaires) et épousent approximativement le contour des surfaces articulaires associées. Chaque plaque 1, 2 présente ainsi un bord curviligne 4, sensiblement elliptique ou ovale, et un bord rectiligne 5, destiné à être contigu au canal rachidien, reliant les deux extrémités tronquées de l'ellipse 4. D'autre part chaque plaque 1, 2 est percée, dans sa partie centrale, d'un trou traversant 6 dans lequel est insérée une pastille 7, 8 respective, ayant un corps dimensionné pour pouvoir s'engager dans le trou 6 correspondant. Ce dernier peut être avantageusement conique, de même que les bases complémentaires des pastilles 7, 8, qui peuvent ainsi être solidarisées de manière amovible avec les plaques ou plateaux correspondant 1, 2.

Les pastilles 7, 8 constituent ensemble l'articulation 3 à rotule. La première pastille 7, insérée dans la plaque inférieure 1, présente une surface sphérique convexe 9, située en saillie par rapport à la face correspondante de la plaque 1, tandis que sa surface opposée 11, plane, affleure la face opposée, tournée vers

l'extérieur de la plaque 1. La pastille 8 de la plaque supérieure 2 fait également saillie de sa face tournée vers la plaque 1, et présente une surface sphérique concave 12. Le rayon de courbure de cette dernière est égal à celui (r) de la surface sphérique 9, afin de pouvoir glisser sur celle-ci en formant une articulation à rotule. La face opposée 13 de la pastille 8 est plane et affleure la face extérieure de la plaque 2.

Le centre de courbure ou de rotation C de la rotule 3, distant des surfaces 9 et 12 du rayon de courbure r, est localisé de la manière suivante :

- ce centre C est, dans un plan antéro-postérieur (OX, OY), décalé vers l'arrière dans la partie postérieure des plaques 1, 2 et des corps vertébraux;

- dans un plan transversal (OX, OZ), le centre de rotation C est situé sensiblement au milieu des plaques 1, 2 et des corps vertébraux;

- et dans un plan vertical (OY, OZ), le centre C est situé juste sous la plaque 1 recouvrant la face supérieure de la vertèbre inférieure, par exemple L5 dans l'exemple illustré à la Fig.1.

Ce positionnement du centre C correspond à un rayon de courbure r compris approximativement entre la hauteur de la prothèse quand les plaques 1, 2 sont parallèles, et la moitié de cette hauteur.

En pratique le centre de rotation C peut être situé, au-dessous de la surface inférieure S1 de la plaque 1 (Fig.3), à une distance d1 comprise entre 0mm - c'est-à-dire être sur la surface S1 elle-même - et environ 5mm selon le cas.

D'autre part, le centre de rotation C est placé à partir du milieu M du côté rectiligne 5 de la plaque 1, contigu au canal rachidien , à une distance du côté 5

comprise entre environ 1/3 et la moitié de la largeur L de la plaque 1 à partir du milieu M : sur la Fig.3 le centre C est donc situé sensiblement entre la distance d2 = 1/3.L et la distance d3 = 1/2.L.

A titre d'exemple numérique non limitatif d2=4mm, d3=10mm et L=20mm, de sorte que C se trouve dans une zone de 6mm de largeur environ.

La prothèse comporte de plus un anneau intercalaire d'amortissement 10, réalisé en une matière souple appropriée, percé d'une ouverture 10a de passage de la rotule 3. L'anneau souple 10 est dimensionné pour pouvoir être logé dans l'espace intercalaire délimité entre les plaques 1, 2 et autour de la rotule 3, en épousant sensiblement le contour des plaques.

A l'état libre non comprimé (Fig.1), l'anneau souple 10 a une épaisseur variable de sa partie antérieure à sa partie postérieure. Sa partie antérieure a une épaisseur maximum H, qui décroît régulièrement, de part et d'autre du centre du bord de cette partie antérieure, jusqu'à la partie postérieure de l'anneau 10, dont l'épaisseur h est ainsi nettement inférieure à H. L'anneau 10 se présente donc sous la forme d'une pièce asymétrique dont les faces opposées sont inclinées l'une par rapport à l'autre, en se rapprochant vers la partie postérieure.

Chaque plaque 1, 2 comporte, sur sa face de laquelle fait saillie la pastille correspondante 7, 8, une surépaisseur annulaire centrale 14, 15. Cette dernière est contiguë à la pastille associée 7, 8 qu'elle entoure en formant un renfort, venu de matière avec le reste de la plaque. De préférence, comme représenté, les renforts 14 et 15 ont une surface conique, dont l'épaisseur décroît à partir de la pastille 7, 8.

Dans chaque plaque 1, 2 sont ménagés un ensemble

de trous 16, convenablement répartis le long des bords de la plaque. Ces trous 16 sont agencés pour recevoir des picots 17, fixés dans la plaque 1, 2 par tout moyen convenable, tel que vissage de leur base cylindrique 17a. Leurs pointes 17b, impactées dans l'os sous-chondral des plateaux vertébraux, assurent la fixation des plaques 1, 2 aux vertèbres telles que L5 L4, L5...

Les pastilles 7, 8 formant l'articulation en rotule 3 sont de faibles dimensions par rapport à celles des plaques 1, 2, et sont de manière générale choisies en un matériau présentant les meilleures caractéristiques tribologiques possibles (caractéristiques mécaniques : statiques, dynamiques et résistance à l'usure), et bien entendu biostable. Leur coefficient de frottement doit être faible et leur durée de vie, ainsi que celle des plaques 1, 2, très élevée (par exemple 40 ans).

Ces pastilles 7, 8 peuvent être réalisées en un matériau approprié tel qu'une céramique notamment un oxyde fritté tel qu'alumine ou zircone, une pierre de synthèse, un alliage métallique avec traitement de surface (dépôt de diamant etc).

L'anneau souple 10 d'amortissement est, de préférence, avantageusement constitué en un élastomère de dureté appropriée.

Les plateaux 1, 2 sont prévus en nombre standard, adaptés à tous les morphotypes possibles des corps vertébraux. Les rotules 3 sont par contre en nombre supérieur, adaptées à la morphologie de chaque individu et de chaque étage vertébral. On peut ainsi réaliser une gamme de pièces (plaques 1, 2, rotules 3, anneaux souples 10) adaptées à toutes les hauteurs discales des patients et permettant des combinaisons en nombre infini, adaptées à

chaque cas particulier.

Outre les avantages techniques déjà mentionnés, la prothèse discale selon l'invention présente les avantages suivants .

Grâce au dimensionnement approprié de la rotule 3 et à la position de son centre d'articulation C, définis ci-dessus, les surfaces en frottement sont réduites et le frottement provoqué par le basculement des plaques 1, 2 l'une par rapport à l'autre (Fig.4) reste faible. Il en résulte une usure réduite des pastilles 7, 8. Par ailleurs les surfaces 9, 12 de l'articulation ont cependant un rayon de courbure suffisant pour ne pas entraîner une instabilité excessive de la prothèse, tout en lui assurant une mobilité tridimensionnelle convenable, pratiquement identique à celle des vertèbres naturelles.

Durant les mouvements tridimensionnels des plaques 1, 2 et des vertèbres correspondantes, l'anneau souple 10 assure une fonction d'amortissement des contraintes multiples qui limite les mouvements, les faces opposées de l'anneau 10 restant toujours en contact avec les faces correspondantes des plaques 1. La variation de la hauteur, ou de l'épaisseur de l'anneau 10 de l'avant vers l'arrière présente l'avantage de l'adapter à la lordose physiologique du rachis lombaire. Le rapport H/h s'adapte ainsi à la statique rachidienne de profil, en fonction de l'étage discal concerné. L'inclinaison des faces de l'anneau 10 l'une sur l'autre peut varier en fonction de l'étage et de la morphologie du patient. A titre d'exemple elle peut atteindre 15° en L5/S1.

Il convient par ailleurs d'observer que le fait que l'épaisseur de la partie antérieure de l'anneau 10 soit supérieure à celle de sa partie postérieure permet une mise en jeu plus précoce du matériau souple consti-

tutif de cet anneau. Ceci entraîne donc la production d'un effet amortisseur dès l'apparition d'un mouvement des corps vertébraux associés à la prothèse. D'autre part, le choix convenable d'un matériau souple pour l'anneau 10, permet l'obtention d'une raideur optimale pour reproduire les pentes des rotations d'un disque sain dans les diverses sollicitations. Finalement, la prothèse selon l'invention permet d'obtenir une raideur et un amortissement très proches ou même identiques à ceux d'un disque naturel.

La mise en place par le chirurgien de la prothèse qui vient d'être décrite se fait que la manière suivante.

Tout d'abord le chirurgien place sur la vertèbre inférieure, par exemple L5, la plaque correspondante 1, la centre convenablement par rapport au corps vertébral, et la fixe par enfoncement des picots 17 dans la vertèbre.

Ensuite le chirurgien met en place sur la vertèbre supérieure, par exemple L4, la plaque supérieure 2, en la positionnant convenablement par rapport à la plaque inférieure 1.

Le chirurgien dispose ensuite entre les plaques 1, 2 un "sandwich" composite constitué par l'assemblage de l'anneau souple 10 et de la rotule 3, formée par les pastilles 7, 8. Il place cet assemblage dans la zone centrale entre les plaques 1, 2, avec les pastilles 7, 8 en regard des trous coniques 6, puis relâche la distraction imposée jusque là aux corps vertébraux recevant les plaques 1, 2. Il en résulte une impaction qui provoque l'entrée des bases coniques des pastilles 7, 8 dans les trous 6, et leur solidarisation à force avec les plaques 1, 2.

Les valeurs des amplitudes angulaires des mouvements possibles avec la prothèse selon l'invention sont

proches des amplitudes ci-dessous d'un disque sain :

	L4/L5	L5/S1
- Flexion/extension	24°	18°
- Inclinaison	14°	≤14°
- Rotation axiale	4°	4°

La prothèse selon l'invention garantit par sa solidité la restauration de l'espace intersomatique de hauteur H, tout en présentant une stabilité intrinsèque, c'est-à-dire n'autorisant pas une mobilité non physiologique, surtout en translation.

Les matériaux susceptibles d'être utilisés pour la constitution de la prothèse sont bien entendu biocompatibles et doivent être biologiquement neutres, c'est-à-dire non toxiques, insensibles à la corrosion. De plus ils ne doivent pas être pro-inflammatoires, leurs qualités mécaniques et biologiques ne devant pas être altérées par le mode de stérilisation choisi. A titre d'exemple les plaques 1, 2 peuvent être en acier inoxydable, stellite titane ou alliage de titane.

L'alliage de titane présente l'avantage de posséder des caractéristiques radiologiques et magnétiques avantageuses pour le suivi iconographique de la pathologie rachidienne, ainsi qu'une excellente biotolérance et des caractéristiques mécaniques élevées.

Dans la seconde forme de réalisation de l'invention, illustrée aux Fig.5 à 8, chaque pastille 21 et 22 est logée dans une cuvette respective 23, 24 de réception formée dans la plaque support 25, 26 associée. Les pastilles 21, 22 font partiellement saillie de leurs cuvettes 23, 24 de logement, dans lesquelles elles sont montées librement, et non à force. Autour de chaque cuvette et de

chaque pastille, la surépaisseur annulaire 29, 31 est conique et a une hauteur au sommet h1 sensiblement égale à l'épaisseur d de la plaque 25, 26.

Les pastilles 21, 22 sont coniques, de même que leurs cuvettes de réception 23, 24, et ont un angle de conicité de 1 à 7° environ, et de préférence de 5°.

Par ailleurs la prothèse illustrée aux Fig.5 à 8 est similaire à celle des Fig.1 à 4, notamment pour le positionnement du centre de rotation C. L'anneau souple d'amortissement 10 n'a toutefois pas été représenté.

L'agencement de cuvettes 23, 24 de réception des pastilles 21, 22 dont les dimensions extérieures correspondent aux dimensions intérieures des cuvettes, dans lesquelles elles ne sont pas fixées et dont elles peuvent être aisément enlevées si nécessaire après un certain temps, sans devoir désolidariser les plaques 25, 26 des vertèbres et les remplacer, présente un avantage appréciable. En effet elle permet d'éviter aux plaques une flexibilité locale au niveau des trous traversants 6 de la réalisation précédente, flexibilité qui n'est pas souhaitable en raison des efforts localisés de serrage auxquels sont soumis les pastilles.

Bien entendu celles-ci peuvent en variante être de forme cylindrique, ainsi que les parois des cuvettes correspondantes. Mais cette géométrie ne facilite pas la pose et ultérieurement la dépose éventuelle des pastilles. On a en effet constaté qu'il pouvait se produire une adhésion appréciable des parois des pastilles aux parois des cuvettes, de nature à gêner leur dépose.

C'est la raison pour laquelle la légère conicité des pastilles 21, 22 et de leurs cuvettes 23, 24 a été avantageusement prévue, car elle évite cet inconvénient.

Les efforts exercés par le corps du patient sur

les plaques 25, 26 sont réduits du fait de la présence des fonds 27, 28, d'épaisseur e suffisante, par exemple les 3/4 de l'épaisseur d de chaque plaque ou même cete valeur d. Ainsi les plaques ne présentent aucune faiblesse mécanique locale à la flexion.

Le renfort ou surépaisseur annulaire 29, 31 de chaque plaque 25, 26 accroît par ailleurs la surface des faces en contact entre les parois coniques des cuvettes 23, 24 et des pastilles 21, 22, grâce à l'augmentation de leur hauteur par rapport aux surépaisseurs 14, 15 de la réalisation précédente. Cette augmentation est en effet nécessitée par l'aménagement des fonds 27, 28.

Une telle disposition permet de réaliser une prothèse dont la hauteur totale peut être adaptée à la hauteur désirée par le chirurgien, après consultation des radiographies du système rachidien local de l'opéré.

Pour obtenir la hauteur totale à conférer à la prothèse, le chirurgien dispose d'un jeu de plusieurs rotules 21, 22 dont la hauteur est progressivement croissante, par exemple 11, 13 et 15 centimètres. Pour chacun de ces jeux, le rayon de courbure des faces en contact 9, 12 formant la rotule est adapté pour qu'il soit compris approximativement entre la hauteur H1 de la prothèse lorsque les plaques 25, 26 sont parallèles entre elles (comme représentées à la Fig.7), et la moitié de cette hauteur.

La Fig.8 illustre la position respective des plaques 25, 26 dans leur ouverture angulaire maximum A, par exemple 32° environ.

Les Fig.9 à 12 illustrent diverses variantes de réalisation possibles des moyens de fixation des plaques ou plateaux aux corps vertébraux, en remplacement des picots 17. Ainsi la Fig.9 montre des plateaux 32, 33 dont

la surface 34 tournée vers les vertèbres est moletée, la Fig.10 montre des plateaux 35, 36 à surface ondulée 37, la Fig.11 montre des plateaux 38, 39 comportant des surfaces bombées 41.

La Fig.12 montre des plateaux 42, 43 dont les surfaces 44 d'appui aux corps vertébraux ont subi un traitement adapté : fixation d'un tissu métallique de manière connue en soi, projection d'un métal ou d'une céramique, ou revêtement de collage.

Ce traitement de surface peut du reste être combiné aux variantes des Fig.9 à 11 pour être appliqué aux surfaces 34, 37, 41.

Les picots 17 peuvent aussi être remplacés par des vis ou plots.

En revanche, la fixation par ciment (méthylméthacrylate) n'est pas envisageable, compte tenu de la proximité des éléments nerveux et du dégagement de chaleur lors de la polymérisation. Pour des étages non lombaires, l'anneau souple 10 peut ne pas présenter l'asymétrie décrite et donc avoir une épaisseur uniforme.

Il convient d'observer que la prothèse discale selon l'invention ne comporte pas de pièce libre, contrairement à certaines prothèses discales connues. Ceci présente l'avantage d'éliminer tout risque d'éjection d'une telle pièce libre contre l'aorte ou vers le canal rachidien.

REVENDICATIONS

1. Prothèse discale intervertébrale, comprenant deux plaques (1, 2) équipées de moyens de fixation aux vertèbres correspondantes (L4, L5), et un dispositif (7, 8) d'articulation des plaques l'une sur l'autre, caractérisée en ce que le dispositif d'articulation est une rotule (3) dont le centre de rotation (C), dans un plan antéro-postérieur (OX, OY) est décalé vers l'arrière dans la partie postérieure des plaques et du corps vertébral, dans un plan transversal (OX, OZ) est situé sensiblement au milieu des plaques et du corps vertébral, et dans un plan vertical (OY,OZ) est situé sous la plaque (1) de la vertèbre inférieure (L5), et en ce que cette prothèse comporte de plus un anneau intercalaire d'amortissement (10), réalisé en une matière souple, percé d'une ouverture (10a) de passage de la rotule (3) et dimensionné pour se loger dans l'espace délimité entre les plaques et autour de la rotule en épousant sensiblement le contour des plaques.

2. Prothèse selon la revendication 1, caractérisée en ce que l'articulation à rotule (3) est constituée par une première pastille (7) à surface sphérique convexe (9) et une seconde pastille (8) à surface sphérique concave (12) recevant la surface sphérique convexe, ces deux surfaces sphériques ayant le même rayon de courbure (r) et les pastilles étant montées dans les parties centrales des plaques respectives (1, 2), sur les faces en vis-à-vis desquelles elles font saillie.

3. Prothèse selon la revendication 2, caractérisée en ce que, chaque plaque (1, 2 ; 25,26) ayant un côté rectiligne (5) destiné à être positionné près du canal rachidien et un contour (4) complémentaire sensiblement ovale, ou elliptique, la pastille (7; 22) à surface

sphérique convexe (9) est montée dans la plaque (1; 26) de la vertèbre inférieure et son centre de rotation (C) est situé, à partir du milieu (M) du côté rectiligne de la plaque contigu au canal rachidien, à une distance dudit côté comprise entre environ un tiers (d2) et la moitié (d3) de la largeur (L) de la plaque à partir dudit milieu et sous la plaque de la vertèbre inférieure, le centre de rotation est situé à une distance (d1) de la plaque comprise entre 0 et environ 5mm.

4. Prothèse selon la revendication 2 ou 3, caractérisée en ce que chaque plaque (1,2; 25,26) comporte, sur la face de laquelle fait saillie la pastille (7, 8; 21,22), une surépaisseur annulaire centrale (14,15; 29,31), contiguë à la pastille qu'elle entoure en formant renfort.

5. Prothèse selon la revendication 4, caractérisée en ce que le renfort (14,15; 29,31) a une surface conique, dont l'épaisseur (h1) décroît à partir de la pastille (7, 8).

6. Prothèse selon l'une des revendications 2 à 5, caractérisée en ce que les pastilles (7,8; 21,22) ont une base conique adaptée à des trous coniques conjugués ménagés dans les plaques (1,2; 25,26).

7. Prothèse selon l'une des revendications 1 à 6, caractérisée en ce que les moyens de fixation des plaques (1,2; 25,26...) aux vertèbres (L5, L4) comprennent des picots coniques (17) vissés dans des trous (16) formés dans les plaques et convenablement répartis sur celles-ci, ou un moletage (34), ou une surface ondulée (37), ou une surface bombée (41).

8. Prothèse selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la fixation des plaques (42, 43) aux vertébres est assurée par un tissu métallique

(44), un métal ou une céramique projeté(e) sur la surface de la plaque en regard de la vertèbre, ou par collage, ou encore par combinaison de l'un de ces moyens avec, soit une surface moletée (34) ou ondulée (37) ou bombée (41).

9. Prothèse selon l'une des revendications 1 à 8, caractérisée en ce que les plaques (1,2; 25,26...) ont des dimensions identiques et sensiblement égales à celles d'une vertèbre, notamment lombaire.

10. Prothèse selon l'une des revendications 1 à 9, caractérisée en ce que l'anneau souple (10) d'amortissement a une partie antérieure d'épaisseur maximum (H), supérieure à celle (h) de sa partie postérieure, ladite épaisseur (H) décroissant régulièrement du centre du bord de la partie antérieure à la partie postérieure, et les faces opposées de l'anneau (10), à l'état non comprimé, sont corrélativement inclinées l'une par rapport à l'autre.

11. Prothèse selon l'une des revendications 1 à 10, caractérisée en ce que les pastilles (7,8; 21,22) de la rotule (3) sont réalisées en l'un des matériaux suivants: céramique notamment oxyde fritté tel qu'alumine ou zircone, pierre de synthèse, alliage métallique avec traitement de surface.

12. Prothèse selon l'une des revendications 1 à 11, caractérisée en ce que l'anneau souple (10) est en élastomère de dureté appropriée.

13. Prothèse selon l'une des revendications 2 à 12, caractérisée en ce que chaque pastille (21, 22) est logée dans une cuvette (23, 24) de réception formée dans la plaque support (25, 26) dont elle fait partiellement saillie et dans laquelle elle est montée librement.

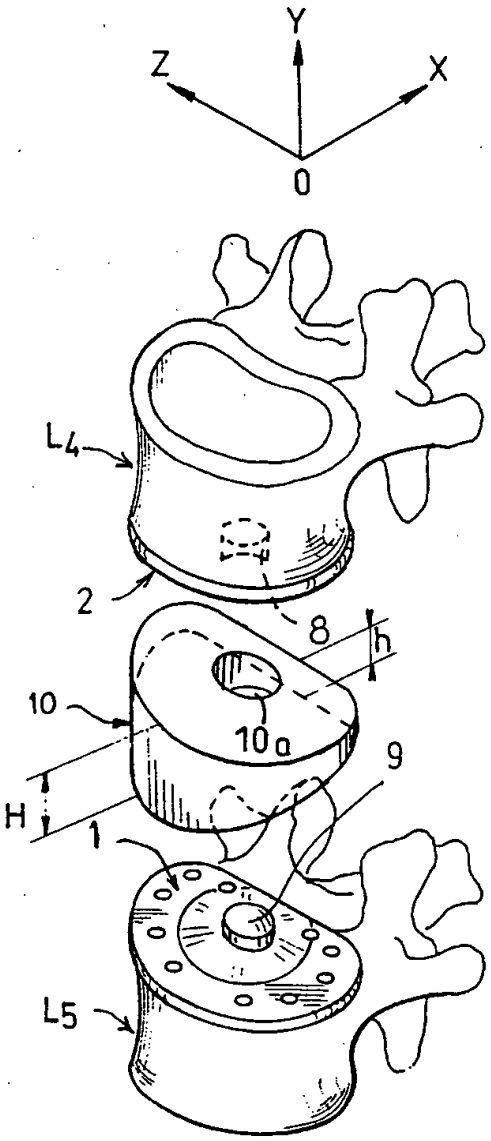
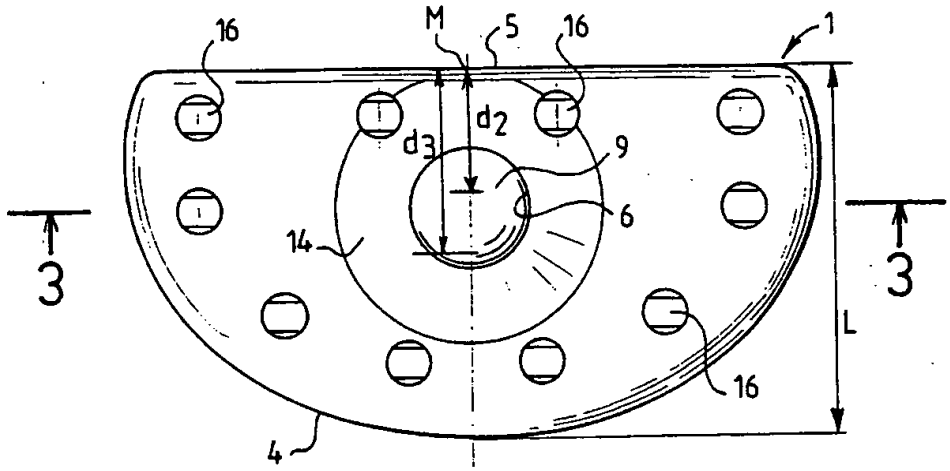
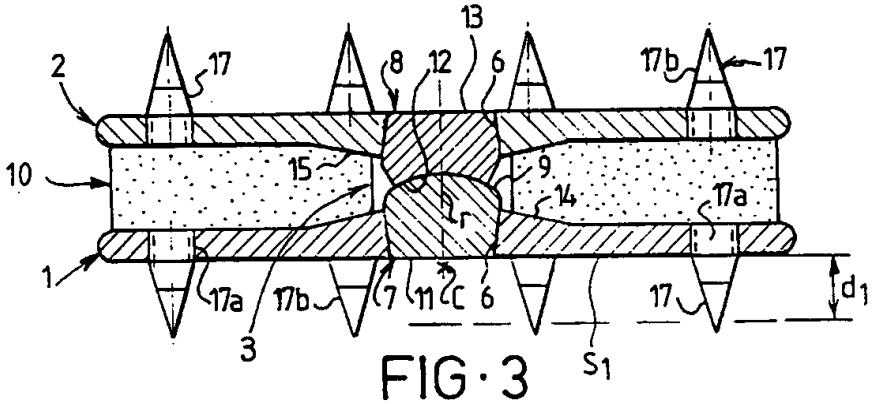


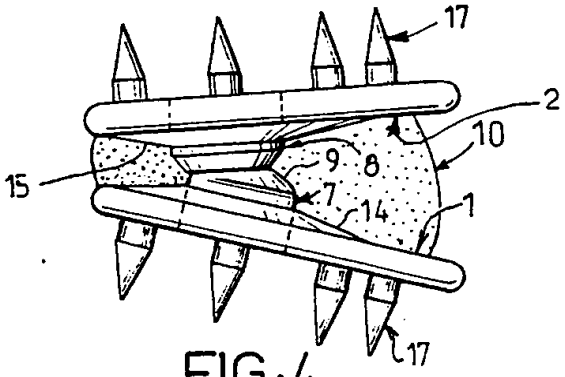
FIG.1



FIG·2



FIG·3



FIG·4

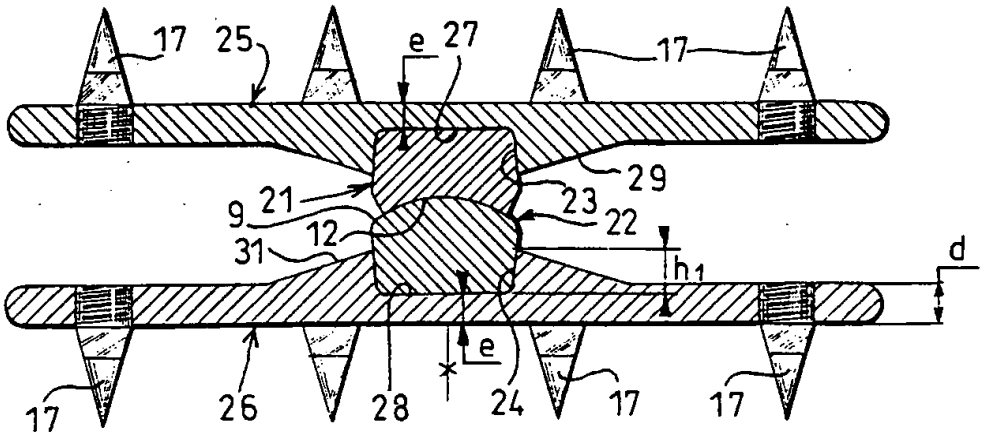

17
25
e
27
17
29
9
21
23
22
31
12
h1
d
e
17
26
28
24
17
17

FIG.5

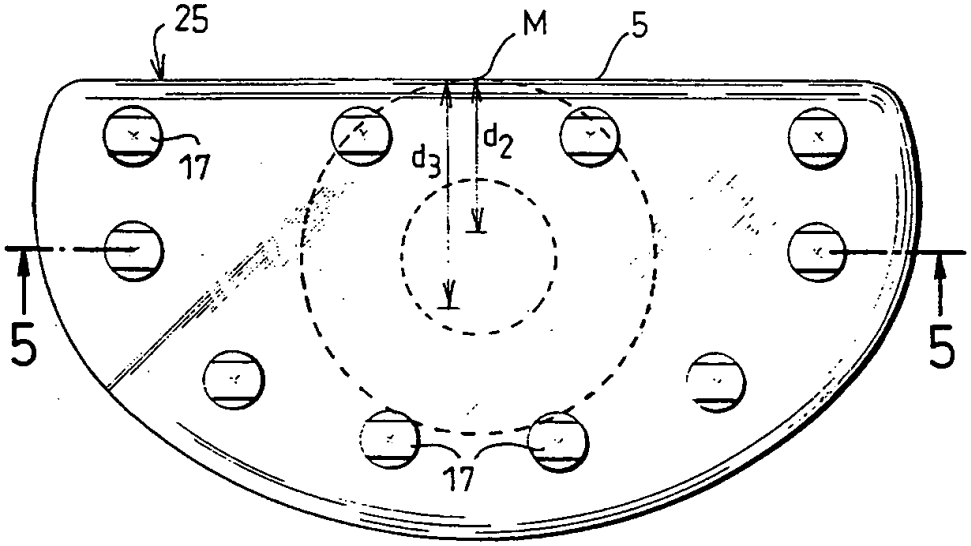
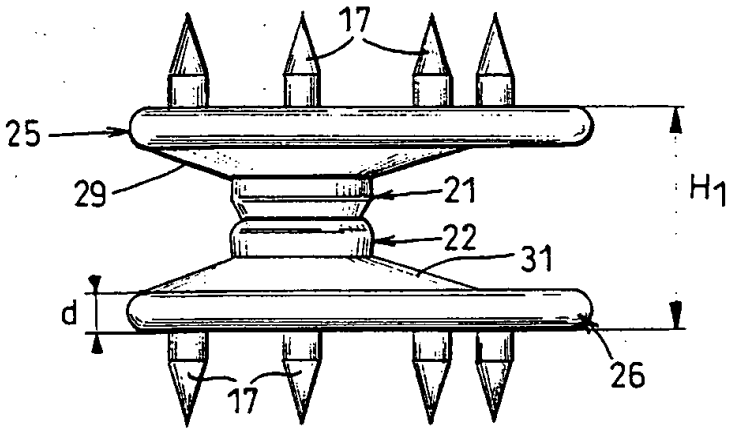

25
M
5
17
d3
d2
5
5
17

FIG.6

FIG.7



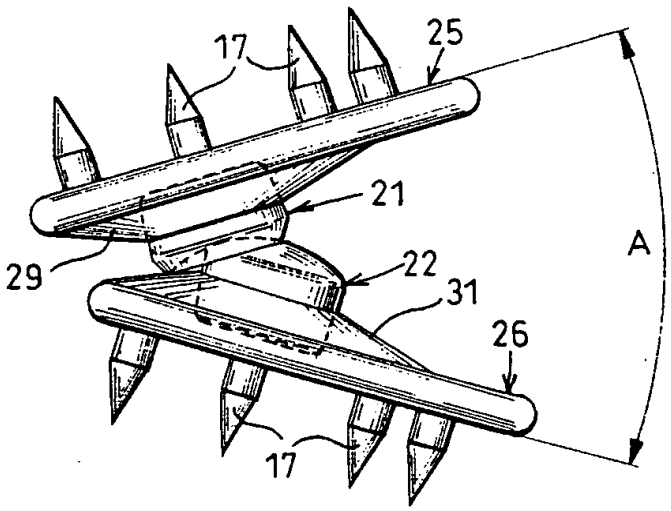


FIG.8

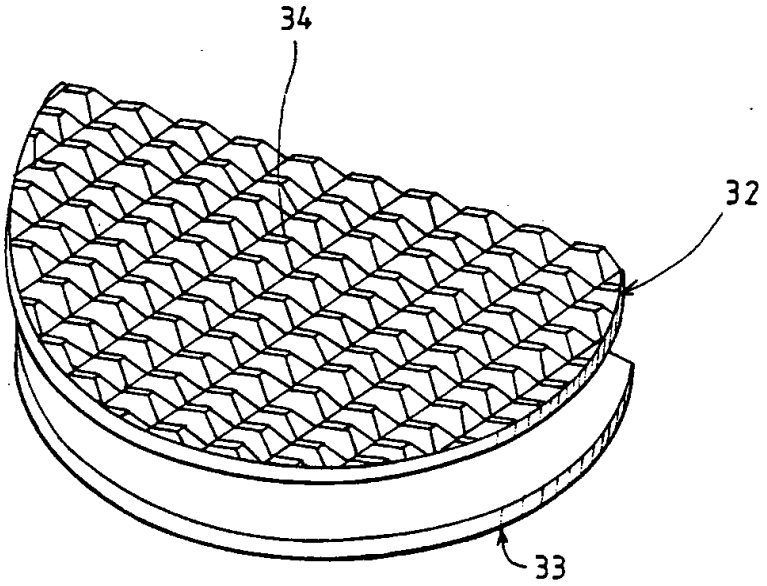


FIG.9

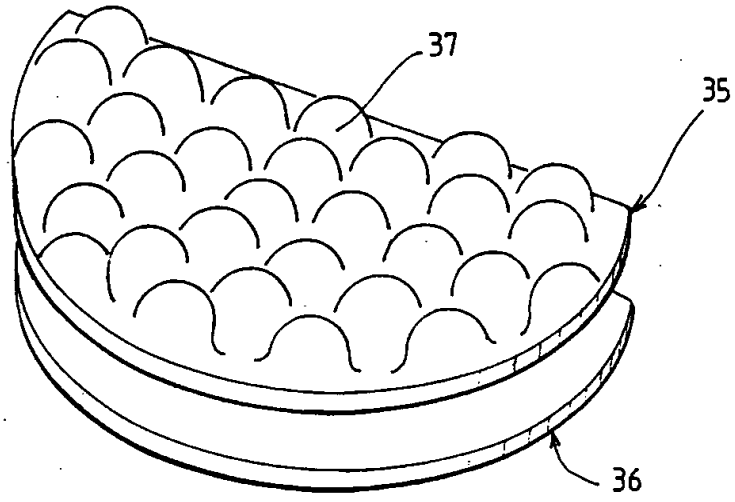


FIG.10

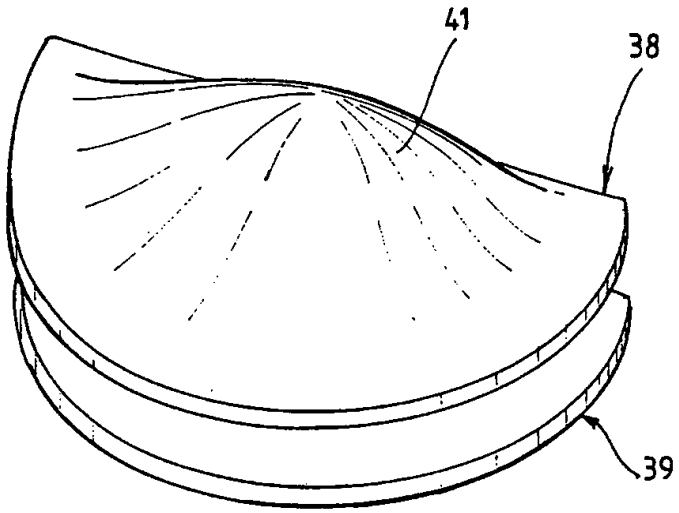


FIG.11

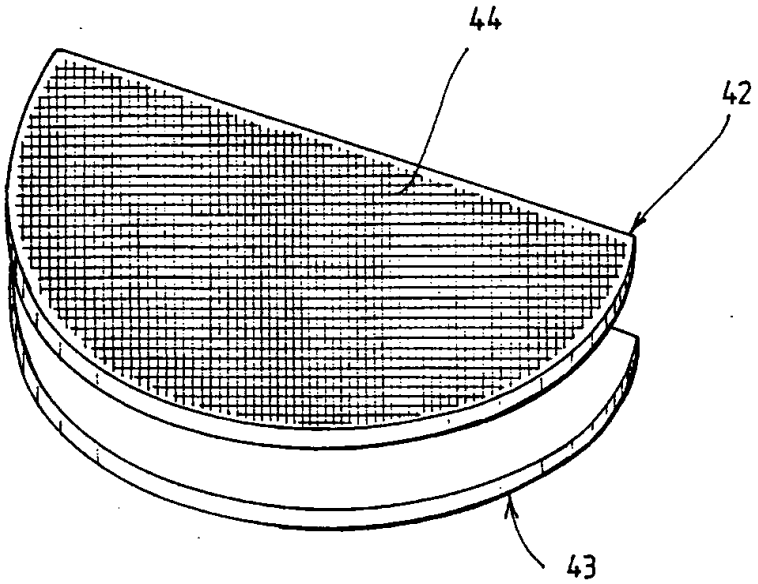


FIG.12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FR 93/00825

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl.5 A61F2/44; A61L27/00; A61F2/30

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)

Int.Cl.5 A61F

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4 759 769 (HEDMAN) 26 July 1988	1,9,12
A	see abstract see column 2, line 44 - column 3, line 15; figures 1,2,8	11
Y	DE, A, 2 263 842 (HOFFMANN-DAIMLER) 4 July 1974	1,9,12
A	see page 18, line 23 - page 19, line 25; claim 4; figure 9	2,4,5,11
A	WO, A, 9 113 598 (MARNAY) 19 September 1991 see page 10, line 16 - page 11, line 3; claim 1; figures 1-3 cited in the application	1,2,7,9, 13
A	US, A, 4 932 975 (MAIN) 12 June 1990 see column 2, line 45 - column 3, line 16	1,9,11, 12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 1993 (06.10.93)	12 October 1993 (12.10.93)
Name and mailing address of the ISA/ EUROPEAN PATENT OFFICE Facsimile No.	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FR 93/00825

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	see column 3, line 46 - line 59; figures 1,8,12	
A	US, A, 4 714 469 (KENNA) 22 December 1987 see column 3, line 52 - line 58; figures 1-3	3,7,8
A	WO, A, 9 011 740 (ROBERT BOSCH) 18 October 1990 see claims; figures	3,10-12
A	DE, U 8 912 648 (MECRON) 22 November 1990 see claim 1; figures	7,8
A	US, A, 4 309 777 (PATIL) 12 January 1982 see column 2, line 7 - line 13; figures 1,4	7,9
A	EP, A, 0 298 235 (SULZER) 11 January 1989 see column 3, line 15 - line 21; figures 1-3	8
A	DE, A, 3 023 353 (SULZER) 9 April 1981 see page 4, line 21 - line 25; figures	8

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

FR 9300825
SA 78503

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 06/10/93

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4759769	26-07-88	CA-A-	1283501	30-04-91
		DE-A-	3873566	17-09-92
		EP-A,B	0282161	14-09-88
		JP-A-	1308557	13-12-89
DE-A-2263842	04-07-74	None		
WO-A-9113598	19-09-91	FR-A-	2659226	13-09-91
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		EP-A-	0471821	26-02-92
		JP-T-	4505574	01-10-92
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US-A-4714469	22-12-87	AU-B-	588724	21-09-89
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US-A-4309777	12-01-82	None		
EP-A-0298235	11-01-89	CH-A-	672589	15-12-89
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		US-A-	4917704	17-04-90
DE-A-3023353	09-04-81	CH-A-	640131	30-12-83

EPO FORM P0479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale No PCT/FR 93/00825

I. CLASSEMENT DE L'INVENTION (si plusieurs symboles de classification sont applicables, les indiquer tous) [7]

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

CIB 5 A61F2/44; A61L27/00; A61F2/30

II. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée[8]

Système de classification	Symboles de classification
CIB 5	A61F

Documentation consultée autre que la documentation minimale dans la mesure où de tels documents font partie des domaines sur lesquels la recherche a porté[9]

III. DOCUMENTS CONSIDERES COMME PERTINENTS[10]

Catégorie *	Identification des documents cités, avec indication, si nécessaire,[12] des passages pertinents [13]	No. des revendications visées [14]
Y	US,A,4 759 769 (HEDMAN) 26 Juillet 1988	1,9,12
A	voir abrégé voir colonne 2, ligne 44 - colonne 3, ligne 15; figures 1,2,8	11
Y	DE,A,2 263 842 (HOFFMANN-DAIMLER) 4 Juillet 1974	1,9,12
A	voir page 18, ligne 23 - page 19, ligne 25; revendication 4; figure 9	2,4,5,11
A	WO,A,9 113 598 (MARNAY) 19 Septembre 1991 voir page 10, ligne 16 - page 11, ligne 3; revendication 1; figures 1-3 cité dans la demande	1,2,7,9, 13

-/--

* Catégories spéciales de documents cités:[11]

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent

"E" document antérieur, mais publié à la date de dépôt international ou après cette date

"L" document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée)

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"P" document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée

"T" document ultérieur publié postérieurement à la date de dépôt international ou à la date de priorité et n'appartenenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention

"X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive

"Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier.

"&" document qui fait partie de la même famille de brevets

IV. CERTIFICATION

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
06 OCTOBRE 1993	12. 10. 93
Administration chargée de la recherche internationale	**Signature du fonctionnaire autorisé**
OFFICE EUROPEEN DES BREVETS	KLEIN C.

Formulaire PCT/ISA/210 (deuxième feuille) (Janvier 1985)

III. DOCUMENTS CONSIDERES COMME PERTINENTS [14] (SUITE DES RENSEIGNEMENTS INDIQUES SUR LA DEUXIEME FEUILLE)

Catégorie *	Identification des documents cités, [16] avec indication, si nécessaire des passages pertinents [17]	No. des revendications visées [18]
A	US,A,4 932 975 (MAIN) 12 Juin 1990 voir colonne 2, ligne 45 - colonne 3, ligne 16 voir colonne 3, ligne 46 - ligne 59; figures 1,8,12	1,9,11, 12
A	US,A,4 714 469 (KENNA) 22 Décembre 1987 voir colonne 3, ligne 52 - ligne 58; figures 1-3	3,7,8
A	WO,A,9 011 740 (ROBERT BOSCH) 18 Octobre 1990 voir revendications; figures	3,10-12
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A	US,A,4 309 777 (PATIL) 12 Janvier 1982 voir colonne 2, ligne 7 - ligne 13; figures 1,4	7,9
A	EP,A,0 298 235 (SULZER) 11 Janvier 1989 voir colonne 3, ligne 15 - ligne 21; figures 1-3	8
A	DE,A,3 023 353 (SULZER) 9 Avril 1981 voir page 4, ligne 24 - ligne 25; figures	11

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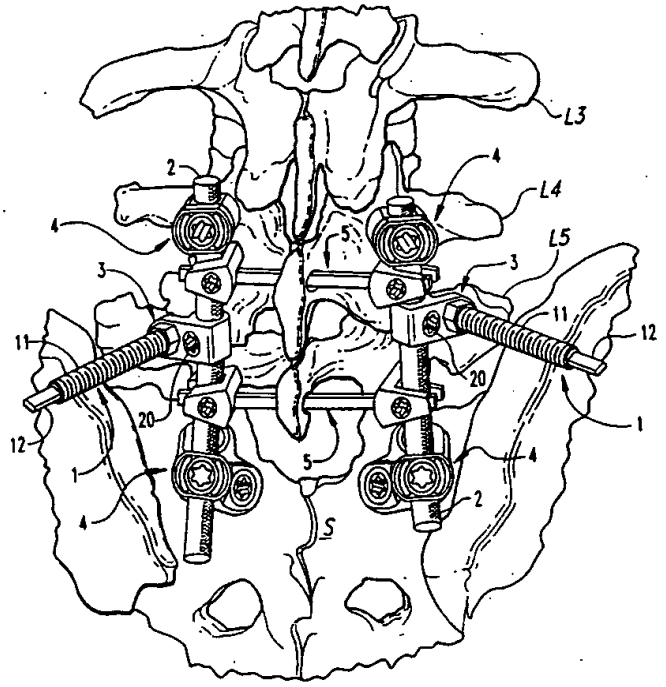
(57) Abstract

The instrumentation comprises for each lumbar vertebra (L5), two pedicular screws (1) having two screw threads (9, 11), one (9) of the screw threads corresponding to the region of penetration of the screw in the pedicle, two rods (2) having asperities respectively associated with a pedicular screw and secured to the latter by connection elements (3) provided with elements for clamping the rods. Each connection element (3) is in one piece and the screw thread (9) corresponding to the region of penetration of the screw in the pedicle terminates in an annular shoulder (16) against which the connection element bears which is separated by a smooth part (15) from the screw thread (11) outside the region of penetration in the pedicle. This instrumentation permits both returning the slipped vertebrae rearwardly and pivoting it in the desired direction of rotation, it being possible to carry out the derotation action slowly and by controlling the movement so that the surgeon achieves on the whole in the two movements an excellent precision in the repositioning of the vertebrae relative to the neighbouring vertebrae.



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PEDICULAR SCREW AND POSTERIOR SPINAL INSTRUMENTATION

The invention relates to lumbar osteosynthesis instrumentation for the correction of spondylolisthesis.

It is known that, substantially, spondylolisthesis is the forward displacement of a vertebra relative to its lower neighbour. In theory, any vertebra may be affected, but the fifth and the fourth lumbar vertebrae are the most commonly concerned.

Affecting more frequently women or young girls than men, spondylolisthesis is usually classified into five types: dysplastic, isthmian, traumatic, degenerative and pathological.

Its degree of seriousness is measured by the distance travelled through by the displaced vertebra with respect to its lower neighbour.

There are four stages:

The first stage is a displacement of a quarter of the antero-posterior diameter of the vertebral body.

The fourth stage corresponds to a complete displacement of the vertebral body.

The second and third stages are the intermediate stages.

Heretofore, although there are certain surgical techniques for the treatment of spondylolisthesis, either by the direct traction on the slipped vertebra, or by the screwing of the pedicles of this slipped vertebra, the

reduction of the spondylolisthesis is not always satisfactory, above all in the cases of serious spondylolisthesis.

Surgery is indeed indicated for those who have a long past of lumbalgia or sciatica, in the case of evidence of a vertebral canal stenosis, a compression of the cauda equina or a subjacent motor lesion, or those whose spondylolisthesis rapidly evolves toward stage 3 or stage 4.

Generally, in surgery, an anterior or posterior vertebral fusion, laminectomy with decompression of the posterior structures and an excision of the hypertrophied mass of the fibrous tissue in the region of the lysis may be indicated.

In isthmian spondylolisthesis, the bilateral isthmian lyses are liable to be associated with a considerable pseudoarthrosis in relation with an emerging nerve root. The discal state in the region of the spondylolisthesis sometimes requires a radiculographic or discographic assessment. In vertebral canal stenoses, the decompression without fusion may be a surgical operation.

In actual fact, an effective orthopedic surgery consists in returning the vertebra not only onto the axis of the spine but also to a position which is as correct as possible relative to the neighbouring vertebrae. Over a period of time, or in the course of its displacement, this vertebra in fact might have been subjected to lateral thrusts which have caused it to pivot horizontally to a more or less large

extent so that a correct repositioning of the vertebra of course implies its rearward return but also a derotation.

Attempts have already been made to correct spondylolisthesis, for example by means of devices consisting of two pedicular screws interconnected by a transverse plate which, by screwing a nut bearing against the plate, act solely by translation of the concerned vertebra for putting it into alignment with the neighbouring vertebrae.

Thus, the device disclosed in French patent 2 615 095 (87 06 864) employs two rods which are longitudinally fixed in the vertebral column with the aid of pedicular screws and each serve as support means for two screws having a double screw thread connected to the vertebra to be corrected. These two double thread screws are transversely connected by a rigid plate constituting a bipedicular base. It is this transverse plate which permits acting on the vertebra to be corrected owing to the provision of a median opening for receiving traction forceps.

In fact, such a device does not permit acting in a sufficiently satisfactory manner, and experience has shown that a traction on the median part of the plate has for effect to rearwardly return the vertebra to be corrected too rapidly. Further, if this vertebra must be derotated, it has been found that the presence of the plate is liable to prevent the required derotation action owing to the fact that this induces at the same time a certain return of the

vertebra.

Now, surgical experience has revealed that it is desirable to act slowly on the vertebra by acting on each one of the double thread screws independently, so that the surgeon can gradually adjust for each particular case his vertebra derotation and/or return action.

Moreover, such a device is relatively complex and costly owing to the number of its component parts which further increases the mounting difficulties encountered by the surgeon during the surgical operation. As concerns in particular the double thread screw, in addition to the fact that it is long and costly to produce, its implantation in the pedicles is not at all convenient.

Further, this double thread screw is subjected to extremely high shear stresses, mainly in the region of the junction with the instrumentation appliances or in the upper part of the screw thread.

An object of the invention is to provide a lumbar osteosynthesis instrumentation for the correction of spondylolisthesis, which permits both returning the vertebra to the rear and pivoting it in the desired direction of rotation. Another object of the invention is to provide a double thread pedicular screw so arranged as to overcome the aforementioned drawbacks while permitting mass production which is cheaper than in the case of screws known in the art which can only be produced on a small scale.

The osteosynthesis instrumentation according to the

invention comprises, for each lumbar vertebra, two pedicular double thread screws, one thread of which corresponds to the region of penetration of the screw in the pedicle, two rods having surface asperities respectively associated with a pedicular screw and connected to the latter by connection elements provided with elements for clamping the rods.

According to the invention, each connection element is in one piece and the screw thread corresponding to the region of penetration of the screw in the pedicle terminates on an annular shoulder on which the connection element bears.

The derotation action exerted by means of this instrumentation has the advantage that it can be carried out slowly and with a certain amount of control over the movements, thereby affording on the whole in the two movements an excellent precision in the repositioning of the vertebra relative to its neighbouring vertebrae.

Further, the arrangement of a transverse shoulder into which tangentially fades the screw thread of the part of the screw serving to penetrate the pedicle, provides a reinforcement or strengthening resisting the shear stresses in this region. The continuous peripheral shoulder may also act as a support for an added part.

According to a particular feature of the invention, the end of the screw thread outside the part of the screw serving to penetrate the pedicle is extended by a screw threaded rod adapted to cooperate with an ancillary screwing

device.

The instrumentation according to the invention comprises an ancillary device for screwing the pedicular double thread screw, this device bearing against the screw threaded extension of said screw. This ancillary device comprises a rod provided with an end grip and includes a tubular end part which is arranged to permit the insertion of the operating part of the double thread screw, has a conical free end part remote from the grip tapering toward the grip and is provided with at least one longitudinal slot. This ancillary device further comprises a tube freely slidable on the rod for the purpose of surrounding and gripping the conical end part of its tubular end part for the purpose of clamping it on the operating part of the pedicular screw.

With this ancillary device, the length of the operating screw thread is almost completely enclosed in the tubular end part and clamped owing to the action of the second tube when the latter surrounds the conical end part of the tubular end part. After having provided a prior bore in the pedicle, the surgeon can in this way easily screw the double thread screw in position.

Further features and advantages of the invention will be apparent from the following description with reference to the accompanying drawings which illustrate two embodiments of the invention by way of non-limitative examples.

In the drawings:

Fig. 1 is a perspective view from above of one

embodiment of the lumbar osteosynthesis instrumentation according to the invention, mounted on the first lumbar vertebra and on the sacrum.

Fig. 2 is a partial perspective view of the instrumentation shown in Fig. 1.

Fig. 3 is an elevational view in the transverse direction, partly in section, of the instrumentation shown in Figs. 1 and 2.

Fig. 4 is an elevational view to a larger scale of a pedicular double thread screw which is part of the instrumentation shown in Figs. 1 to 3.

Fig. 5 is a perspective view of an embodiment of the ancillary device for mounting the pedicular screw shown in Fig. 4.

Fig. 6 is a perspective view to a larger scale of an alternative embodiment of the connection element between the osteosynthesis rod and the screw.

Fig. 7 is a sectional view taken on line 7-7 of Fig. 6.

The lumbar osteosynthesis instrumentation shown in Figs. 1 to 3 is adapted to correct spondylolisthesis by the posterior approach.

It comprises, for each lumbar vertebra to be corrected, for example the vertebra L5, two pedicular screws 1 having two screw threads, two cylindrical rods 2, preferably two rods of the so-called Cotrel type having surface asperities or knurling extending longitudinally along the concerned lumbar segment (vertebrae L5, L4 and sacrum S in the

assembly shown in Fig. 1), connection elements 3 connecting each pedicular screw 1 to the adjacent rod 2, pedicular screws 4 for securing the rods 2 to the vertebra L4 and to the sacrum S, and devices 5 providing a transverse connection between the rods. All these elements except the pedicular screws 1 and the connection elements 3 are known per se and therefore need no special description.

Each connection element 3 has, when viewed in the transverse direction, a substantially L-shaped profile consisting of an enlarged base 3a in which is provided a through passage 10 receiving the rod 2 and having an axis X-X. This portion 3a has on one side a cylindrical surface and on the other side a planar surface and is extended by a thin portion 3b. The latter has two parallel planar surfaces and is provided with an opening 7 for the passage of the pedicular screw 1. The opening 7 consists of a cylindrical central part having an axis Z-Z extended on each side by two conical parts 7b, 7c opening onto the planar surfaces. The taper of these conical parts is such that it permits an inclination of the axis of the screw 11 relative to the axis Z-Z of about $\pm$ 15°, the angular limits of this axis corresponding to the axes Y-Y and Y'-Y' (Fig. 7). A tapped opening 6 transversely opens onto the bore or passage 10 and receives a screw 20 for radially clamping the rod 2. The surface 3c of the element 3 remote from the passage 10 is completely planar.

The element 3 constitutes the means for securing the rod

2 and the means for screwing the screw 1. The distance between the axes of the screw 1 and rod 2 vary with the subject so that the surgeon can choose the most appropriate element 3.

Each screw 1 comprises from its point 8 a first screw threaded part 9 extending to the length of penetration of the screw 1 in the pedicular and a second screw threaded part 11 which is outside the region of penetration in the pedicle and is termed the "operating" part. On the side remote from the screw threaded part 9 the operating part 11 is extended by a profiled end portion 12, constituted for example by two flats 13 adapted to permit both the gripping of the double thread screw 1 and the screwing thereof by means of an ancillary device 14 (Fig. 5) which will be described hereinafter.

At the end remote from the profiled end portion 12, the screw threaded operating part 11 is extended by a short smooth region 15 terminating in a continuous peripheral shoulder 16 constituting the end of the screw threaded part 9. This shoulder 16 bears against the planar surface of the element 3 which is the most remote from the screw threaded part 11, consequently the screw 1 cannot pass through the element 3.

The screw thread 18 of this screw threaded part is adjacent the shoulder 16 and the depth of the thread 21 close to the shoulder 16 gradually diminishes until it tangentially merges with or fades onto a cylindrical sector

22 bordered by the shoulder 16 which thus forms a screw reinforcing region in this position. The shoulder 16 may act as a support for a device or an associated connection element 3.

The operating part 11 of the screw 1 is constituted by a metal screw thread of small pitch, for example between 0.5 and 2 mm and preferably between 0.8 and 1 mm, adapted to receive a nut 23 for clamping the connection element 3 against the shoulder 16.

This instrumentation has the following advantages:

The fact that the connection element 3 is made in a single piece not only makes this element cheaper to manufacture but also simplifies the positioning of the element by the surgeon, and above all improves the strength of the connection between the rod 2 having asperities and the pedicular screw 1.

As previously explained, the pedicular double thread screw 1 is subjected to high mechanical stresses of multiple origins; it must resist these various stresses for a relatively long period of time the duration of which depends on each patient. The screw 1 must therefore be as simple as possible to mount during the surgical operations, but must also have sufficient strength to withstand all the forces during and after the operation. Now, with the pedicular screws employed heretofore, it has been found that fractures generally occur in the region between the two screw threads. The invention remedies this situation by terminating the

screw thread 18 for anchoring in the pedicle in the substantially tangential region 22. Consequently, the screw thread 18 does not "open out" onto the shoulder 16 for supporting the connection element 3 and consequently ensures that this shoulder 16 has a peripheral continuity and a sufficient supporting thickness. This supporting thickness thus affords the maximum mechanical resistance to the forces transmitted to the connection element 3 and therefore exerted by the latter.

Another advantage afforded by this arrangement of the anchoring screw thread 18 resides in the fact that, when it is desired to effect a bicortical anchorage by reaching the opposite cortical part of the vertebra and with the screw thread length corresponding to the length of the passage through the vertebra, the surgeon is informed of the desired final position of the screw thread. The stoppage of the latter in its upper part indeed constitutes a warning in that the surgeon must suddenly exert a higher torque. He must therefore stop his screwing effort.

Owing to the provision of the profiled end portion 12, the engagement of the pedicular screw 1 by the ancillary device 14 no longer occurs in the central region of the screw, as described in said patent 2 615 095, but at the free end of the screw. This end region may be in the form of two flats 13 provided on a smooth, or optionally screw threaded, end part to permit the ancillary device 14 to act on the screw.

This ancillary device comprises a rod 24 provided with a tubular end part 25 and, at its opposite end, a manual grip 26. The tubular part 25 is so dimensioned as to permit the insertion therein of the operating part 11 of the screw 1, and the ancillary device 14 is completed by a tube or sleeve 27 coaxial with the rod 24 and slidably mounted on the latter so as to be capable of surrounding the tubular part 25 at the end of its travel.

The tubular part 25 is provided with longitudinal slots 28 starting at its free end, for example three slots as illustrated, extending along a part of the length of the region 25. The free end portion 29 of the latter is conical and tapers in the direction toward the grip 26. Beyond the slots 28, at a certain distance from the latter, there is provided a hollow profile matching the profiled end portion 12 of the screw, for example, as shown in Fig. 5, two flats 31 whose longitudinal surfaces are parallel. The two flats 31 are adapted to receive corresponding flats 13 of the screw 1 and thus lock the latter against rotation after the insertion of the operating part 11 in the tubular part 25. In the direction toward the conical end part 29, the flats 31 are extended by longitudinal recesses 32 for receiving the operating part 11 of the screw 1. Lastly, in order to permit a visual checking of the position of the profiled end portion 12 on the flats 31, the tubular part 25 is provided with a transverse opening 33 in the region of the flats.

When the operating part 11 is inserted in the tubular

part 25 with its end portion 12 locked against rotation between the flats 31, the surgeon slides the tube 27 along the tubular part 25 until the conical end portion 29 is made to grip round the operating part 11, the tapered portion 29 thus constituting a holding chuck for the screw 1. The two flats constitute additional means for preventing a reverse rotation of the pedicular screw 1 in the ancillary device 14. The ancillary device 14 also serves to screw the nut 23 clamping the screw 1 in the connection element 3. It is provided in its end 29 with a corresponding recess for engaging this nut 23.

The instrumentation just described is used in the following manner.

Before placing in position the support rods 2, which are for example the known Cotrel rods (Registered Trademark), the surgeon suitably anchors with his ancillary device 14 the double thread screws 1 in each of the pedicles of the vertebra L5 to correct. Then he secures the support rods 2 to the neighbouring vertebrae, or, as in the embodiment shown in Fig. 1, to the sacrum S and vertebra L4. Then he firmly fixes the connection elements 3 to the rods 2 by means of a radial clamping screw 20 (Fig. 1).

At this stage, the two transverse connection rods 5 are not yet installed. In order to correct the vertebra L5, i.e. to return it rearwardly (spondylolisthesis) and/or derotate it, the surgeon acts on the nuts 23 clamping the connection elements 3 by means of an ancillary device and

preferably two ancillary devices, each being disposed on one of the nuts 23 of the two screws 1. He is now free to act, as desired, more on the screwing of one of the nuts 23 than on the screwing of the other, depending on the movement he wishes to impart to the vertebra L5, as he is free to act in an identical manner on the two nuts 23.

Each time the surgeon acts on one of the nuts 23, he exerts by the bearing of the screw thread-nut system on the connection element 3 firmly connected to the support rod 2, a traction on the vertebra L5 in a direction toward the connection element 3. When he acts on a single one of the nuts 23, he also produces a slight rotation of the vertebra L5 about itself. When he acts equally on both nuts 23, he produces a rearward return of the vertebra L5.

In all cases, the fine pitch of the screw thread 11 supporting the correction nut 23 permits acting very progressively on the vertebra. When the vertebra is finally in the position required by the surgeon, the latter severs the double thread screw 1 above the nut 23. The severing of the rod deforms the screw thread 11 and this subsequently prevents the unscrewing of the nut 23.

It is only at this moment that the transverse rods 5 interconnecting the rods 2 can be mounted, thereby achieving a rectangulation of the whole final instrumentation.

The instrumentation according to the invention is easier to place in position by the surgeon than that disclosed in said French patent 2 615 095, cheaper as concerns the

fabrication of the screw, and more reliable in use; it no longer requires a transverse handling plate in the region of the connection elements 3. The screwing of the pedicular screws 1 by their profiled end portions 12 rather than by their central regions as in the aforementioned prior instrumentation, is also more convenient for the surgeon.

It must be understood that the scope of the invention is not intended to be limited to the described embodiments and various modifications may be made. For example, it is obvious that the end portion 12 may have any suitable profile other than that described, the same being true of the corresponding two flats 31 of the ancillary device 14.

Likewise, in the alternative embodiment shown in Fig. 6, the connection element 3 may be constructed to have, as viewed in the transverse direction, a substantially L-shaped profile and be disposed in such manner that its planar surface 3c (in contact with the nut 23 in Fig. 3) is inverted, by turning the element round, so as to be closer to the adjacent vertebra.

WHAT IS CLAIMED IS:

1. Lumbar osteosynthesis instrumentation for the correction of spondylolisthesis by a posterior approach, comprising in combination for each lumbar vertebra, two pedicular screws each having a first screw thread and a second screw thread, said first screw thread corresponding to a region of penetration of said pedicular screw in the pedicle of the vertebra, two cylindrical rods each associated with a respective pedicular screw, connection elements each interconnecting each rod and the associated pedicular screw, an annular bearing shoulder for the connection element interposed between said first and second srew threads on each pedicular screw, clamping elements each associated with a respective connecting element for clamping the respective rod, said first screw thread of each pedicular screw terminating on said shoulder and said shoulder being separated by a smooth part from said second screw thread outside said region of penetration of said first screw thread in said pedicle.

2. Instrumentation according to claim 1, wherein each connection element has a substantially L-shaped profile and a planar surface and is disposed, when the instrumentation is placed in position, in such manner that said planar surface is placed as close as possible to the adjacent vertebra.

3. Instrumentation according to claim 1, wherein each connection element has a substantially L-shaped profile and

a planar surface and is disposed, when the instrumentation is placed in position, in such manner that said planar surface is spaced away from the adjacent vertebra.

4. Instrumentation according to claim 1, wherein each connection element has two opposed planar surfaces and is provided with an opening for receiving the respective pedicular screw, said opening having a cylindrical central part extended at both ends by conical parts each opening out onto a respective one of said planar surfaces of said connection element.

5. Instrumentation according to claim 1, comprising a profiled end portion at an end of said second screw thread remote from said shoulder of each pedicular screw for cooperation with an ancillary screwing device.

6. Instrumentation according to claim 1, wherein each second screw thread has a pitch of substantially 0.5 to 2 mm.

7. Instrumentation according to claim 1, wherein each second screw thread has a pitch of 0.8 to 1 mm

8. Instrumentation according to claim 5 in combination with an ancillary device for screwing each pedicular screw by a part thereof, termed operating part, outside said region of penetration of said pedicular screw in said pedicle, said ancillary device comprising a rod provided with an end grip and a tubular end part which is arranged to permit the insertion therein of said operating part of the respective pedicular screw, has a conical free end portion

remote from said grip and tapering in a direction toward said grip, and defines at least one longitudinal slot, and a tube freely slidably mounted on said rod of said device so as to be capable of surrounding and gripping said conical free end portion of said tubular end part for causing it to grip said operating part of said pedicular screw.

9. Instrumentation according to claim 5 in combination with an ancillary device for screwing each pedicular screw by a part thereof, termed operating part, outside said region of penetration of said pedicular screw in said pedicle, said ancillary device comprising a rod provided with an end grip and a tubular end part which is arranged to permit the insertion therein of said operating part of the respective pedicular screw, has a conical free end portion remote from said grip and tapering in a direction toward said grip, and defines at least one longitudinal slot, and a tube freely slidably mounted on said rod of said device so as to be capable of surrounding and gripping said conical free end portion of said tubular end part for gripping and tightening a nut.

10. Instrumentation according to claim 9, wherein said ancillary device comprises, in said tubular end part and beyond said conical free end portion, a hollow profile matching said profiled end portion of said pedicular screw so as to prevent rotation of said pedicular screw relative to said tubular end part.

11. Instrumentation according to claim 10, wherein said

hollow profile defines two flats having parallel surfaces and said profiled end portion of said pedicular screw defines two flats having parallel surfaces cooperative with said two flats of said hollow profile.

12. Instrumentation according to claim 10, wherein said hollow profile is extended in a direction toward said conical free end portion by longitudinal recesses for receiving said second screw thread of said pedicular screw.

13. Instrumentation according to claim 10, comprising a transverse opening in said tubular end part in the region of said hollow profile for a visual checking of the engagement of said pedicular screw with said hollow profile for preventing relative rotation.

14. Pedicular screw for use in an osteosynthesis instrumentation, said pedicular screw comprising a first screw thread and a second screw thread and a transverse shoulder interposed between said two screw threads for supporting a connection element forming part of said instrumentation, said first screw thread being for screwing into the pedicle of a vertebra and having an end thread helix which fades tangentially on a cylindrical sector of said transverse shoulder.

15. Ancillary device intended for an osteosynthesis instrumentation for screwing a pedicular screw which forms part of said instrumentation and comprises a first screw for screwing into the pedicle of a vertebra and a second screw constituting an operating part, said ancillary device

comprising a rod which has a tubular end part and terminates in an end grip, said tubular end part being so dimensioned as to permit the insertion therein of said operating part of said pedicular screw, said tubular end part having a conical free end portion remote from said grip which tapers in a direction toward said grip, and at least one longitudinal slot, said ancillary device further comprising a tube freely slidably mounted on said rod of said ancillary device for the purpose of surrounding and gripping said conical end portion of said tubular end part and causing it to grip said operating part of said pedicular screw.

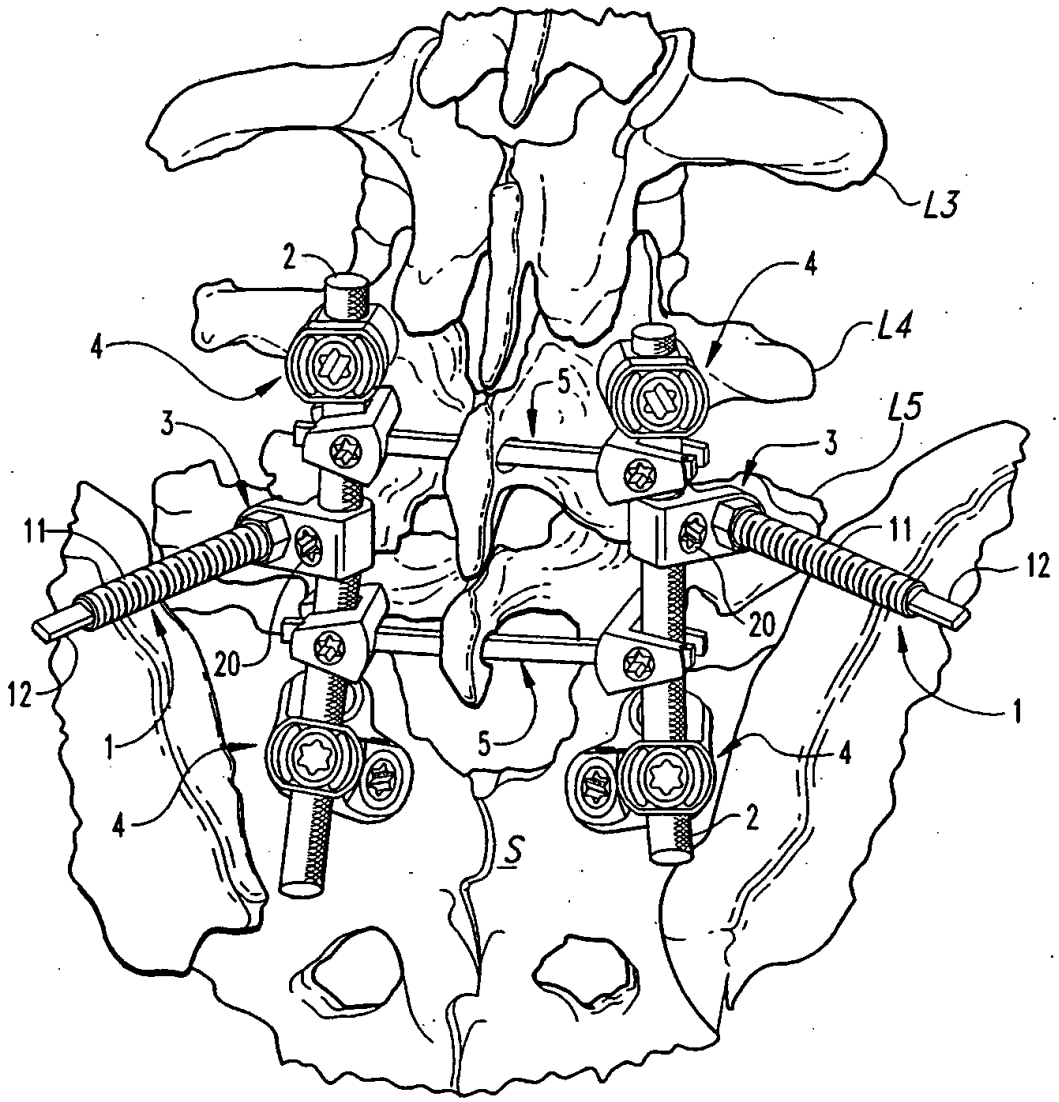

Fig. 1

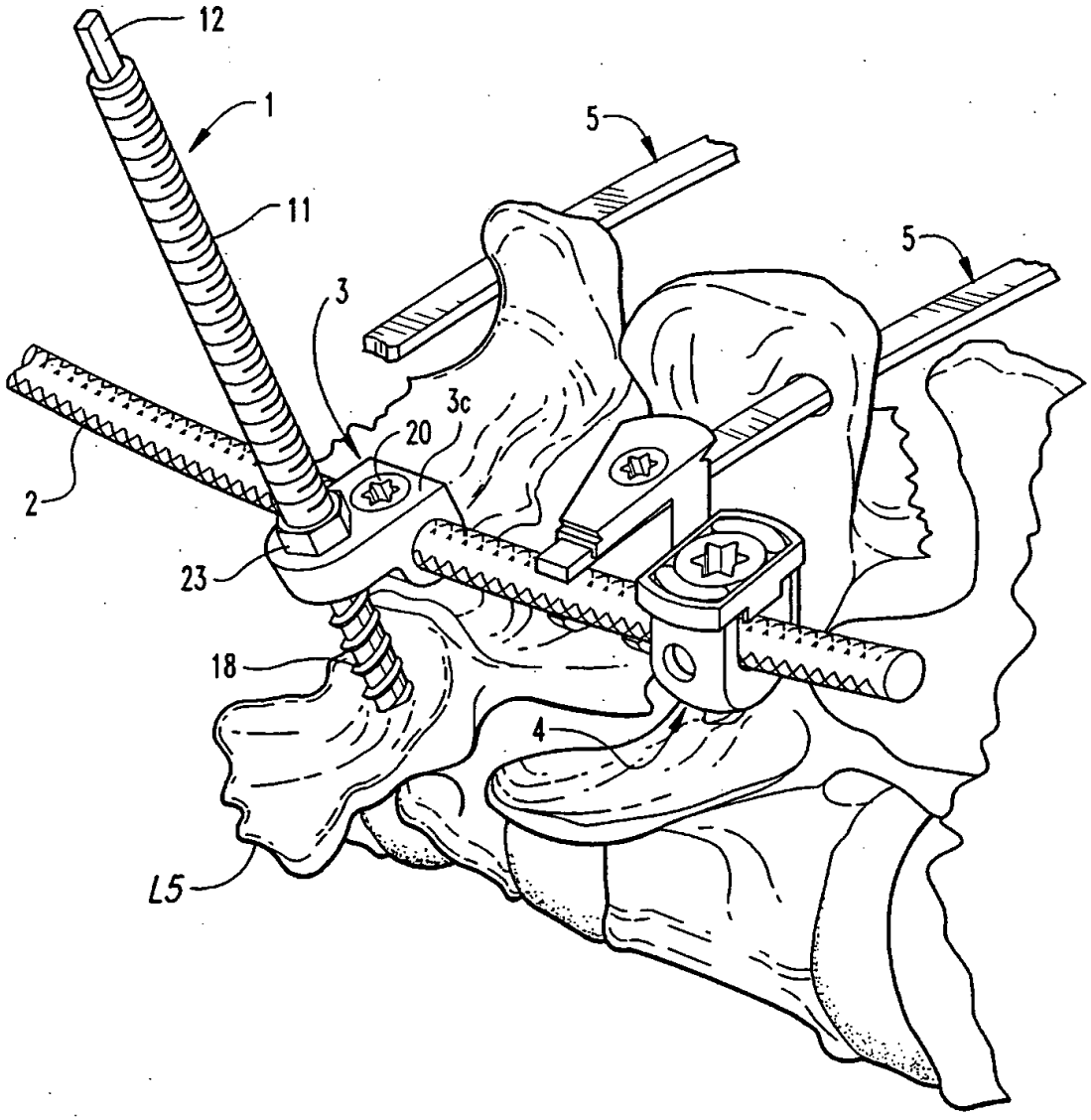

Fig. 2

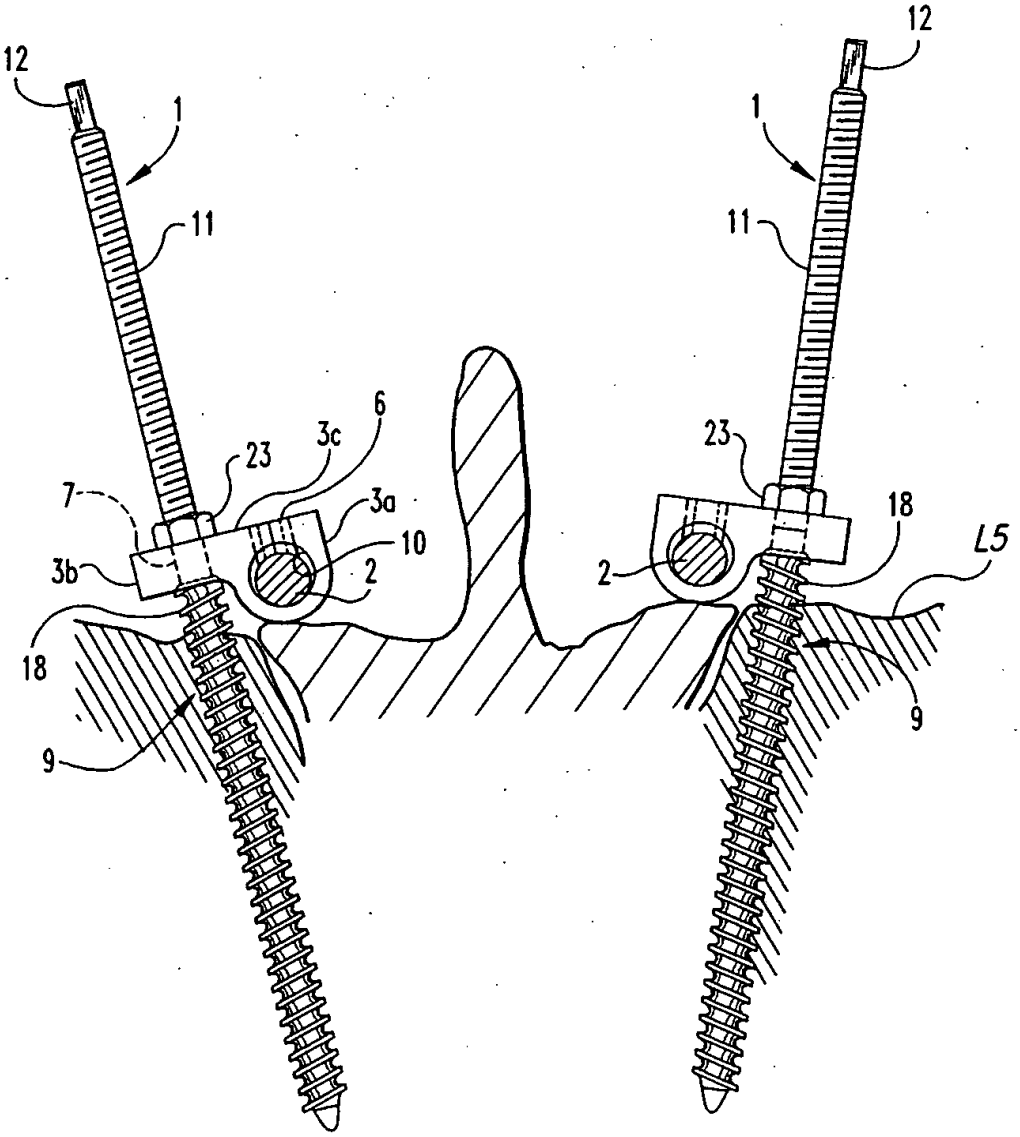

Fig. 3

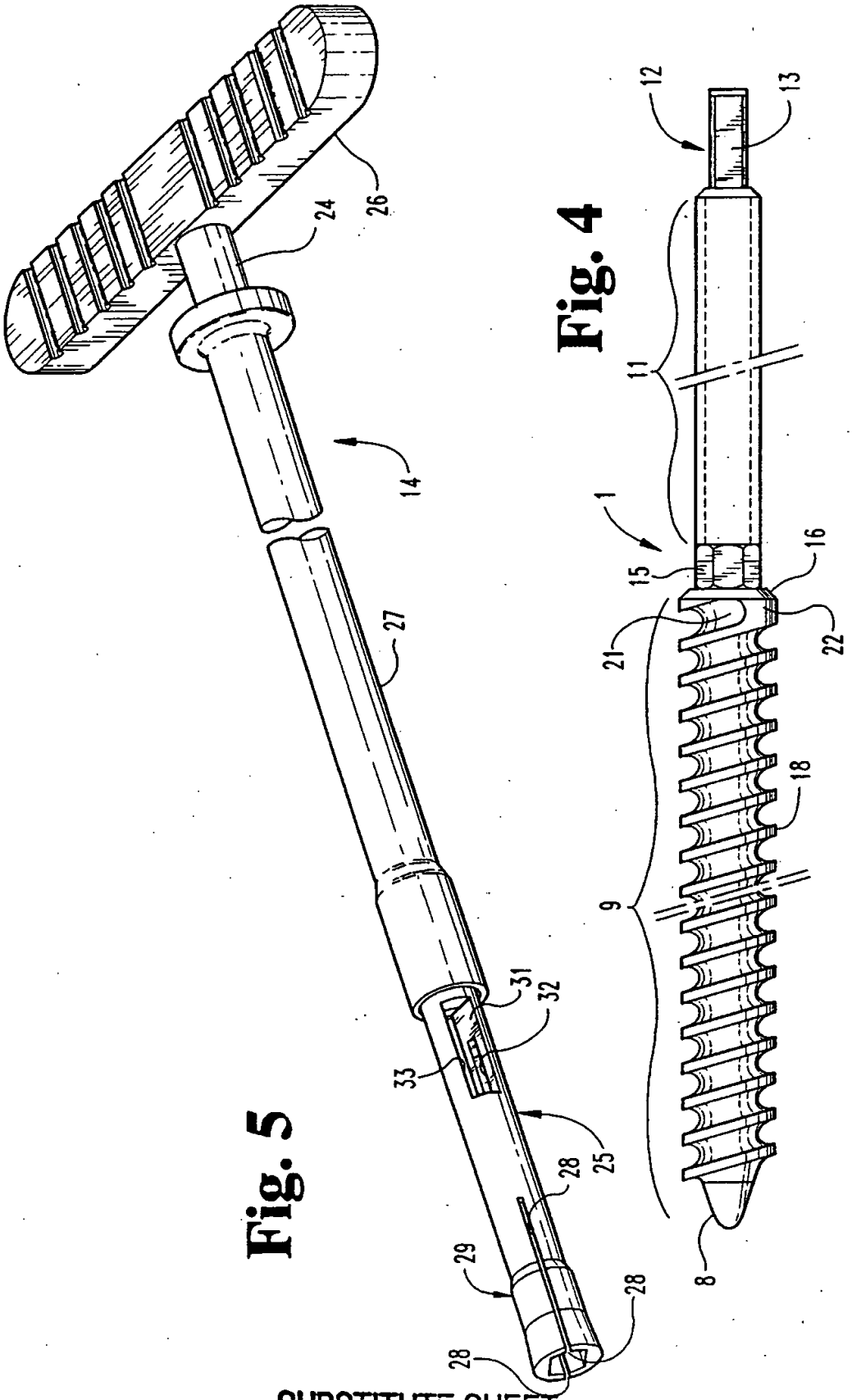

Fig. 4

Fig. 5

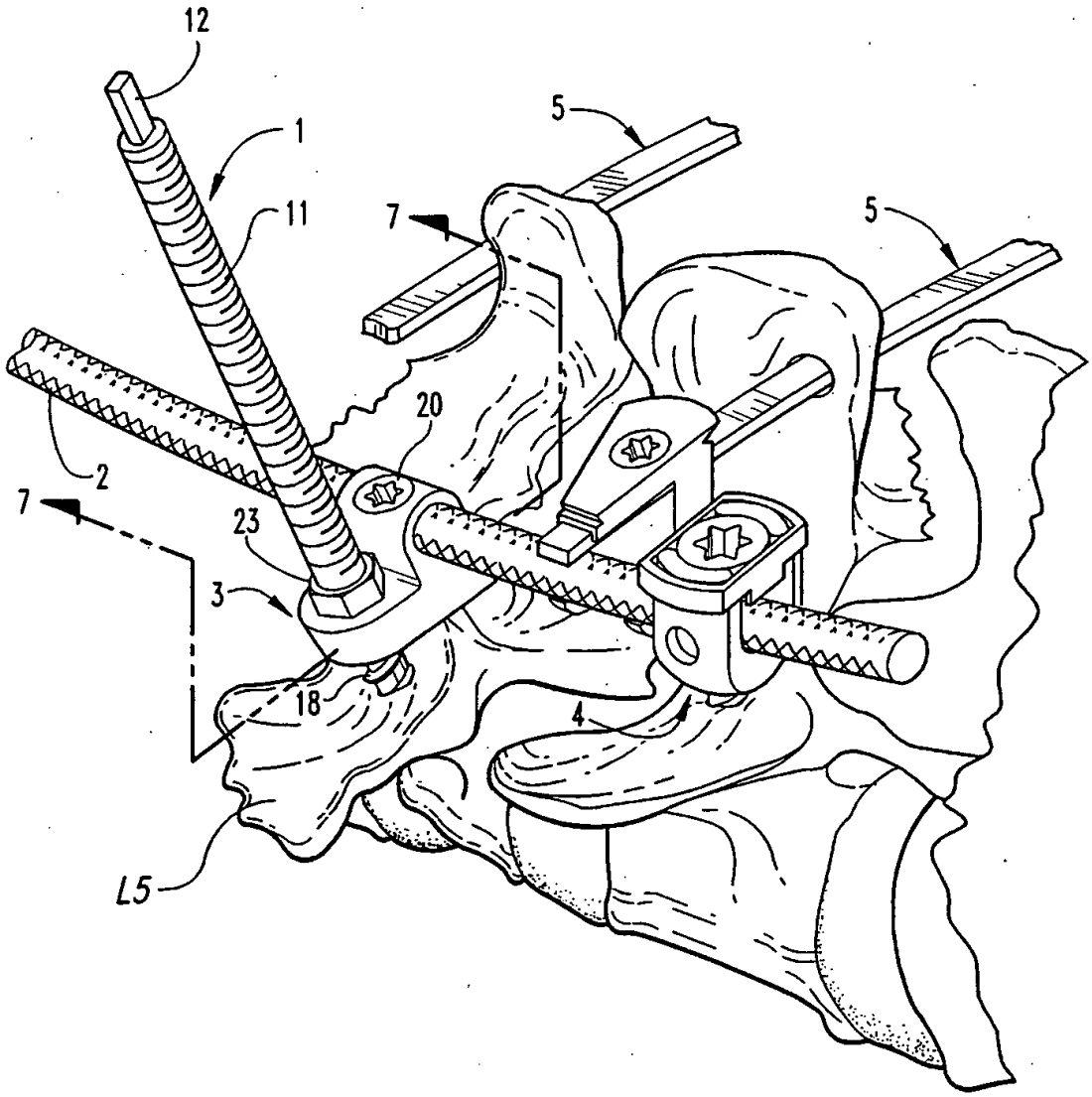

Fig. 6

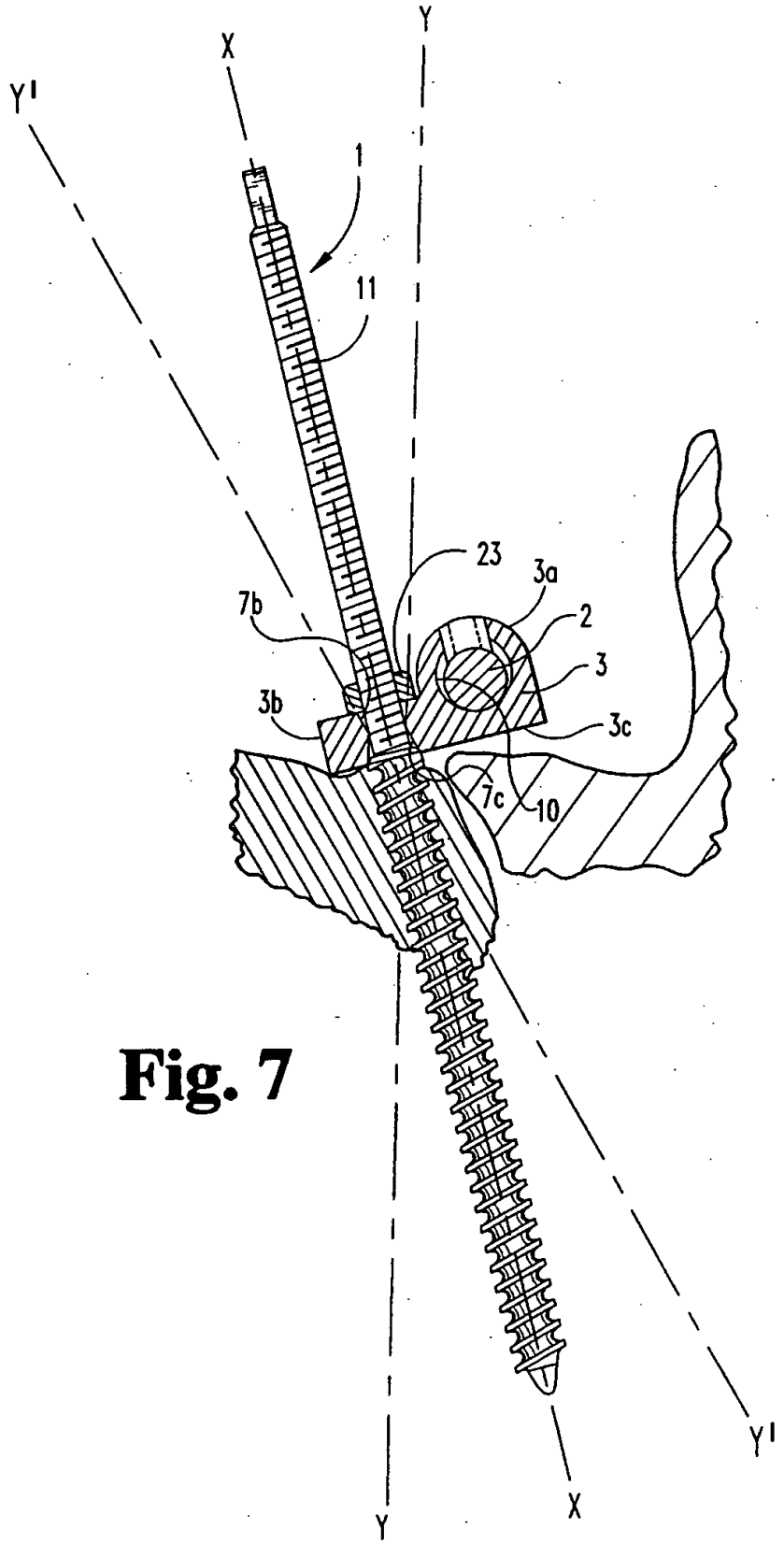

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/10966

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) : A61B 17/56
US CL : 606/61, 73
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)

U.S. : 606/60, 61, 72, 73, 104

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,129,900, (Asher et al.), 14 July 1992.	1, 2, 4 --------- 3, 5-8
X --- Y	US, A, 5,147,363, (Harle), 15 September 1992, see Figure 6, element 33.	14 ---- 5
X --- Y	US, A, 3,604,487, (Gilbert), 14 September 1971.	15 ---- 8
X	US, A, 4,648,388, (Steffee), 10 March 1987.	14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
07 FEBRUARY 1994

Date of mailing of the international search report
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