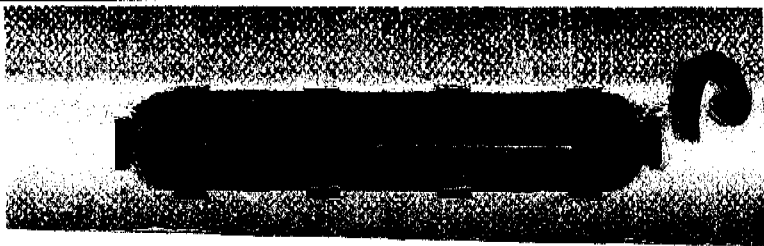


1c511 U.S. PTO  
09/114996

606	61
Class	Subclass
ISSUE CLASSIFICATION	



PATENT NUMBER
6228085
6228085

U.S. UTILITY PATENT APPLICATION

O.I.P.E. <i>SM</i> <i>KB</i>	PATENT DATE MAY 08 2001
SCANNED	Q.A.

SECTOR	CLASS 606	SUBCLASS 61	ART UNIT 3737	EXAMINER ROBERT
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PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)					
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
606	61						
INTERNATIONAL CLASSIFICATION							
A61B	17/58						

☐ Continued on Issue Slip Inside File Jacket

<input type="checkbox"/> <b>TERMINAL DISCLAIMER</b>	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg. 21	Figs. Drwg. 33	Print Fig. 16	Total Claims 33	Print Claim for O.G. 1
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed.	<i>Eduardo C. Robert</i> (Assistant Examiner) 12/12/00			NOTICE OF ALLOWANCE MAILED	
<input type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U.S. Patent. No. _____	<i>Gene Mancone</i> Supervisory Patent Examiner Group 3700 (Primary Examiner) 12/12/00			12/13/00	
				ISSUE FEE	
				Amount Due 620	Date Paid 7/13/01
<input type="checkbox"/> c) The terminal _____ months of this patent have been disclaimed.	<i>Let. Inf</i> 1400 (Legal Instruments Examiner) (Date)			ISSUE BATCH NUMBER W31	

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Form PTO-436A  
(Rev. 10/97)

ISSUE FEE IN FILE

(LABEL AREA)

Formal Drawings (set)

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# PATENT APPLICATION



09114996

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INITIALS

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## CONTENTS

	Date received (Incl. C. of M.) or Date Mailed	Date received (Incl. C. of M.) or Date Mailed
1. Application _____ papers.		
2. <u>CFR</u>	<u>3-20-99</u>	
3. <u>IDS</u>	<u>7-14-98</u>	
4. <u>Power to Inspect</u>	<u>8/10/99</u>	
5. <u>Status Rr</u>	<u>5-19-99</u>	
6. <u>Interview Summary</u>	<u>9-16-99</u>	
7. <u>Rejection (3rd time)</u>	<u>9-21-99</u>	
8. <u>Log 3408</u>	<u>9-23-99</u>	
9. <u>IDS</u>	<u>11-24-99</u>	
10. <u>Supple IDS</u>	<u>1-27-00</u>	
11. <u>Ext of time (ms) with a</u>	<u>2-1-00</u>	
12. <u>DIAF Means Rr</u>	<u>2-1-00</u>	
13. <u>Final log (3 months)</u>	<u>4/6/00</u>	
14. <u>Rev 4 of 1/01</u>	<u>6-15-00</u>	
15. <u>Rev 4 of 1/01 Concept</u>	<u>6-27-00</u>	
16. <u>Ext of time (2ms)</u>	<u>9-6-00</u>	
17. <u>Log Rr</u>	<u>9-6-00</u>	
18. <u>Supple Andt B</u>	<u>9-6-00</u>	
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20. <u>Interview Summary</u>	<u>12-1-00</u>	
21. <u>Formal Drawings</u>	<u>12-1-00</u>	
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POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	<i>AE</i>		<i>7/21/98</i>
O.I.P.E. CLASSIFIER		<i>20</i>	<i>7/23</i>
FORMALITY REVIEW	<i>Natay</i>	<i>66000</i>	<i>8/3/98</i>

INDEX OF CLAIMS

✓ ..... Rejected  
 = ..... Allowed  
 - (Through numeral) Canceled  
 ÷ ..... Restricted  
 N ..... Non-elected  
 I ..... Interference  
 A ..... Appeal  
 O ..... Objected

Claim	Final	Original	Date
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SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	Date	Exmr.

<b>INTERFERENCE SEARCHED</b>			
<b>Class</b>	<b>Sub.</b>	<b>Date</b>	<b>Exmr.</b>
606	61 64 69 70 71 60	12/11/00	<del>SK</del>
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SERIAL NUMBER 09/114,996	FILING DATE 07/14/98	CLASS 606	GROUP ART UNIT <del>3731</del> 3732	ATTORNEY DOCKET NO. 23724-3
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APPLICANT	RANDALL R. THEKEN, BARBERTON, OH; LUKAS EISERMANN, CLEVELAND, OH; BEN TAYLOR, HARTFORDSHIRE, ENGLAND.
	**CONTINUING DOMESTIC DATA***** VERIFIED <i>None GAV</i>
	**371 (NAT'L STAGE) DATA***** VERIFIED <i>None GAV</i>
	**FOREIGN APPLICATIONS***** VERIFIED <i>None GAV</i>

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 08/03/98 \*\* SMALL ENTITY \*\*

Foreign Priority claimed 35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY OH	SHEETS DRAWING 11	TOTAL CLAIMS 36	INDEPENDENT CLAIMS 3
Verified and Acknowledged <i>Examiner's Initials</i> <i>Initials</i>					

ADDRESS	<del>BENSECH FRIEDLANDER COPLAN &amp; ARONOFF</del> <del>2300 BR AMERICA BUILDING</del> <del>200 PUBLIC SQUARE</del> <del>CLEVELAND OH 44114-2378</del>	<i>Robert H. Eichenberger</i> <i>120 West Spring Street</i> <i>Suite 400</i> <i>New Albany, IN. 47150</i>
	BONE FIXATION SYSTEM	

FILING FEE RECEIVED \$571	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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PATENT APPLICATION SERIAL NO. \_\_\_\_\_

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FEE RECORD SHEET

07/21/1998 ASELLMAN 00000022 09114996

01 FC:201  
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395.00 OP  
176.00 OP

PTO-1556  
(5/87)

### ABSTRACT

An internal bone fixation system for the treatment of bone anomalies, such as thoraco-lumbar spinal instability. In accordance with a preferred embodiment, the fixation system includes a plate anatomically contoured to match the profile of lateral aspects common to thoracic and lumbar vertebrae, as well as the anterior profile. The contour of the plate allows for quicker implantation time, a lower profile, and a fit which allows for biomechanical load-sharing which increases the mechanical properties of the construct (i.e., stiffness, strength, and fatigue life). Moreover, the fixation system includes a fastener screw-plate interface which forces proper alignment between fastener screws and the plate, provides "pull-out" resistance and evenly distributes stresses on both the screw and the plate. Ledges are located on the medial surface at either end of the plate. The fixation system also includes set screws which effectively turn the screw construct into a bolt construct.

DOCKET NO. 23724-3

## BONE FIXATION SYSTEM

### Field of Invention

The present invention relates generally to a bone fixation system, and more particularly to an internal bone fixation system for the treatment of bone anomalies, such as thoraco-lumbar spinal instability.

### Background of the Invention

Trauma, lumbar burst fractures, tumors, severe disc degeneration, and anterior fusion following multiple posterior operations, are just some of the causes of anterior thoraco-lumbar spinal instability. Anterior treatment of thoraco-lumbar spinal instability has included the use of a conventional fixation system comprised of a generally planar plate and fasteners. The plate is arranged between a pair of vertebrae, and has openings for receiving the fasteners. The fasteners engage the appropriate vertebra to affix the plate thereto.

Prior art fixation systems have several disadvantages. In this respect, the fixation systems have relatively flat plates that connect to the vertebrae by some combination of bolts or screws. Loading of such an implant system is primarily onto the smallest, weakest, and least stiff components of the fixation system. The entire load is taken by the screws at one end of the plate, and transferred through the plate to the screws at the other end of the plate. Furthermore, maximal stress on the plate occurs at the



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5 tensile (lateral) side of the plate. Accordingly, the stiffness, strength and fatigue properties of prior art fixation systems are deficient.

Moreover, prior art fixation systems have a profile that matches only the anterior profile of the vertebral bodies. As a result, surgeons are forced to cut a channel in the bone in order for the plate to fit properly. This leads to complex surgical procedures, long implantation times, and an anatomical fit which does not allow for biomechanical load-sharing which leads to improvements in mechanical properties such as stiffness, strength and fatigue life.

10 The present invention addresses these and other drawbacks of prior art bone fixation systems.

#### Summary of the Invention

According to the present invention, there is provided a bone fixation system comprised of a plate and fasteners, wherein said plate is dimensioned to fit both the anterior and lateral profile of vertebral bodies.

15 An advantage of the present invention is the provision of a bone fixation system having greater stiffness than prior art systems.

Another advantage of the present invention is the provision of a bone fixation system having greater strength than prior art systems.

20 Still another advantage of the present invention is the provision of a bone fixation system having greater fatigue life than prior art systems.

Still another advantage of the present invention is the provision of a bone fixation system having an enhanced screw-plate interface for easier installation and improved security over prior art systems.

5 Still another advantage of the present invention is the provision of a bone fixation system having a plate contoured to fit the lateral profile of the vertebrae, thus providing added thickness for improved rigidity and forming a ledge for supporting the vertebrae in direct compression.

Yet another advantage of the present invention is the provision of a bone fixation system having an improved anatomical fit over prior art systems.

10 Yet another advantage of the present invention is the provision of a bone fixation system that provides improved interoperative graft access and postoperative graft evaluation.

Yet another advantage of the present invention is the provision of a bone fixation system requiring less surgical complexity for installation.

15 Yet another advantage of the present invention is the provision of a fastener system for securely fastening a plate to a bone structure.

Still other advantages of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description, accompanying drawings and appended claims.

### Brief Description of the Drawings

The invention may take physical form in certain parts and arrangements of parts, a preferred embodiment and method of which will be described in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

Fig. 1 is an exploded perspective view of the bone fixation system according to a preferred embodiment of the present invention;

Fig. 2 is a perspective of the bone fixation system according to a preferred embodiment of the present invention;

Fig. 3 is a lateral side view of the bone fixation system according to a preferred embodiment of the present invention, as affixed to a pair of vertebral bodies;

Fig. 4 is a posterior sectional view of the bone fixation system, as affixed to a pair of vertebral bodies;

Fig. 5 is a lateral side view of the bone plate;

Fig. 6 is a medial side view of the bone plate shown in Fig. 5;

Fig. 7 is a top plan view of the lateral side of the bone plate;

Fig. 8 is a sectional view of the bone plate, taken along line 8-8 of Fig. 7;

Fig. 9 is an end view of the bone plate;

Fig. 10 is a sectional view of the bone plate, taken along line 10-10 of Fig. 9;

Fig. 11 is a sectional view of a screw, taken along line 11-11 of Fig. 12;

Fig. 12 is a top view of the screw shown in Fig. 1;

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Fig. 13 is a side view of a set screw shown in Fig. 1;

Fig. 14 is a top view of the set screw shown in Fig. 1;

Figs. 15 and 16 are perspective views of a bone plate according to an alternative embodiment of the present invention;

Fig. 17 is a top plan view of the bone plate shown in Figs. 15 and 16; and

Fig. 18 is a cross-sectional view of the bone plate, taken along line 18-18

of Fig. 17;

#### Detailed Description of the Preferred Embodiment

It should be appreciated that while a preferred embodiment of the present invention will be described with particular reference to a bone fixation system for anterior treatment of thoraco-lumbar spinal instability, the present invention is also contemplated for use in connection with the treatment of other bone anomalies. In this regard, the present invention finds application in the treatment of bone structures in other regions of the spine, as well as bones located in regions outside the spine.

Referring now to the drawings wherein the showings are for the purposes of illustrating a preferred embodiment of the invention only and not for purposes of limiting same, Fig. 1 shows an exploded view of a bone fixation system 10, according to a preferred embodiment of the present invention. Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140. As fully assembled, screws 100 are inserted through holes formed in plate 20 and driven into a bone structure (e.g., a vertebral body). Set screws 140 are also arranged

inside the holes to further lock screws 100 in position (Fig. 2). Figs. 3 and 4 illustrate fixation system 10 as attached to vertebral bodies  $V_1$  and  $V_2$ . A complete description of the assembly and installation of fixation system 10 is provided in detail below. In the preferred embodiment illustrated herein, fixation system 10 is configured for treatment of vertebrae T11 to L3.

Turning now to Figs. 3 thru 10, plate 20 will be described in detail. Plate 20 is generally comprised of a top (cephalad) portion 40, a bottom (caudal) portion 60, and a bridge portion 80. Moreover, plate 20 has an anterior side 22, a posterior side 24, a lateral side 26, a medial side 28, and upper and lower sides 30A, 30B. Plate 20 has a length which is at least sufficient to enable plate 20 to connect at least two vertebrae. However, it will be appreciated that the length of the plate in any particular installation will depend upon the condition to be corrected and the number of vertebrae to be held in a desired spatial relationship relative to each other by plate 20.

Top portion 40 includes a pair of generally circular openings 42, which are dimensioned to receive fastener means, namely, bone screw 100 and set screw 140. Each circular opening 42 has a tapered section 44 and a threaded section 46, as best seen in Fig. 10. Tapered section 44 is generally concentric with threaded section 46. Tapered section 44 has a taper (e.g., Morse taper) extending from a first end adjacent to threaded section 46 to a second end terminating at medial side 28. The taper formed in circular opening 42 matches a mating taper formed on screw 100, as will be explained in detail below in connection with Fig. 11. Threaded section 46 includes threads that mate with threads formed on set screw 140, as will also be explained below.

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Tapered section 44 has a diameter which is smaller than the diameter of the adjacent threaded section 46. As a result, an annular shoulder 48 is formed at the interface between tapered section 44 and threaded section 46. Set screw 140 is driven against the top of screw 100, thus forcing screw 100 into tapered section 44.

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Bottom portion 60 is similar to top portion 40. Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. Tapered section 64 is generally concentric with threaded section 66. Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (Figs. 8 and 10). The taper formed in circular opening 62 matches a mating (Morse) taper formed on screw 100, as will be explained below in connection with Fig. 11. Threaded section 66 includes threads that mate with the threads formed on set screw 140, as will also be described below.

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Tapered section 64 has a diameter which is smaller than the diameter of the adjacent threaded section 66. As a result, an annular shoulder 68 is formed at the interface between threaded section 66 and tapered section 64. Set screw 140 is driven against the top of screw 100, thus forcing screw 100 into tapered section 64.

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It should be appreciated that generally circular openings 42, 62 could be replaced with a plurality of elongated slots.

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Bridge portion 80 interconnects top portion 40 and bottom portion 60, and is dimensioned to span an intervertebral space. It is understood that bridge portion 80 can be lengthened or shortened depending upon the total length of plate 20 required for

the particular vertebral anatomy. Bridge portion 80 is generally comprised of an anterior wall 82 and posterior wall 84. Anterior wall 82 and posterior wall 84 extend downward from lateral side 26 and act as "struts." It should be appreciated that the length and width of walls 82, 84 may vary. A recess 90 is defined by anterior wall 82, posterior wall 84, and top and bottom portions 40, 60. Recess 90 provides an observation window in plate 20. The observation window allows interoperative graft access and postoperative graft evaluation (i.e., visualization of the healing process in the bone graft) from a lateral X-ray. Graft is not obscured radiographically from any standard view. As illustrated in Figs. 1-3 and 5-7, recess 90 has a generally elliptical or oval shape. However, it will be appreciated that recess 90 may have varying geometries, including a rectangle, a square, an oval, a parallelogram, or an irregular shape. Moreover, recess 90 could be comprised of a plurality of smaller recesses or holes. Recess 90 could also narrow inward toward the center region to allow visualization of the edges of a graft.

Furthermore, other types of observation windows may be formed in plate 20. In this regard, one or more suitable openings may be formed in walls 82 and 84 to provide improved anterior-posterior plane visualization. Other embodiments include an observation window formed of solid material, wherein the material is radiolucent, such as a carbon-fiber reinforced polyaryletherketone polymer, and an observation window which has a cap or lid that may be attached to the plate to retain and/or compress graft.

Gaps or notches 34A are formed between anterior wall 82 and top and bottom portions 40, 60. Likewise, gaps or notches 34B are formed between posterior wall 84 and top and bottom portions 40, 60. The gaps or notches 34A bounding anterior

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wall 82 define a ledge 86A at the upper end of anterior wall 82, and a ledge 86B at the lower end of anterior wall 82. Likewise, the gaps or notches 34B bounding posterior wall 84 define a ledge 88A at the upper end of posterior wall 84, and a ledge 88B at the lower end of posterior wall 84.

5 Referring now with particular reference to Figs. 3 and 4, the gaps or notches 34A, 34B are dimensioned to receive a portion of a vertebral body. Ledges 86A, 86B, 88A and 88B provide support surfaces that protrude into the corpectomy space, so that the endplates of the adjacent vertebral bodies rest on at least one ledge at either end of plate 20 (Fig. 4). It should be noted that suitable graft material will fill the gap between vertebral bodies  $V_1$  and  $V_2$ . The graft material has been omitted from Fig. 3 and 4 so as to more clearly illustrate the present invention

It should be understood that ledges 86A, 88A, and ledges 86B, 88B may be respectively spaced apart from each other by various dimensions. This may allow plate 20 to be used after a corpectomy procedure or after a discectomy procedure. The ledges may extend the full width of the vertebral body. In such case, a pair of "struts" may be connected to each other, effectively forming an intervertebral cage device as an integral unit to the plate. According to alternative embodiments of the present invention, plate 20 could have ledges which are composed of bioresorbable compound (e.g., polylactic acid), a bone graft, or a bone graft substitute material. In yet another embodiment of the present invention all of the ledges could be omitted to form a plate which has a flatter, generally planar profile.



It should be appreciated that medial side 28 has an outer surface that is anatomically contoured to match the profile of aspects common to vertebral bodies (e.g., thoracic and lumbar vertebrae). The surface of medial side 28 is contoured to fit the vertebrae. Accordingly, the anterior portion of the medial side surface is relatively curved. The posterior portion of the medial side surface is generally flat in cross-section. Furthermore, as indicated above, plate 20 has gaps or notches 34A, 34B which are dimensioned to receive a portion of the vertebral bodies. The above-mentioned properties allow: (1) plate 20 to have a low profile (i.e., plate 20 sits "down into," rather than "on top of" the bone), (2) bio-mechanical load-sharing, which increases the mechanical properties of fixation system 10 (i.e., stiffness, strength and fatigue life), and (3) faster implantation times, as will be explained in detail below.

It will be appreciated that the surface of medial side 28 may have a varied geometry (e.g., engagement members) to allow fitting into the waist(s) of the vertebral bodies, such as steps, spines or teeth. Moreover, the surface of medial side 28 may be formed so as to bite into a bone at the waist of the vertebral bodies, such as with a spike or sharp tooth. Furthermore, the surface of medial side 28 may have a surface treatment which allows bone ingrowth, such as plasma spray, bead-sintering, knurling, hydroxyapatite, bioactive material, a plurality of small holes, roughened or otherwise irregular surfaces.

Screws 100 will now be described in detail with reference to Figs. 1-2 and 11-12. Each screw 100 is generally comprised of threaded portion 102 and a head portion 110. Threaded portion 102 extends from the lower end of head portion 110 to rounded

tip 106. Threads 104 are formed along the length of threaded portion 102. Threaded portion 102 is screwed into a vertebral body  $V_1$ ,  $V_2$ , as will be explained below.

Head portion 110 includes a tapered outer surface 112 and a recess 114, as best seen in Fig. 11. Tapered outer surface 112 tapers from the top of head portion 110 to the adjacent threaded portion 102. The taper of outer surface 112 matches the taper formed in tapered sections 44 and 64 of plate 20. The mating tapers align screw 20 with circular openings 42, 62, minimize local stress concentration, and provide pull-out resistance.

Recess 114 has a threaded section 116 and an inner recess section 118. Threaded section 116 has a radius greater than the radius of inner section 118. Notches 120 are formed in head portion 110. Recess 114, threads 116 and notches 120 are dimensioned to interface with a conventional instrument (e.g., a screw driver with a draw rod) for rotating screw 100. It should be understood that head portion 110 may take other forms suitable for interfacing with other types of instruments for rotating screw 100. Moreover, it should be appreciated that other types of suitable fastening devices may be substituted for screws 100.

In a preferred embodiment of the present invention, screws 100 have a diameter of approximately 7.0mm, and have a length in the range of approximately 30mm to 60mm.

It will be appreciated that screw 100 may have other suitable geometries. For instance, the tapered head could be replaced by a spherical head. The spherical head would allow variable screw angulation. Other suitable alternative geometries include a

screw with a flat or oval head which could be captured by a set screw. Moreover, the head of the screw could have a diameter greater than the opening in the bone plate, such that the head of the screw sits on top of the bone plate.

Set screw 140 will now be described with reference to Figs. 1-2 and 13-14.

5 Set screws 140 are generally comprised of a head portion 142 and a "dog point" or alignment member 160 integral therewith. Head portion 142 includes a threaded outer surface 144, a recess 146 and a front face 148. Threaded outer surface 144 has threads that mate with the threads of threaded sections 46 and 66 of plate 20. In a preferred embodiment of the present invention, head portion 142 has an outer diameter of approximately 9.5mm. Recess 146 has internal threads. Moreover, notches 150 are formed at the upper end of head portion 142. Similar to the head portion 110 of screw 100, recess 146, threads 145 and notches 150 are dimensioned to interface with a conventional instrument (e.g., a screw driver with a draw rod) for rotating set screw 140. It should be understood that head portion 142 may take other forms suitable for interfacing with other types of instruments for rotating set screw 142.

Alignment member 160 is integrally attached to head portion 142 at front face 148. According to a preferred embodiment, alignment member 160 includes a generally cylindrical elongated portion 162 and a full spherical radius tip 164 at the distal end thereof. It will be appreciated elongated portion 162 may have other suitable geometries (e.g., hex, square, etc.). Moreover, tip 164 may be flat or have other suitable geometries.

It will be appreciated that set screw 140 may have alternative configurations. In this regard, the alignment member could have a non-circular shape or a sharp tip. In another embodiment alignment member 160 may be omitted from set screw 140, thus providing a set screw with a generally planar front face. Moreover, the alignment member 160 could be omitted and replaced with a hole extending through the entire set screw. In this case, the alignment member (e.g., dog point) could be located on the driving instrument. In yet another embodiment, a cannulated (i.e., tubular) bone screw could be used with a set screw that is aligned by driving it along a wire inserted through the bone screw (and also through the set screw).

In a preferred embodiment of the present invention, set screw 140 has a diameter of approximately 9.5mm.

It will be appreciated that in an alternative embodiment of the present invention, set screws 140 could be replaced by other suitable locking mechanisms.

Both screws 100 and set screws 140 are preferably made of implant grade titanium alloy (Ti-6Al-4V (ELI) per ASTM F-136), or other biocompatible material, such as stainless steel, carbon fiber reinforced polyaryletherketone composites and the like.

It should be appreciated that screws 100, set screws 140, and the respective screw and set screw interfaces formed in plate 20 (i.e., screw-plate interface) are suitable for use with other similar connecting devices, including hooks, rod connectors, ligament anchors, and the like.

Moreover, it should be appreciated that the screws, set screws, and screw and set screw interface formed in plate 20 may take various alternative forms. For

instance, a slightly offset set screw could be used to provide the locking force. In yet another embodiment, the plate could be arranged with only a taper interface for receiving only tapered-head screws, without the use of any set screws. Other alternatives, include the use of a press fit mechanism in which a screw is driven into an undersized hole formed in the plate. As a result, locking is provided by material deformation. In yet another embodiment, an alternative locking screw geometry, such as a spherical-head screw with a set screw driven directly down onto them could be employed. Such an arrangement could provide a variable-screw angle system. Another option is to provide a screw with slots or holes arranged to correspond to similar geometries formed on the plate. The holes could be filled with bone cement or similar material to prevent screw movement, in lieu of a set screw. Other alternatives include a set screw which compresses more than one screw to provide locking, and a plate which has a plurality of slots for variable screw placement.

As indicated above, fixation system 10 is particularly well suited for the treatment of thoraco-lumbar spinal instability caused by such conditions as trauma, tumor, severe disc degeneration, and anterior fusion following multiple posterior operations including pseudoarthrosis. A brief summary of the preferred surgical technique will now be described.

Prior to installation, medial-lateral and anterior-posterior X-rays, CT scans, and MRI images may be useful in determining angular deformity, degree of canal compromise, and potential instability. Moreover, such images may also be useful to approximate the correct size of plate 20 and length of screw 100.

5 The patient undergoing treatment is positioned in a lateral decubitus position. Preferably, a retroperitoneal or combined thoraco-lumbar surgical approach is used. Next, the spine is exposed one level above and one level below the damaged segment. The site is then prepared by removing the disc material adjacent to the damaged vertebrae. A vertebral body distractor is placed inside the site, against the caudal endplate of the cephalad body and the cephalad endplate of the caudal body. A distraction sufficient to assist in the corpectomy procedure is then applied. Following distraction a corpectomy procedure is performed.

10 Graft placement is carried out by: (1) measuring the medial-lateral width of the vertebral bodies to determine the screw length required, (2) measuring the graft site, (3) harvesting and shaping an autologous tri-cortical iliac crest graft to fit within the site created, (4) determining the appropriate plate size by comparison to the graft site measurement, (5) placing the graft, (6) removing the vertebral body distractor, and (7) placing additional morselized graft anterior to the strut graft, if needed.

15 Installation of fixation system 10 will now be described with particular reference to Fig. 1- 4. After the graft has been properly sized and an appropriate sized plate 20 has been selected, plate 20 will fit into the narrow waist of the adjacent vertebral bodies. At least one ledge of 86A and 88A, and one ledge of 86B and 88B, should contact each adjacent vertebral body. This allows the load to be transferred through the "struts" (i.e., walls 82 and 84) of plate 20, rather than through screws 100. It should be noted that unusual anatomy may require some bone material to be removed to allow plate 20 to seat properly on the vertebral body.

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Next, a first hole is created at the posterior caudal location. An awl cannula is inserted into the appropriate circular opening 42, 62 in plate 20. The awl shaft is then inserted through the awl cannula. The lateral cortex is punctured by firmly pushing down on the awl shaft. As an alternative procedure, the awl shaft may be screwed onto the awl cannula, and the awl is then used as a one-piece instrument. However, this may cause difficulty in creating a properly aligned hole, which in turn may cause difficulty in placing screws 100.

A first screw 100 is then driven into the bone. In this regard, a screw 100 is loaded onto the driver using a flat-ended draw rod. Turning the draw rod clockwise will pull screw 100 firmly against the driver. Screw 100 is then driven into the bone. However, screw 100 is not fully tightened. This prevents the opposite end of plate 20 from lifting off the bone slightly, making it difficult to place subsequent screws. Proper screw length should be verified, either radiographically or by direct palpation. At least one full thread should engage the contralateral cortex. It should be appreciated that the driving tapered head 112 of screw 100 into mating tapered section 44, 64 of plate 20, forces proper alignment between screw 100 and plate 20, provides "pull-out" resistance, and evenly distributes stresses on both screw 100 and plate 20. The latter may significantly affect the fatigue life of screws 100.

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The above steps are repeated for the remaining screws 100. The second screw inserted should be the other posterior side location. The third and fourth screws should be the remaining anterior side locations. None of the screws should be completely tightened until all of the screws have been inserted.

Next, set screws 140 are loaded onto the driver. Alignment member 160 of set screw 140 is inserted into recess 114 of screw 100 to aid in locating set screw 140 and prevent cross-threading. Alignment member 160 forces an orthogonal alignment of threaded outer surface 144 and mating threaded section 46, 66 of plate 20. It should be appreciated that the radius of threaded section 116 is larger than the radius of alignment member 160. Set screws 140 are preferably tightened to approximately 60 inch-pounds. It should be noted that set screws 140 may be inserted into circular openings 42, 62 in any sequence desired.

It should be appreciated that driving set screws 140 on top of screws 100 forces screws 100 deeper into tapered section 44, 64, and prevents screws 100 from moving. As a result, the set screws have effectively turned an all-screw construct into an all-bolt construct.

Following installation, the wound is closed, and post-operative procedures are implemented.

As indicated above, plate 20 itself is contoured to fit the lateral profile of the thoraco-lumbar vertebrae. Since the primary use of the present invention is some form of a corpectomy or discectomy procedure, plate 20 takes advantage of the removed bone medial to the implant. The added thickness provides for better rigidity for plate 20, and allows for ledges 86A, 86B, 88A, 88B that are able to support the vertebrae in direct compression. Since the material is added into the corpectomy space, the profile of the construct is lower, as compared to prior art plate designs.



The present invention also provides significant improvements in stiffness and stress. Computer simulations show plate 20 to be approximately 7X to 10X stiffer than prior art plates. Moreover, the maximal stress concentrations of plate 20 were found to be approximately 1/4 to 3/4 the maximal stress concentrations of prior art plates.

5 As indicated above, plate 20 is anatomically fitted to the vertebral bodies. Consequently, a significant portion of the stress will be transferred directly to plate 20, rather than through screws 100. Plate 20 supports vertebral bodies in a manner similar to a corpectomy cage. Such loading condition shields screws 100, thus extending their fatigue life.

The present invention provides an enhanced screw-plate interface. As indicated above, the head portion of screws 100 have a taper, which matches a taper on plate 20. The mating tapers prevent screws 100 from backing out once tightening force is applied. In addition, set screws 140 are driven into plate 20 directly on top of screws 100, thus preventing any noticeable movement.

It should be appreciated that plate 20 may take other suitable forms. For instance, plate 20 could have a generally flat profile, thus virtually eliminating the downward extending walls 82 and 84 and corresponding ledges 86 and 88. Moreover, plate 20 could be modified to receive only a screw, rather than a screw and a set screw.

Turning now to Figs. 15-18, an alternative embodiment of the bone plate will be described. Bone plate 20' is similar in many respects to bone plate 20 described above. However, bone plate 20' reduces the amount of material needed to form the bone plate. Moreover, bone plate 20' has a reduced profile, which in turn is less intrusive to

body tissue. In order to provide these features, the lateral side of the bone plate has been modified as shown in the figures. In particular, lateral side 26' has three primary surface levels. Lower surface 124 is located adjacent to the anterior side circular openings 42, 62. Upper surface 128 is located adjacent to the posterior side circular openings 42, 62. A middle surface 126 is located between lower surface 124 and upper surface 128. Middle surface 126 comprises the majority of lateral side 26', as best seen in Fig. 17. Generally sloping surfaces provide a transition between the lower, middle and upper surfaces, as best seen in Figs. 15-16 and 18.

It should be appreciated that upper surface 128 is at the same general level as the surface of lateral side 26 of bone plate 20 (Fig. 8). Middle surface 126 and lower surface 124 are reduced from this level. The level of lower surface 124 is reduced to a level wherein the threaded sections of anterior side circular openings 42, 62 are removed. In this regard, anterior side circular openings 42, 62 include only a respective tapered section 44, 64. Consequently, no set screw 140 is used in connection with the anterior side circular openings 42, 62 of bone plate 20'. The top surface of head portion 110 of screw 100 is generally flush with lower surface 124, when bone plate 20' is appropriately installed. Posterior side circular openings 42, 62 are configured the same as those described in connection with bone plate 20.

It should also be noted that bone plate 20' has slightly modified medial side 28'. In this regard, a rounded corner portion 29 is formed at the anterior end of medial side 28' (Fig. 18). This differs from the protruding corner formed at the anterior

end of medial side 28 of bone plate 20 described above (Fig. 8). Rounded corner portion 29 allows for yet more reductions in material.

The invention has been described with reference to a preferred embodiment. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. It is intended that all such modifications and alterations be included insofar as they come within the scope of the appended claims or the equivalents thereof.

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Having thus described the invention, it is now claimed:

Sub B2

1. A bone fixation system comprising:  
elongated plate means having a top portion, a bottom portion, and a  
bridge portion integrally spanning between the top portion and bottom portion, said  
bridge portion for connecting at least two bone structures; and  
fastener means for fastening the plate means to said at least two  
bone structures.

2. A bone fixation system according to claim 1, wherein said support  
means include ledge members located adjacent to said top and bottom portions.

Sub B3

3. A bone fixation system according to claim 2, wherein said ledge  
members are connected together to form an intervertebral cage device.

4. A bone fixation system according to claim 2, wherein said ledge  
members include at least one of: bioresorbable compound, bone graft, or bone graft  
substitute material.

Sub B4

5. A bone fixation system according to claim 1, wherein said bridge  
means includes a window means for observation of a graft area.

Sub 27

6. A bone fixation system according to claim 5, wherein said window means includes an opening having a general shape of : an ellipse, rectangle, square, oval or parallelogram.

7. A bone fixation system according to claim 5, wherein said window means includes a plurality of holes.

8. A bone fixation system according to claim 5, wherein said window means has an irregular shape.

9. A bone fixation system according to claim 1, wherein said top and bottom portions include at least one opening dimensioned to receive said fastener means.

Sub B5

10. A bone fixation system according to claim 9, wherein said at least one opening includes a first fastener receiving section having a tapered surface, said fastener means including a mating tapered surface, wherein said mating tapered surface generally matching the tapered surface of said first fastener receiving section.

Sub 27

11. A bone fixation system according to claim 10, wherein said fastener means includes a set screw member having a threaded surface.

12. A bone fixation system according to claim 11, wherein said at least one opening includes a second fastener receiving section having a mating threaded surface, said mating threaded surface generally matching the threaded surface of said set screw member.

13. A bone fixation system according to claim 12, wherein said set screw member includes an alignment means for aligning said set screw with said at least one opening.

14. A bone fixation system according to claim 9, wherein said fastener means includes a head portion, said at least one opening dimensioned to receive at least a portion of said head portion.

15. A bone fixation system according to claim 14, wherein said head portion is generally spherical, oval, hex or flat.

Sub 3  
16. A bone fixation system according to claim 9, wherein said fastener means includes a head portion, said head portion having a diameter greater than said at least one opening.

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17. A bone fixation system according to claim 9, wherein said at least one opening is an elongated slot.

24. A bone fixation system according to claim 1, wherein said plate means has a medial side having a surface treatment allowing bone ingrowth.

20 25. A bone fixation system according to claim 24, wherein said surface treatment includes at least one of: plasma spray, bead sintering, knurling, hydroxyapatite, bioactive material, a plurality of holes, and roughened or otherwise irregular surfaces.

26. Fastener means for attaching a fixation system to associated bone structures, said fastener means comprising:

screw means having a tapered portion and a threaded portion, said tapered portion having a taper generally matching a mating taper formed in an associated connecting member, and said threaded portion threadably engaging with the associated bone structures; and

set screw means having a threaded portion, said threaded portion having threads for engaging mating threads formed in the associated connecting member.

27. A fastener means according to claim 26, wherein said set screw means includes an alignment means for aligning said set screw means within an opening formed in the associated connecting member.

28. A fastener means according to claim 27, wherein said alignment means includes an elongated portion and a tip at one end thereof.

Sub G47

18. A bone fixation system according to claim 9, wherein said at least one opening includes a section dimensioned to receive a press fit fastener means.

19. A bone fixation system according to claim 1, wherein said plate means has an anterior side having a medial surface that generally matches an anterior profile of a vertebral body.

20. A bone fixation system according to claim 1, wherein said plate means has a posterior side having a medial surface that is generally flat in cross-section.

21. A bone fixation system according to claim 1, wherein said plate means has a medial side having a surface that is anatomically contoured to approximate the profile of lateral aspects of a vertebral body.

22. A bone fixation system according to claim 1, wherein said plate means has a medial side having engagement means for engaging with at least one of said bone structures.

23. A bone fixation system according to claim 22, wherein said engagement means includes at least one of: spikes and teeth.



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29. A fastener means according to claim 26, wherein said set screw means includes a hole extending through said threaded portion.

30. A fastener means according to claim 26, wherein said connecting member is selected from the group consisting of: a plate, a hook, a connector and a rod.

31. A fastener means according to claim 26, wherein said bone structures include vertebral bodies.

32. A bone plate comprising:  
a top portion for attachment to a first bone portion;  
a bottom portion for attachment to a second bone portion; and  
a bridge portion integrally spanning between the top portion and bottom portion, said bridge portion for connecting the first and second bone portions, wherein the top portion includes at least one tapered opening for receiving a tapered fastener means, and the bottom portion includes at least one tapered opening for receiving a tapered fastener means.

33. A bone plate according to claim 32, wherein said top portion includes at least one threaded opening for receiving a threaded fastener means, and said bottom portion includes at least one threaded opening for receiving a threaded fastener means.

34. A bone plate according to claim 33, wherein said threaded openings are generally concentric with said tapered openings.

35. A bone plate according to claim 32, wherein said plate further comprises a lateral side surface having a plurality of surface levels.

36. A bone plate according to claim 35, wherein said surface levels include an upper surface level, a middle surface level and a lower surface level.

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Docket No.: 23724-3

**DECLARATION FOR PATENT APPLICATION**

As the below named inventors, we hereby declare that:

Our residence, post office address, and citizenship are as stated below next to our name.

We believe that we are the original, first and joint inventors of the subject matter which is claimed, and for which a patent is sought on the invention entitled:

**BONE FIXATION SYSTEM**

the specification of which is attached hereto, unless the following box is checked:

\_\_\_\_\_ was filed on \_\_\_\_\_, as United States Application Number \_\_\_\_\_.

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a) - (d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

NONE

We hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

NONE

We hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal

09114996-071498

Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

NONE

We hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:


Alan J. Ross, Reg. No. 33,767  
John X. Garred, Reg. No. 31,830  
Michael A. Jaffe, Reg. No. 36,326  
Susan L. Mizer, Reg. No. 38,245  
Todd R. Tucker, Reg. No. 40,850  
Brian D. Johnson, Reg. No. 40,665

Address all telephone calls to : Michael A. Jaffe  
at telephone number : (216) 363-4495  
Address all correspondence to : Michael A. Jaffe

BENESCH, FRIEDLANDER, COPLAN & ARONOFF L.L.P.  
2300 BP America Building  
200 Public Square  
Cleveland, Ohio 44114-2378  
(Customer No. 021130)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Randall R. Theken

Inventor's signature X   
Date : X 6/24/98  
Residence : Barberton, Ohio  
Citizenship : United States of America  
Post Office Address : 1100 Nola Avenue  
Barberton, Ohio 44203

Full name of second inventor: Lukas Eisermann

Inventor's signature X

Date : X JUNE 24, 1998

Residence : Cleveland, Ohio

Citizenship : ~~United States of America~~ GERMANY

LE 6/24/98

Post Office Address : 2490 East 126th Street  
Cleveland, Ohio 44120

Full name of third inventor: Ben Taylor

Inventor's signature X

Date : X

Residence : Hertfordshire, England

Citizenship : United Kingdom

Post Office Address : The Farmhouse  
Marshcroft Lane  
Tring  
Hertfordshire, England  
HP235QN

00114986-071498

**DECLARATION FOR PATENT APPLICATION**

As the below named inventors, we hereby declare that:

Our residence, post office address, and citizenship are as stated below next to our name.

We believe that we are the original, first and joint inventors of the subject matter which is claimed, and for which a patent is sought on the invention entitled:

**BONE FIXATION SYSTEM**

the specification of which is attached hereto, unless the following box is checked:

\_\_\_\_\_ was filed on \_\_\_\_\_, as United States Application Number \_\_\_\_\_.

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a) - (d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

NONE

We hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

NONE

We hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, we acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal

09114996-071498

Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

NONE

We hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

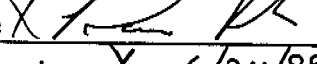
Alan J. Ross, Reg. No. 33,767  
John X. Garred, Reg. No. 31,830  
Michael A. Jaffe, Reg. No. 36,326  
Susan L. Mizer, Reg. No. 38,245  
Todd R. Tucker, Reg. No. 40,850  
Brian D. Johnson, Reg. No. 40,665

Address all telephone calls to : Michael A. Jaffe  
at telephone number : (216) 363-4495  
Address all correspondence to : Michael A. Jaffe

BENESCH, FRIEDLANDER, COPLAN & ARONOFF L.L.P.  
2300 BP America Building  
200 Public Square  
Cleveland, Ohio 44114-2378  
(Customer No. 021130)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Randall R. Theken

Inventor's signature X   
Date : X 6/24/98  
Residence : Barberton, Ohio  
Citizenship : United States of America  
Post Office Address : 1100 Nola Avenue  
Barberton, Ohio 44203

Sent by:

Jul-13-98 08:51am

from 75399253634411

Page 2 / 3

Received Jul-12-98 05:10pm

from 44 01442 891318 -> 7539925

page 3

Sent by:

Jun-24-98 05:28pm

from 7539925344 01442 891318 Page 4

Full name of second inventor: Lukas Eisermann

Inventor's signature *[Signature]*

Date : *X* JUNE 24, 1998

Residence : Cleveland, Ohio

Citizenship : ~~United States of America~~ GERMANY *CF/ATK*

Post Office Address : 2490 East 126th Street  
Cleveland, Ohio 44120

Full name of third inventor: Bob Taylor

Inventor's signature *X* *[Signature]*

Date : *X* 9th JULY 1998

Residence : Hertfordshire, England

Citizenship : United Kingdom

Post Office Address : The Farmhouse

Marshcroft Lane

Tring

Hertfordshire, England

HP235QN

0911496-07149



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Randall R. Theken et al.  
FOR : BONE FIXATION SYSTEM  
ATTORNEY DOCKET NO. : 23724-3  
Cleveland, Ohio 44114-2378

37 C.F.R. 1.27  
STATEMENT OF STATUS AS  
A SMALL BUSINESS ENTITY

Assistant Commissioner For Patents  
Washington, DC 20231

Dear Sir:

The undersigned affirms:

That he is an officer of the assignee, Theken Surgical L.L.P, and is empowered to act on behalf of the assignee; the assignment is being filed concurrently herewith for recording;

That the assignee, Theken Surgical L.L.P, together with all of its affiliates combined had fewer than five hundred (500) employees including full-time, part-time, and temporary employees on the average during each pay period of the previous fiscal year of the assignee and its affiliates; and,

That the assignee has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

The undersigned acknowledges a duty to file, in this application or patents issuing thereon, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

09114996-071498

The undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: X 6/30/98

By: X [Signature]  
Name: Randall R. Theken  
Title: President

0914995-071499

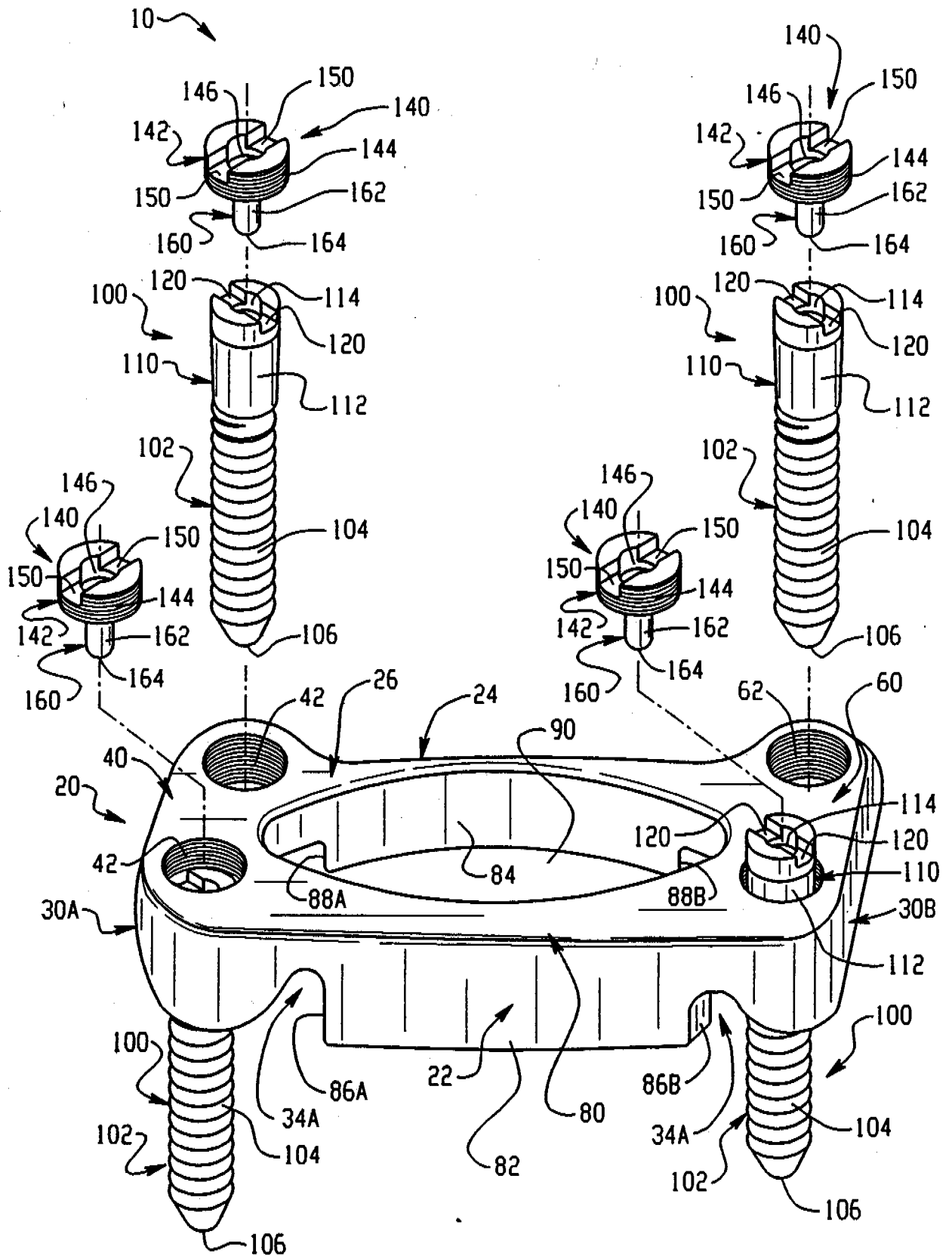


Fig. 1

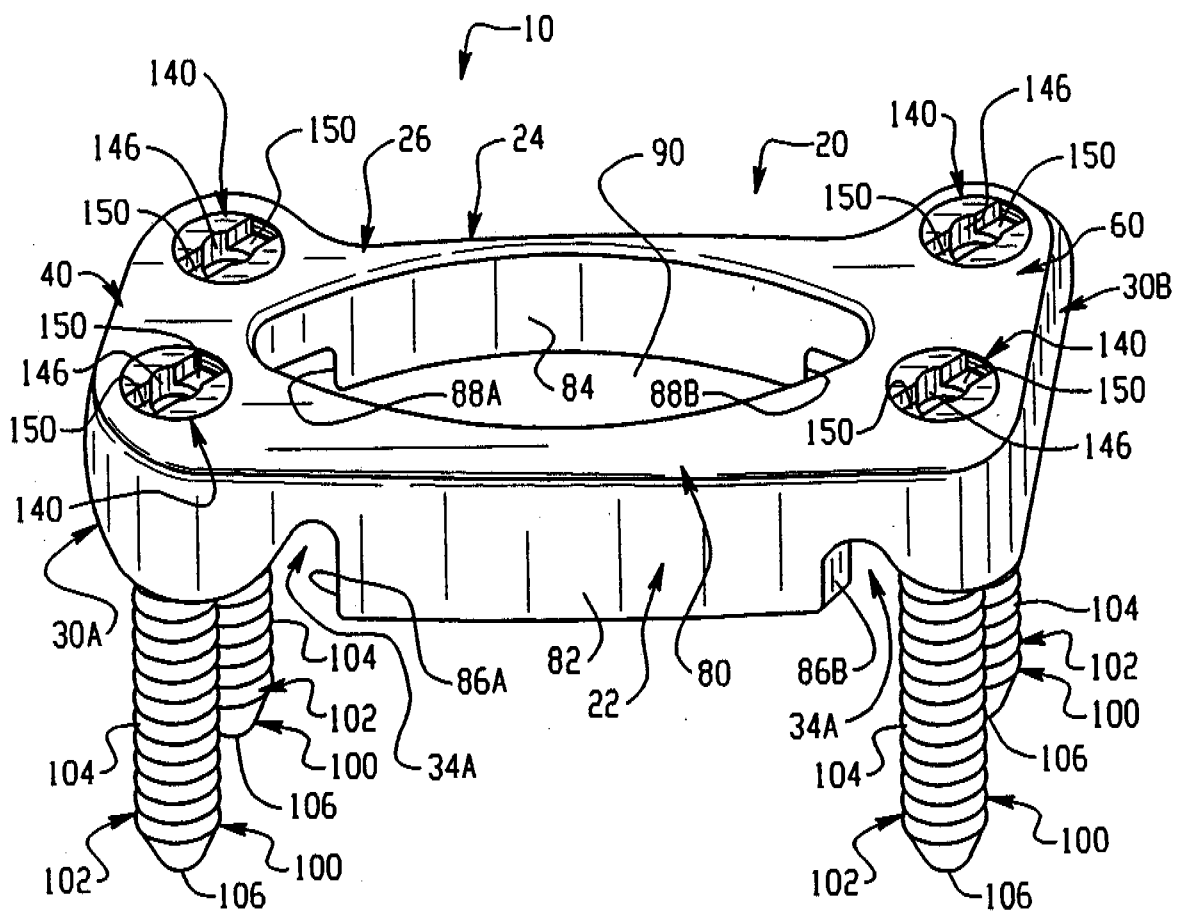


Fig. 2

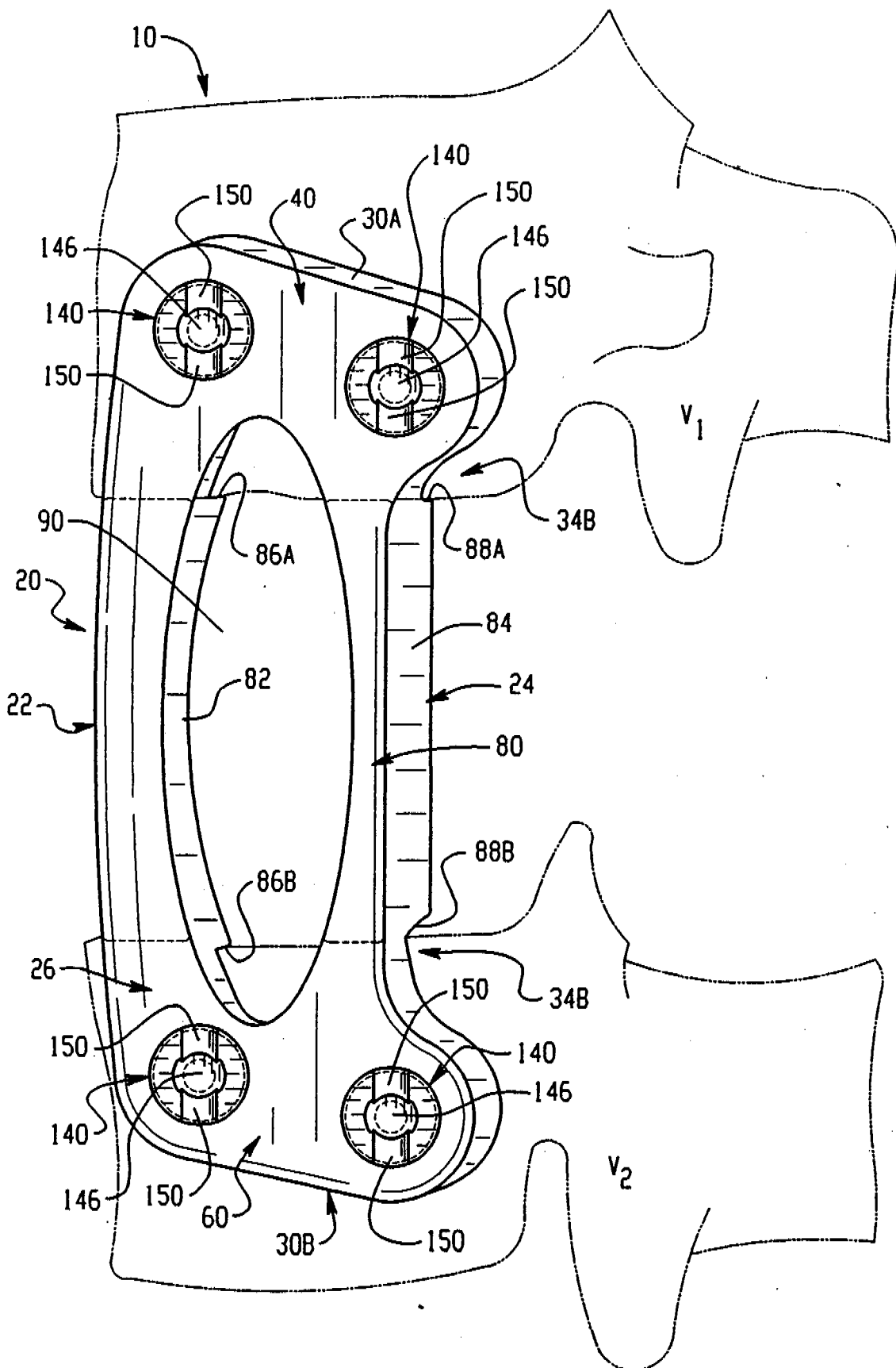


Fig. 3

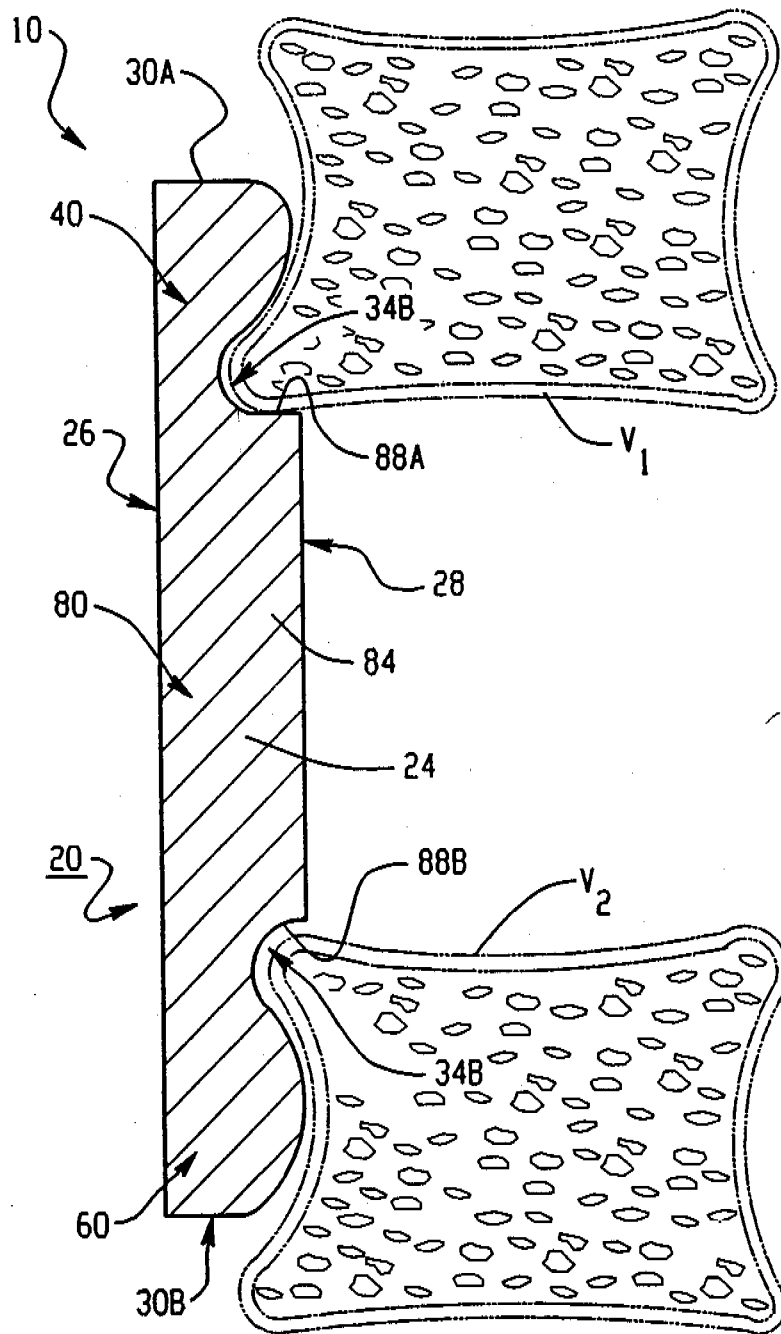


Fig. 4

Fig. 5

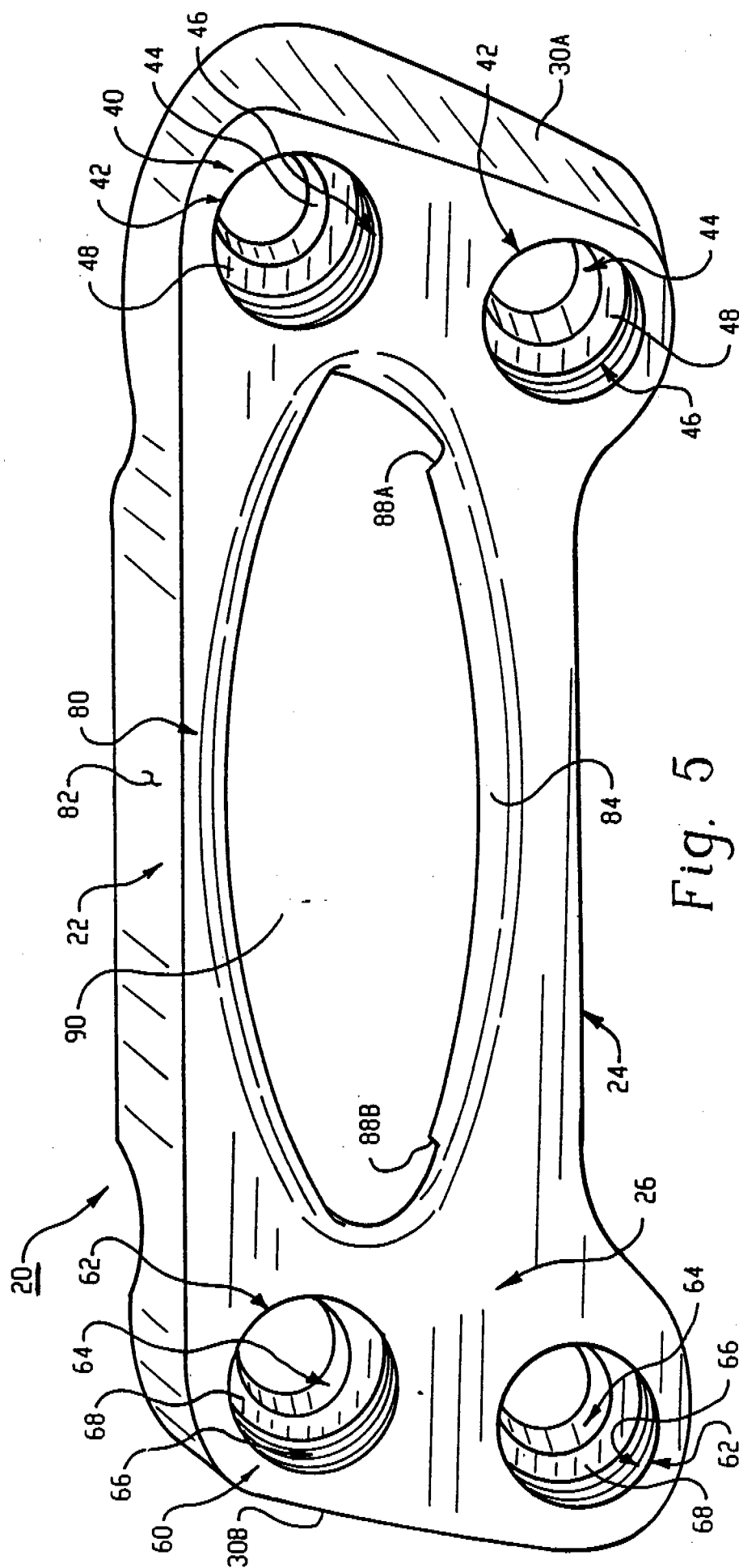


Fig. 6



7/11

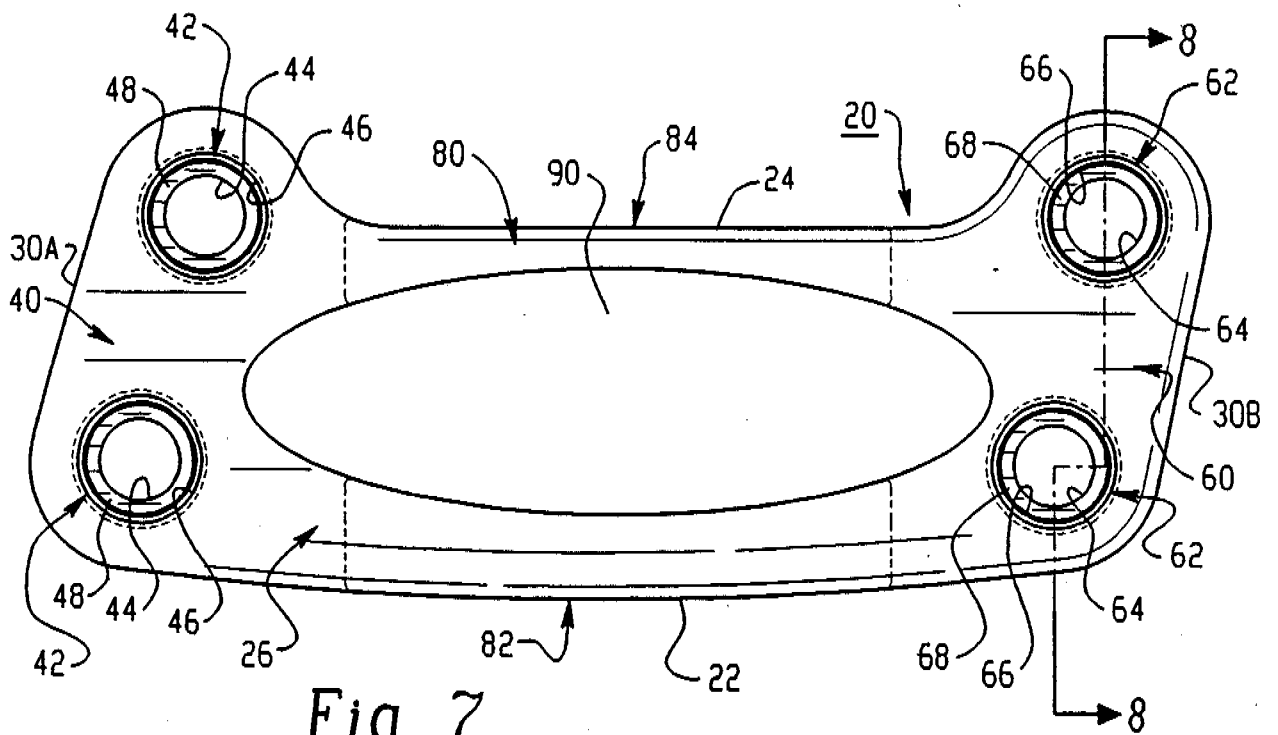


Fig. 7

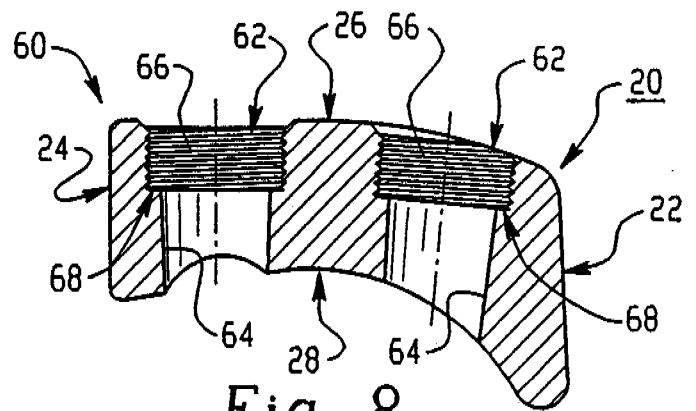


Fig. 8

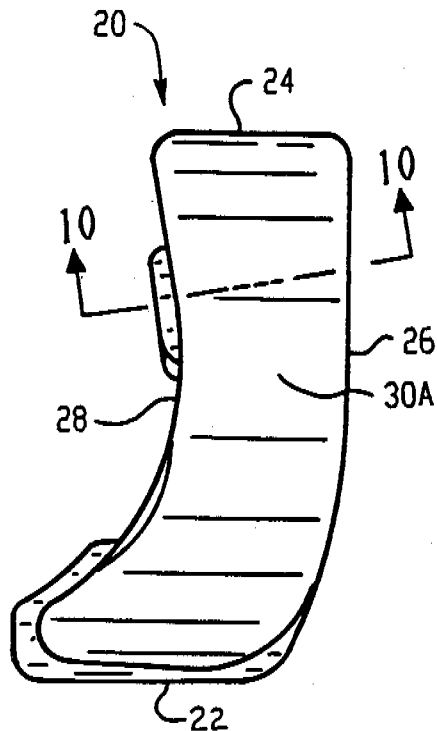
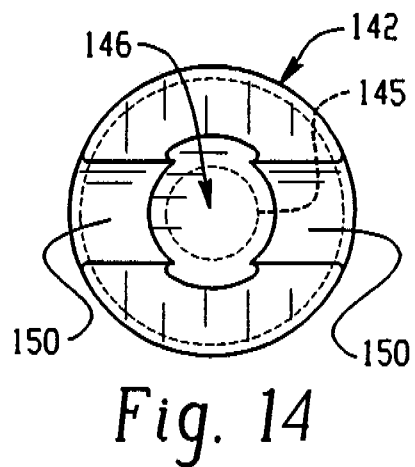
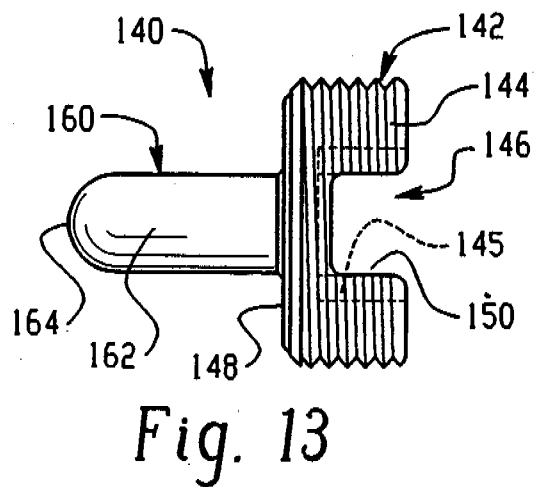
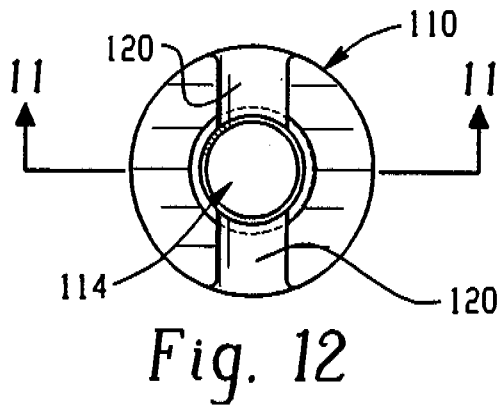
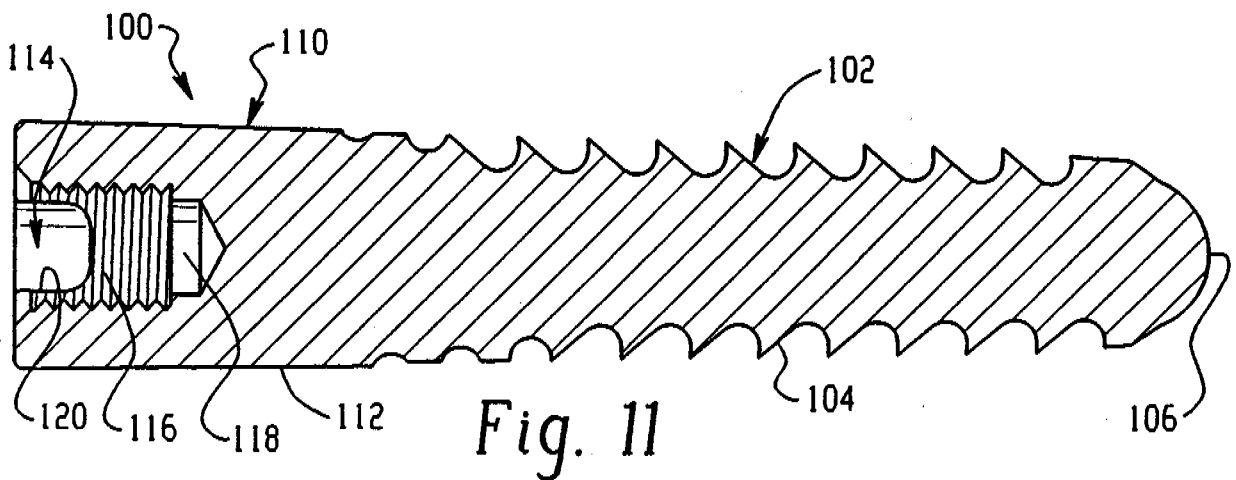
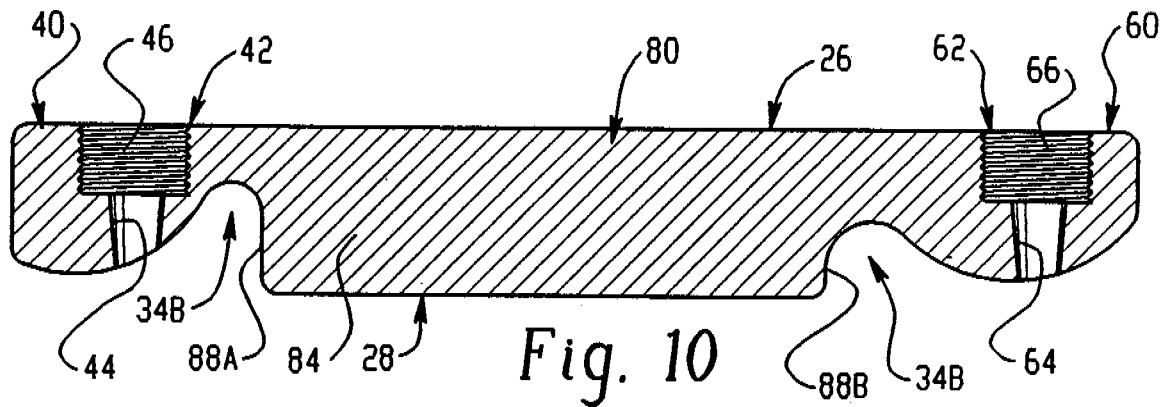


Fig. 9

8/11



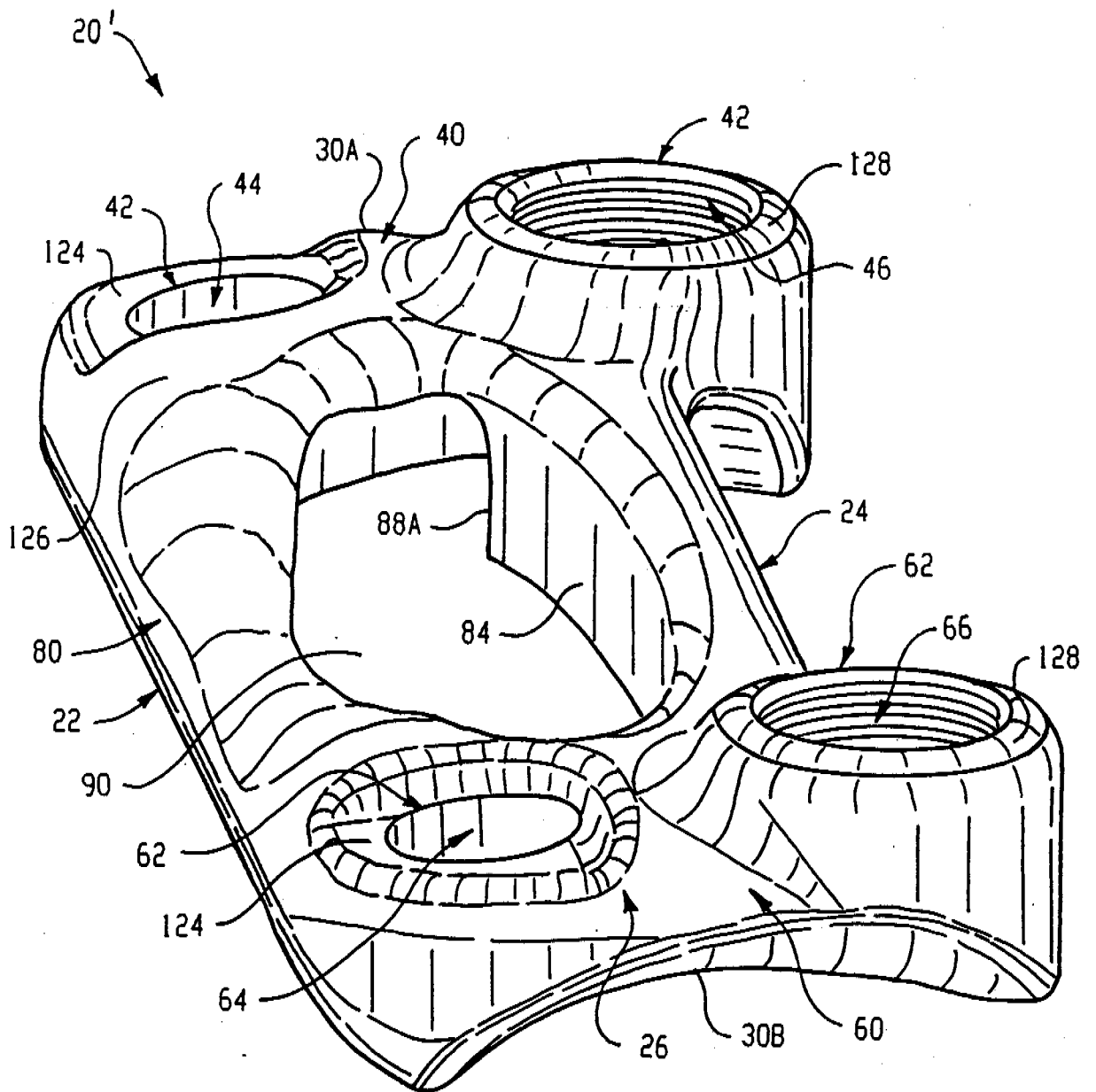


Fig. 15



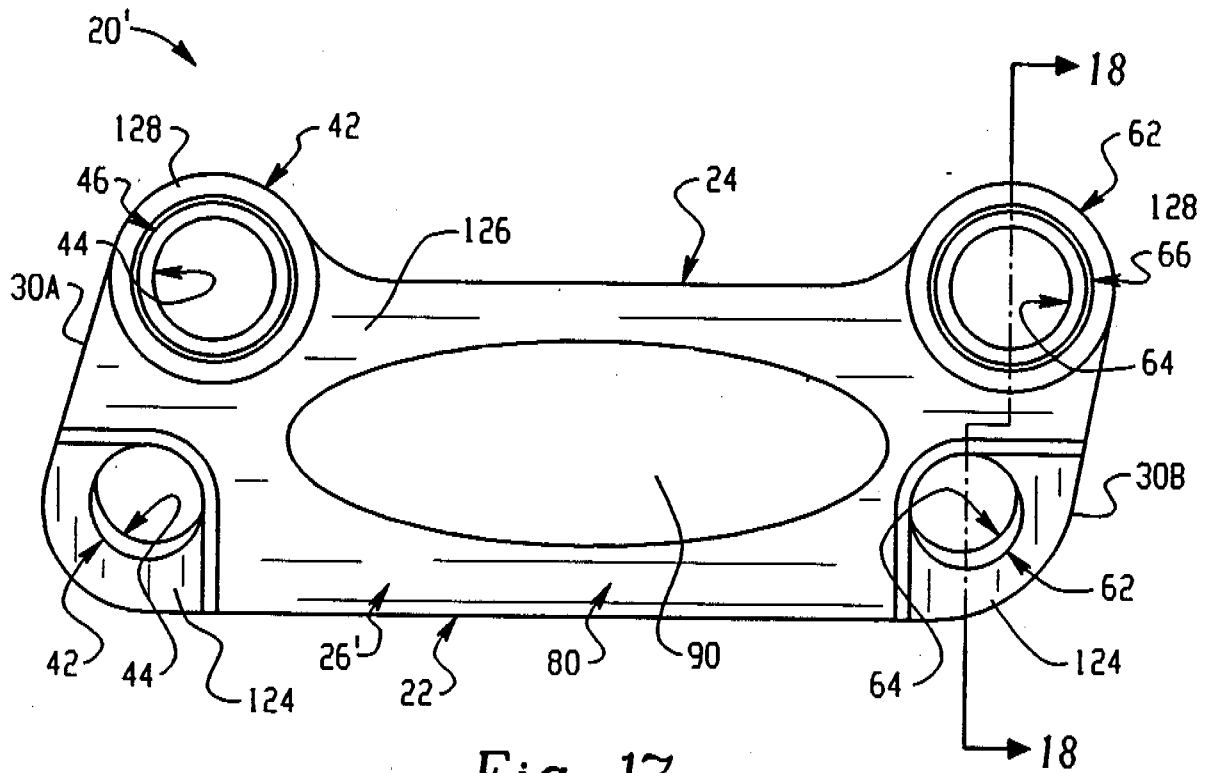


Fig. 17

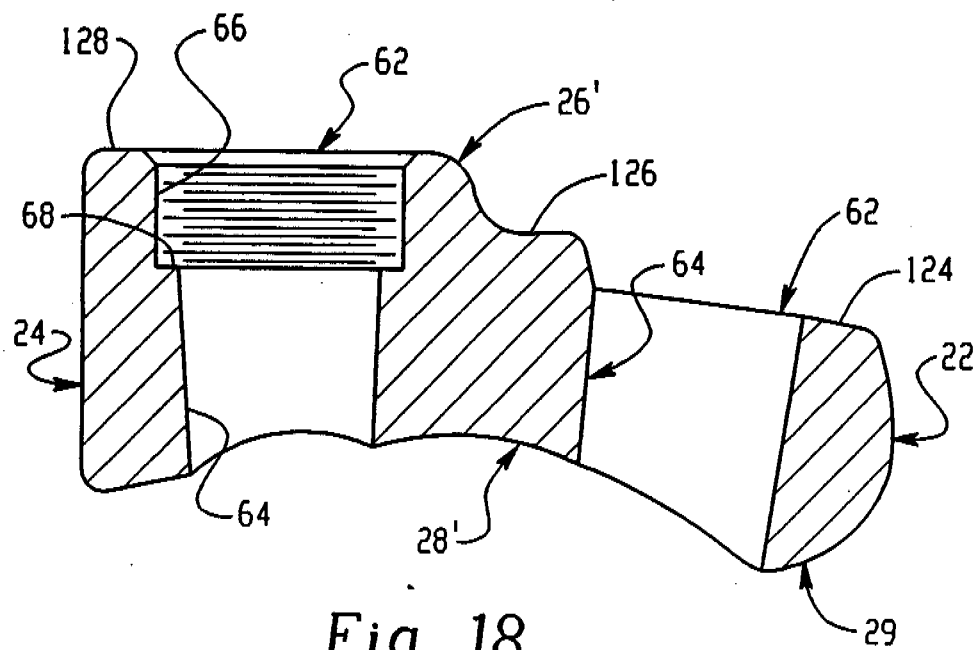


Fig. 18

07/14/98  
1c549 U.S. PTO

EXPRESS MAIL LABEL NO. EMO16592133US

Attorney Docket No. 23724-3

Box Patent Application  
Assistant Commissioner for Patents  
Washington, DC 20231

1c511 U.S. PTO  
09/11/99  
09/11/99

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s) : Randall R. Theken; Lukas Eisermann; and Ben Taylor

For (title) : BONE FIXATION SYSTEM

1. Type of Application

This new application is for a(n):

- (X) Original (nonprovisional)  
( ) Continuation  
( ) Continuation-in-part (CIP)  
( ) Divisional  
( ) Design  
( ) Plant

NOTE: If continuation, CIP or divisional, then complete section 2.

CERTIFICATION UNDER 37 C.F.R. 1.10\*  
(Express Mail label number is mandatory.)  
(Express Mail certification is optional.)

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date July 14, 1998, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EMO16592133US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Pamela A. Matheis  
(type or print name of person mailing paper)

*Pamela A. Matheis*

Signature of person mailing paper

WARNING:

Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

\*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

NOTE: If the new application being transmitted is a continuation, CIP or divisional, of a parent case, or where the parent case is an International Application which designated the U.S., or the benefit of a prior provisional application is claimed, then check the following item and complete section as follows.

- ☐ The new application being transmitted claims the benefit of prior U.S. application(s).
- 2.1 Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed Reg. 20,195, at 20,205.

(complete the following, if applicable)

Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. 120, 121 and 365(c)

- ☐ "This is a  
☐ continuation  
☐ continuation-in-part  
☐ divisional

of copending application(s) serial number filed on."

- ☐ International Application\_\_\_\_\_ filed on\_\_\_\_\_ and which designated the U.S."

Note: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S. Moreover, (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

- ☐ "The nonprovisional application designated above, namely application no.\_\_\_\_\_, filed\_\_\_\_\_, claims the benefit of U.S. Provisional Application(s) No(s).:

*{list application no(s). and filing date(s)}*

B. 35 U.S.C. 119(e) (Provisional Application)

- ☐ "This application claims the benefit of U.S. Provisional Application(s) No(s).:

*{list application no(s). and filing date(s)}*

2.2 Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application, including any prior International Application designating the U.S., identified above in item 2.1(A), in turn itself claim(s) foreign priority(ies) as follows:

*{list country, application no(s). and filing date(s)}*

The certified copy(ies) has (have)

☐ been filed on\_\_\_\_, in prior application serial no.\_\_\_\_, which was filed on\_\_\_\_.

☐ is (are) attached.

### 2.3 Maintenance of Copendency of Prior Application

*NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).*

#### A. ☐ Extension of time in prior application

*(This item must be completed and the papers filed in the prior application if the period set in the prior application has run.)*

☐ A petition, fee and response extends the term in the pending **prior** application until Extension of\_\_\_\_\_.

☐ A **copy** of the petition filed in prior application is attached.

#### B. ☐ Conditional Petition for Extension of Time in Prior Application

*(complete this item, if previous item not applicable)*

☐ A conditional petition for extension of time is being filed in the pending **prior** application.

☐ A **copy** of the conditional petition filed in the prior application is attached.

### 2.4 Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

*(complete applicable item A, B and/or C below)*

A. ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) In this application are

☐ the same.

☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

*{ type name(s) of inventor(s) to be deleted }*



- B. ☐ This application discloses and claims additional disclosures by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

- ☐ the following additional inventor(s) have been added:

*(type name(s) of inventor(s) to be added)*

- C. ☐ The inventorship for all the claims in this application are

☐ the same.

- ☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

## 2.5 Abandonment of Prior Application *(if applicable)*

- ☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so to make this application copending with said prior application.

*NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.*

## 2.6 Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

*NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g. experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.*

*(check the next item, if applicable)*

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

## 2.7 Small Entity (37 CFR § 1.28(a))

- ☐ Applicant has established small entity status by the previous submission of a statement in prior application serial no. \_\_\_\_\_ on \_\_\_\_\_.

- ☐ A copy of the amendment previously filed is included.

*WARNING: See 37 CFR § 1.28(a).*

## 2.8. Notification in Parent Application of this Filing

- ☐ A notification of the filing of this  
(check one of the following)

- ☐ continuation  
☐ continuation-in-part  
☐ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

## 2.9 Incorporation by Reference

- ☐ the entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

## 3. Papers Enclosed Which are Required for Filing Date Under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application

- (X) 20 Pages of specification  
(X) 7 Pages of claims  
(X) 1 Pages of Abstract  
(X) 11 Sheets of drawing  
    (X) formal  
    ( ) informal

## 4. Additional papers enclosed

- ☐ Amendment to claims:

- ☐ **Cancel** in this application claims \_\_\_\_\_ before calculating the filing fee. (At least one original independent claim must be retained for filing purposes).  
☐ **Add** the claims shown in the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims).

- ☐ Preliminary Amendment  
(X) Information Disclosure Statement (37 C.F.R. 1.98)  
(X) Form PTO-1449 with references cited  
☐ Citations  
☐ Declaration of Biological Deposit

- ☐ Special Comments  
☐ Other

**5. Declaration or oath (including power of attorney)**

☒ ENCLOSED.

- ☒ Newly executed (original or copy)  
☐ Copy from prior application No. 0 / (37 CFR 1.63(d)-  
continuation/divisional)

- ☐ DELETION OF INVENTOR(S) - signed statement attached deleting  
inventor(s) named in the above-noted prior application (37 CFR 1.63(d) and  
1.33(b))

Declaration or Oath executed by: (check all applicable boxes)

- ☒ inventor(s).  
☐ legal representative of inventor(s). 37 CFR 1.42 or 1.43  
☐ joint inventor or person showing a proprietary interest on behalf of inventor who  
refused to sign or cannot be reached.  
☐ this is the petition required by 37 CFR 1.47 and the statement required by 37 CFR  
1.47 is also attached. See item 13 below for fee.

☐ NOT ENCLOSED.

- ☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf  
of all the above named inventor(s). The declaration or oath, along with the  
surcharge required by 37 CFR 1.16(e) can be filed subsequently.

- ☐ Showing that the filing is authorized. (Not required unless called into question. 37  
CFR 1.41(d)).

**6. Inventorship Statement**

**WARNING:**

If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at  
the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

- ☐ The same  
or  
☐ Not the same. An explanation, including the ownership of the various claims at the time the last  
claimed invention was made,  
☐ is submitted  
☐ will be submitted.

**7. Language**

- ☒ English  
☐ Non-English  
☐ the attached translation is a verified translation. 37 CFR 1.52(d).

8. Assignment

(X) An assignment of the invention to Theken Surgical L.L.P.

(X) is attached. (A separate "ASSIGNMENT COVER LETTER ACCOMPANYING NEW PATENT APPLICATION" is also attached.)

( ) will follow.

( ) The prior application is assigned of record to \_\_ (copy attached).

9. Certified Copy - Foreign Priority Claim Under 35 U.S.C. 119

Certified copy(ies) of application(s)

*{list country, application no(s), and filing date(s)}*

from which priority is claimed

( ) is (are) attached.

( ) will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application form which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 17 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OR PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 C.F.R. 1.16)

A. (X) Regular Application

CLAIMS AS FILED				
	Number Filed	Number Extra	Rate	Basic Fee \$790.00
Total Claims (37 CFR 1.16(c))	36 - 20 =	16	x \$ 22.00	\$ 352.00
Independent Claims (37 CFR 1.16(b))	- 3 =	0	x \$ 82.00	\$ 0.00
Multiple dependent claim(s), if any (37 CFR 1.16(d))	0	0	x \$ 270.00	\$ 0.00

( ) Amendment canceling extra claims enclosed.

( ) Amendment deleting multiple dependencies enclosed.

( ) Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims paid on filing they must be paid or the claims canceled, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency, 37 CFR 1.16(d).

Filing Fee Calculation \$ 1,142.00

**B. () Design Application**  
(\$330.00 - 37 CFR 1.16(f))

Filing Fee Calculation \$

**11. Small Entity Statement(s)**

- (X) Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached.

Filing Fee Calculation (50% of A or B above) \$ 571.00

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

**12. Request for International-Type Search (37 C.F.R. 1.104(d))**

- ( ) Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

**13. Fee Payment Being Made At This Time**

- ( ) NOT ENCLOSED.  
( ) No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

- (X) ENCLOSED  
(X) Filing fee \$ 571.00  
(X) Recording assignment  
(\$40.00; 37 CFR 1.21(h)(1)) \$ 40.00

- ( ) petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. (\$130.00; 37 CFR 1.47 & 1.17(h))  
\$ \_\_\_\_\_

- ( ) for processing an application with a specification in a non-English language. (\$130.00 37 CFR 1.52(d) and 1.17(k))  
\$ \_\_\_\_\_

- ( ) processing and retention fee. (\$130.00; 37 CFR 1.53(d) and 1.21(l))  
\$ \_\_\_\_\_

- ( ) Fee for international-type search report. (\$40.00; 37 CFR 1.21(e))  
\$ \_\_\_\_\_

Total fees enclosed

\$ 611.00

**14. Method of Payment of Fees**

☒ Check in the amount of \$ 611.00

☐ Charge Account No. 02-2051 in the amount of \$ A duplicate of this transmittal is attached.

**15. Authorization to Charge Additional Fees**

WARNING: If no fees are to be paid on filing the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 02-2051, **identifying our Attorney Docket No. 23724-3**.

☒ 37 CFR 1.16(a), (f), or (g) (filing fees)

☒ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

☒ 37 CFR 1.17 (application processing fees)

☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 CFR 1.17(a)(1)-(5) (extension fees pursuant to 37 CFR 1.136(a))

☐ 37 CFR 1.18 (issue fee at or before mailing Notice of Allowance, pursuant to 37 CFR 1.311(b))

**16. Instruction As To Overpayment**

☒ Credit Account No. 02-2051, **identifying our Attorney Docket No. 23724-3**.

☐ Refund

17. Incorporation by reference a. led pages

( ) The following pages are incorporated by reference:

(X) "Assignment Cover Letter Accompanying New Application"; number of pages added 1

(X) Added Pages For Papers Referred To In Item 4 Above; number of pages added 5

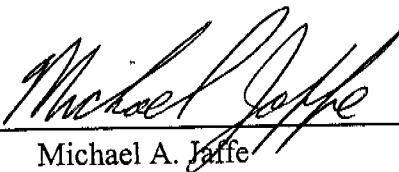
( ) Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application; number of pages added \_\_\_\_\_

(X) no further pages form a part of this Transmittal. The transmittal ends with this page.

---

Date:

7/14/98



Michael A. Jaffe  
Reg. No. 36,326  
BENESCH, FRIEDLANDER,  
COPLAN & ARONOFF LLP  
2300 BP Tower  
200 Public Square  
Cleveland, OH 44114-2378  
Phone: (216) 363-4495

#  
2

(Rel. 7-1-87 Pub. 605)

FORM 5-8

5-63

Practitioner's Docket No. 23724-3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Serial No.: 09 / 114,996

Group No.: 3731

Filed: JULY 14, 1998

Examiner:

For: BONE FIXATION SYSTEM

Assistant Commissioner for Patents  
Washington, D.C. 20231

REQUEST FOR CORRECTED FILING RECEIPT

1. Attached is a copy of the official filing receipt received from the PTO in the above application for which issuance of a corrected filing receipt is respectfully requested.
2. There is an error with respect to the following data, which is:

☒ incorrectly entered

and/or

☐ omitted.

Error in

1. ☒ Applicant's name
2. ☒ Applicant's address
3. ☐ Title
4. ☐ Filing Date
5. ☐ Serial Number
6. ☐ Foreign/PCT Application Re:
7. ☐ Other

Correct data

- 1: BEN TAYLOR
- 2: BARBERTON, OH & HERTFORDSHIRE, ENGLAND
- 3.
- 4.
- 5.
- 6.
- 7.

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8a)

I hereby certify that this correspondence is, on the date shown below, being:

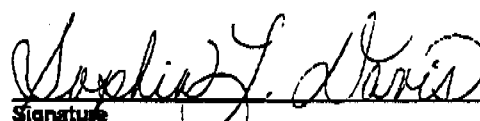
MAILING

☐ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

FACSIMILE

☒ transmitted by facsimile to the Patent and Trademark Office.

Date: 8/10/98

  
Signature  
SOPHIA L. DAVIS  
(type or print name of person certifying)

(Request for Corrected Filing Receipt [5-8]—page 1 of 2)



3. (complete the following applicable item)

- A. ☒ The correction(s) is/are not due to any error by applicant and no fee is due.

OR

- B. ☐ At least one of the above corrections is due to applicant's error and the fee therefor, under 37 C.F.R. 1.19(h), of \$25.00 is paid as follows:

- ☐ Enclosed is check for \$25.00.  
☐ Charge Account \_\_\_\_\_ \$25.00.

  
SIGNATURE OF PRACTITIONER

Reg. No.: 36.326

Tel. No.: (216) 363-4495

Customer No.:

MICHAEL A. JAFFE  
(type or print name of practitioner)  
BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP  
2300 BP AMERICA BUILDING  
P.O. Address  
200 PUBLIC SQUARE  
CLEVELAND, OH 44114-2378

(Request for Corrected Filing Receipt [5-8]—page 2 of 2)

08/10/98 14:26 383 8170

004

PTO-103X  
(Rev. 8-95)

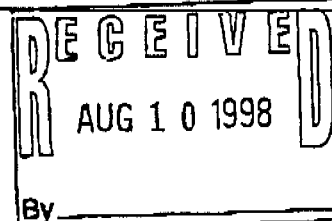
FILING RECEIPT



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/114,996	07/14/98	3731	\$571.00	23724-3	11	36	3

BENSECH FRIEDLANDER COPLAN & ARONOFF  
2300 BP AMERICA BUILDING  
200 PUBLIC SQUARE  
CLEVELAND OH 44114-2378



Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

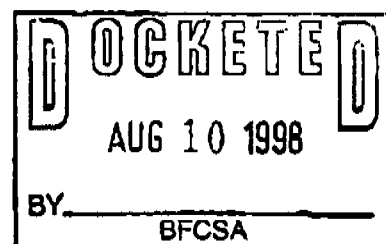
Applicant(s)

~~RANBERTON~~  
RANDALL R. THEKEN, ~~BARDERTON~~ OH; LUKAS EISERMANN,  
CLEVELAND, OH; BEN ~~TAYOR~~, ~~HARTIONDSHIRE~~ ENGLAND.  
TAYLOR ~~HERTFORDSHIRE~~

FOREIGN FILING LICENSE GRANTED 08/03/98  
TITLE  
BONE FIXATION SYSTEM

\* SMALL ENTITY \*

PRELIMINARY CLASS: 606



EXPRESS MAIL NO. EM016592133US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Randall R. Theken et al.  
FOR : BONE FIXATION SYSTEM  
ATTORNEY DOCKET NO. : 23724-3

Cleveland, Ohio 44114-2378  
July 14, 1998

#3

**INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 C.F.R. §1.97**

Assistant Commissioner For Patents  
Washington, DC 20231

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.56 and §1.98, Applicant would like to call the Examiner's attention to the references listed on the attached Form PTO-1449.

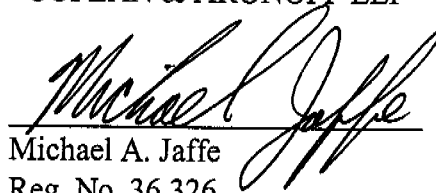
In accordance with 37 C.F.R. §1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the national application, or before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. §1.97(g) and 37 C.F.R. § 1.97(h), filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made and shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 02-2051, our Docket No. 23724-3.

Respectfully submitted,

BENESCH, FRIEDLANDER  
COPLAN & ARONOFF LLP

A handwritten signature in dark ink, appearing to read "Michael A. Jaffe", is written over a horizontal line.

Michael A. Jaffe  
Reg. No. 36,326  
2300 BP America Building  
200 Public Square  
Cleveland, OH 44114-2378  
(216) 363-4495

Paper #3

Subst. Form PTO-1449		Atty. Docket No.: 23724-3		Serial No.: 09/114,996	
APPLICANT'S(S') INFORMATION DISCLOSURE STATEMENT		Applicant(s): Randall R. Theken et al.			
		Filing Date:		Group:	

U.S. PATENT DOCUMENTS							
Initial*		Document No.	Date	Name	Class	Subcl.	Filing Date
	AA	4,743,256	5/10/88	Brantigan	<del>623</del>	<del>17</del>	<del>1/22/87</del>
	AB	5,085,660	2/04/92	Lin	<del>606</del>	<del>73</del>	<del>11/19/90</del>
	AC	5,108,395	4/28/92	Laurain	<del>606</del>	<del>61</del>	<del>9/18/90</del>
	AD	5,261,910	11/16/93	Warden et al.	<del>606</del>	<del>61</del>	<del>2/19/92</del>
	AE	5,324,290	6/28/94	Zdeblick et al.	<del>606</del>	<del>61</del>	<del>9/24/92</del>
	AF	5,360,431	11/01/94	Puno et al.	<del>606</del>	<del>72</del>	<del>4/26/90</del>
	AG	5,466,237	11/14/95	Byrd, III et al.	<del>606</del>	<del>61</del>	<del>11/19/93</del>
	AH	5,474,555	12/12/95	Puno et al.	<del>606</del>	<del>73</del>	<del>8/03/94</del>

OTHER ART	
	AI "University <sup>AM</sup> Plate Titanium Anterior System", by Howard S. An, M.D., and Robert A. McGuire, M.D., AcroMed, pgs. 1-8, 1996
	AJ "Kaneda SR <sup>TM</sup> Anterior Spinal System", by Kiyoshi Kaneda, M.D., and Robert W. Gaines, Jr., M.D., AcroMed, pgs. 1-11
	AK "Ligament Strain and Ankle Joint Opening During Ankle Distraction", by Randy Theken, M.S., et al., Arthroscopy: The Journal of Arthroscopic and Related Surgery, pgs. 469-473, 1992
	AL "Basilar Crescentic Osteotomy A Three-Dimensional Computer Simulation", by Randy Theken, M.S., et al., Orthopedic Clinics of North America, Vol. 20, No. 4, October 1989, pgs. 571-582
	AM "A Theoretical Finite Element and Biomechanical Analysis of Transpedicular Screws for Fixation of the Spine", by Randall Theken, M.S., et al., First presented at The 2nd International Meeting on Advanced Spine Techniques, April 26-29, 1995
	AN "Fatigue Characterization of Anterior Screw/Rod Constructs in Axial Compression", by Randall R. Theken, M.S., et al., First presented at The 2nd International Meeting on Advanced Spine Techniques, April 26-29, 1995

Examiner:	Date Considered: 9/17/99
-----------	--------------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication to applicant.

Subst. Form PTO-1449		Atty. Docket No.: 23724-3		Serial No.: 09/114,996	
APPLICANT'S(S') INFORMATION DISCLOSURE STATEMENT		Applicant(s): Randall R. Theken et al.			
		Filing Date:		Group:	

U.S. PATENT DOCUMENTS							
Initial*		Document No.	Date	Name	Class	Subcl.	Filing Date
<i>RMV</i>	AO	5,496,321	3/05/96	Puno et al.	<del>600</del>	61	<del>12/12/94</del>
	AP	5,603,714	2/18/97	Kaneda et al.	<del>606</del>	61	<del>12/12/94</del>
	AQ	5,624,442	4/29/97	Mellinger et al.	<del>606</del>	61	<del>10/05/95</del>
<i>RMV</i>	AR	5,697,929	12/16/97	Mellinger	<del>606</del>	61	<del>10/18/95</del>
	AS						
	AT						
	AU						
	AV						

FOREIGN PATENT DOCUMENTS							
		Document No.	Date	Country	Class	Subcl.	Translation?

OTHER ART		
<i>RMV</i>	AW	"Fatigue Characterization of Hook/Rod Assemblies Loaded in Compression", by Randall R. Theken, M.S., et al., First presented at The 2nd International Meeting on Advanced Spine Techniques, April 26-29, 1995
<i>RMV</i>	AX	Theken Orthopaedic Brochure, Pinnacle, 1994
	AY	
	AZ	

Examiner: <i>E. Haler</i>	Date Considered: 9/17/99
---------------------------	--------------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication to applicant.

*Handwritten:* Hf  
8/10/99  
T2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Randall R. Theken  
FOR : BONE FIXATION SYSTEM  
SERIAL NO. : 09/114,996  
FILED : July 14, 1998  
ATTORNEY DOCKET NO. : 72258/95945

TECHNOLOGY CENTER 3700

AUG 10 1999

RECEIVED

POWER TO INSPECT

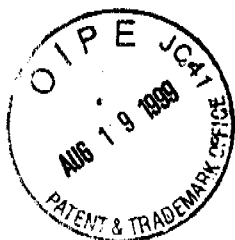
Assistant Commissioner for Patents  
Washington, D.C. 20231

Please permit Attia Nawab, of Landon & Stark Associates, to inspect and make copies of the above-identified application and corresponding assignment records. This power to inspect expires August 9, 1999.

I am the attorney of record.

*Handwritten signature: Michael A. Jaffe*

Michael A. Jaffe  
Reg. No: 36,326  
ARTER & HADDEN  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44114  
(216) 696-3394



3731

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Randall R. Theken  
TITLE OF THE INVENTION : BONE FIXATION SYSTEM  
SERIAL NO. : 09/114,996  
FILED : July 14, 1998  
ATTORNEY DOCKET NO. : 72258/95945

TH  
8-26-99  
#5 / 181

STATUS INQUIRY

Assistant Commissioner for Patents  
Washington, DC 20231

RECEIVED  
AUG 25 1999  
TC 3700 MAIL ROOM

Dear Sirs:

1. More than 12 months have passed since the filing of this application on July 14, 1998. No communication has been received from the Patent and Trademark Office indicating action on this application.
2. Kindly advise the undersigned of the present status of this application.

Respectfully submitted,

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, DC 20231

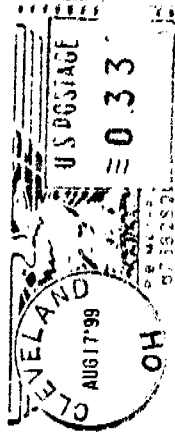
on August 17, 1999  
Doris J. White  
(SIGNATURE)  
Doris J. White

Todd R. Tucker  
Todd R. Tucker  
Reg. No. 40,850 - 416 310 3183  
ARTER & HADDEN  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475

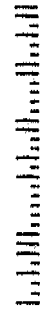


ARTER & HADDEN<sup>LLP</sup>  
ATTORNEYS AT LAW

1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475



Assistant Commissioner for Patents  
Washington, DC 20231



## Interview Summary

Application No.  
09/114,996

Applicant(s)  
Theken, et al.

Examiner  
Eduardo C. Robert

Group Art Unit  
3732



All participants (applicant, applicant's representative, PTO personnel):

(1) Eduardo C. Robert

(3) Jeff Smith

(2) Mr. Todd R. Tucker

(4) \_\_\_\_\_

Date of Interview Sep 16, 1999

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☒ was reached. ☐ was not reached.

Claim(s) discussed: 1-36

Identification of prior art discussed:

None

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:  
Request an oral election and the applicant elected invention I (claims 1-25), drawn to a bone fixation system.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Jeffrey A. Smith  
PRIMARY EXAMINER

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Randall R. Theken  
FOR : BONE FIXATION SYSTEM  
SERIAL NO. : 09/114,996  
FILED : July 14, 1998  
ART UNIT : 3731  
ATTORNEY DOCKET NO. : 72258/95945

September 21, 1999

#6 1/2 / chg  
of  
addressCHANGE OF CORRESPONDENCE ADDRESS - PATENT APPLICATION

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Please change the correspondence address for the above-identified patent application to:

Todd R. Tucker, Esq.  
ARTER & HADDEN LLP  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475  
Telephone: (216) 696-3483  
Fax: (216) 696-2645

I am the attorney or agent of record. In the event any fees are due with the filing of this document, the Commissioner is authorized to charge Deposit Account No. 50-0902, referencing our Docket No. 72258/95945.

Respectfully submitted,

ARTER &amp; HADDEN LLP

I hereby certify that this correspondence is being  
transmitted, via facsimile, to the Assistant  
Commissioner of Patents, Washington, DC 20231

on September 21, 1999

Pamela G. Mathews

(SIGNATURE)

PAMELA A. MATHEWS

Michael A. Jaffe

Reg. No. 36,326

1100 Huntington Building  
925 Euclid Avenue  
Cleveland, OH 44115-1475  
(216) 696-3394

455993.1

\*\* TOTAL PAGE.02 \*\*

0075

# ARTER & HADDEN

ATTORNEYS AT LAW

*founded 1843*

Columbus  
Dallas  
Washington, D.C.  
Woodland Hills

925 Euclid Avenue  
1100 Huntington Building  
Cleveland Ohio 44115-1475  
216/696-1100 telephone  
216/696-2645 facsimile

Irvine  
Los Angeles  
San Francisco

## FAX COVER SHEET

TO:

Examiner Eduardo Rober U.S. Patent and Trademark Office (703)-305-7333

FAX NO.:

(703)-308-2708

FROM: Michael A. Jaffe, Esq.

DATE: 9/21/99

TIME: \_\_\_\_\_

TOTAL NO. OF PAGES: 2  
(including cover page)

CLIENT / MATTER: 72258/95945

## COMMENTS

Type Message - Max 256 Characters  
456004.1

*If you have any problems reading this transmission,  
please call the above telephone number and ask for the fax operator.*

## CONFIDENTIALITY NOTICE

The information in this fax transmission and the documents accompanying it contain confidential information belonging to the sender which is legally privileged. The information is intended only for the use of the individuals or entities named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this faxed information is strictly prohibited. If you have received this fax in error, please immediately notify us by telephone to arrange for return of the original documents to us.

# **Specialized Patent Services**

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[Specialpat@aol.com](mailto:Specialpat@aol.com)

**Internet:**

[www.specializedpatent.com](http://www.specializedpatent.com)

**This file wrapper was thoroughly reviewed by our staff. The original United States Patent Office file is missing paper # 7.**



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/114,996 07/14/98 THEKEN

R 23724-3

EXAMINER

QM12/0923

TODD R. TUCKER, ESQ.  
ARTER & HADDEN LLP  
1100 HUNTINGTON BUILDING  
925 EUCLID AVENUE  
CLEVELAND OH 44115-1475

ROBERT, E

ART UNIT

PAPER NUMBER

3732

DATE MAILED:

09/23/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/114,996

Applicant(s)  
Theken, et al.

Examiner  
Eduardo C. Robert

Group Art Unit  
3732



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-36 is/are pending in the application.
- Of the above, claim(s) 26-36 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-25 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawing(s) filed on Jul 14, 1998 is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

JEFFREY A. SMITH  
PRIMARY EXAMINER

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a bone fixation system, classified in class 606, subclass 61.
- II. Claims 26-31, drawn to fastener means, classified in class 606, subclass 73.
- III. Claims 32-36, drawn to a bone plate, classified in class 606, subclass 69.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed such as screw means having a taper portion and a threaded portion. The subcombination has utility in other combination such as being used with a plate which is not elongated, e.g. circular.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination



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as claimed does not require the particulars of the subcombination as claimed such as the top portion including at least one tapered opening and the bottom portion including at least one tapered opening. The subcombination has utility in other combination such as being used in combination with nail, pins, staples.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as for connecting a neck component to a stem component of a modular multiple component assembly used to replace a femur or humerus. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Todd R. Tucker on September 16, 1999 a provisional election was made with traverse to prosecute the invention I, claims 1-25.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 26-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment wherein the ledge members are connected together to form an intervertebral cage device, as per claim 3, the embodiment wherein the window means includes a plurality of holes, as per claim 7, and the embodiment wherein the engagement means includes at least one of : spikes and teeth, as per claim 23, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

- a) A *separate* letter to the Draftsman in accordance with MPEP § 608.02(r); and
- b) A print or pen-and -ink sketch showing changes in *red ink* in accordance with MPEP § 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch

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with proposed corrections shown in red ink is required in response to this Office Action, and *may not be deferred.*

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8 and 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, line 1, "said support means" lacks a prior antecedent.

In claim 5, line 1, "said bridge means" lacks a prior antecedent.

In claim 9, lines 1 and 2, "said top and bottom portions include at least one opening" is indefinite because it is unclear if each portion, i.e. top and bottom, has at least one opening or the top and bottom portions in combination has at least one opening.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 16, 17, 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuzaki, et al.

Matsuzaki, et al. disclose a system comprising an elongated plate means and fastener means 21 for fastening the plate means. The plate means has a top portion, a bottom portion, and a bridge portion (see Figure 9). The bridge portion comprises ledge members which are connected together to form an intervertebral cage device or medial side (see Attachment A). The ledge members include a bioresorbable compound, i.e. a coating of calcium phosphate compound (see col. 6, lines 65-67). The bridge portion includes an aperture or window. Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener means 21. Each of the fastener means 21 include a head portion which has a diameter greater than the at least one opening (see Figure 10). The plate means has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section. The medial side has ribs or teeth for engaging with the bone structures.

Claims 1, 5, 6, 9, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Osmk Med. Inst.

Osmk Med. Inst. discloses a system comprising an elongated plate means and fastener means for fastening the plate means. The plate means has a top portion, a bottom portion, and a bridge portion. The bridge portion includes a window for observation. The window has an oval

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shape. The top and bottom portions, each includes at least one opening to receive the fastener means which have a head portion. The plate means has a posterior side having a medial surface that is flat in cross-section..

Claims 1-4, 9, 10, 14, 15, 17, 19-21, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kehr.

Kehr discloses a system comprising an elongated plate means and fastener means for fastening the plate means. The plate means has a top portion, a bottom portion, and a bridge portion (see Figure 1). The bridge portion comprises an insert, medial side, or artificial graft 16 which includes ledge members. Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener means. The at least one opening of each portions include a first fastener receiving section having a tapered surface and the fastener means including a mating tapered surface (see Figure 4). The plate means has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section.

Claims 1, 9-11, 14, 15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson, et al.

Nilsson, et al. disclose a system comprising an elongated plate means 13 and fastener means for fastening the plate means (see Figure 2) . The plate means has a top portion, a bottom portion, and a bridge portion. Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener means. The at least one opening of each

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portions includes a fastener receiving section having a gradual decrease in width along the section (see Figure 2) and the fastener means have mating surfaces. Each fastener means includes a set screw member 18 having a threaded surface. The plate means has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osmk Med. Inst.

Osmk Med. Inst. discloses the claimed invention except for the window being a plurality of holes (claim 7) or having an irregular shape (claim 8). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the window of Osmk Med. Inst. as a plurality of holes or having an irregular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an opening for observation. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Application/Control Number: 09/114,996

Page 9

Art Unit: 3732

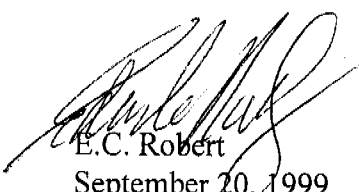
*Allowable Subject Matter*

Claims 12 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liu, et al.; Nuwayser; Ramirez Jimenez; Hednerson, et al.; Pohndorf, et al.; Crook; Beck, et al.; Rezaian; Doty; Day, et al.; Yuan, et al.; Vignaud, et al.; and Benzel, et al. are cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is (703) 305-7333.

  
E.C. Robert  
September 20, 1999

  
JEFFREY A. SMITH  
PRIMARY EXAMINER

09/114996

NOTICE OF DRAFTERPERSON'S  
PATENT DRAWING REVIEWThe drawing filed (insert date) 7/14/98 are:A. ☒ not objected to by the Draftperson under 37 CFR 1.84 or 1.152.B. ☐ objected to by the Draftperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this notice.

## 1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:

Black ink. Color.

☐ Color drawing are not acceptable until petition is granted.

Fig.(s) \_\_\_\_\_

☐ Pencil and non black ink is not permitted. Fig(s) \_\_\_\_\_

## 2. PHOTOGRAPHS. 37 CFR 1.84(b)

☐ Photographs are not acceptable until petition is granted,☐ 3 full-tone sets are required. Fig(s) \_\_\_\_\_☐ Photographs not properly mounted (must be on Bristol board or photographic double-weight paper). Fig(s) \_\_\_\_\_☐ Poor quality (half-tone). Fig(s) \_\_\_\_\_

## 3. TYPE OF PAPER. 37 CFR 1.84(e)

☐ Paper not flexible, strong, white and durable.

Fig.(s) \_\_\_\_\_

☐ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not acceptable. (too thin)☐ Mylar, vellum paper is not acceptable (too thin).

Fig(s) \_\_\_\_\_

## 4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:

☐ 21.0 cm by 29.7 cm (DIN size A4)☐ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)☐ All drawings sheets not the same size.

Sheet(s) \_\_\_\_\_

## 5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm  
SIZE: A4 SizeTop 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm  
SIZE: 8 1/2 x 11☐ Margins not acceptable. Fig(s) \_\_\_\_\_☐ Top (T) \_\_\_\_\_ Left (L)☐ Right (R) \_\_\_\_\_ Bottom (B)

## 6. VIEWS. 37 CFR 1.84(h)

REMINDER: Specification may require revision to correspond to drawing changes.

☐ Views connected by projection lines or lead lines.

Fig.(s) \_\_\_\_\_

Partial views. 37 CFR 1.84(h)(2)

☐ Brackets needed to show figure as one entity.

Fig.(s) \_\_\_\_\_

☐ Views not labeled separately or properly.

Fig.(s) \_\_\_\_\_

☐ Enlarged view not labeled separately or properly.

Fig.(s) \_\_\_\_\_

## 7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3)

☐ Hatching not indicated for sectional portions of an object.

Fig.(s) \_\_\_\_\_

☐ Sectional designation should be noted with Arabic or

Roman numbers. Fig.(s) \_\_\_\_\_

## 8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)

☐ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned, so that the top becomes the right side, except for graphs. Fig.(s) \_\_\_\_\_☐ Views not on the same plane on drawing sheet. Fig.(s) \_\_\_\_\_

## 9. SCALE. 37 CFR 1.84(k)

☐ Scale not large enough to show mechanism with crowding when drawing is reduced in size to two-thirds in reproduction.

Fig.(s) \_\_\_\_\_

## 10. CHARACTER OF LINES, NUMBERS, &amp; LETTERS. 37 CFR 1.84(l)

☐ Lines, numbers & letters not uniformly thick and well defined, clean, durable and black (poor line quality).

Fig.(s) \_\_\_\_\_

## 11. SHADING. 37 CFR 1.84(m)

☐ Solid black areas pale. Fig.(s) \_\_\_\_\_☐ Solid black shading not permitted. Fig.(s) \_\_\_\_\_☐ Shade lines, pale, rough and blurred. Fig.(s) \_\_\_\_\_

## 12. NUMBERS, LETTERS, &amp; REFERENCE CHARACTERS. 37 CFR 1.48(p)

☐ Numbers and reference characters not plain and legible.

Fig.(s) \_\_\_\_\_

☐ Figure legends are poor. Fig.(s) \_\_\_\_\_☐ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(3) Fig.(s) \_\_\_\_\_☐ English alphabet not used. 37 CFR 1.84(p)(3) Fig.(s) \_\_\_\_\_☐ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig.(s) \_\_\_\_\_

## 13. LEAD LINES. 37 CFR 1.84(q)

☐ Lead lines cross each other. Fig.(s) \_\_\_\_\_☐ Lead lines missing. Fig.(s) \_\_\_\_\_

## 14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.48(t)

☐ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Fig.(s) \_\_\_\_\_

## 15. NUMBERING OF VIEWS. 37 CFR 1.84(u)

☐ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig.(s) \_\_\_\_\_

## 16. CORRECTIONS. 37 CFR 1.84(w)

☐ Corrections not made from PTO-948 dated \_\_\_\_\_

## 17. DESIGN DRAWINGS. 37 CFR 1.152

☐ Surface shading shown not appropriate. Fig.(s) \_\_\_\_\_☐ Solid black shading not used for color contrast.

Fig.(s) \_\_\_\_\_

COMMENTS

REVIEWER Tamus DATE 8/13/98 TELEPHONE NO. 203 305 8404

ATTACHMENT TO PAPER NO. \_\_\_\_\_

PTO COPY



<b>Notice of References Cited</b>		Application No. <b>09/114,996</b>	Applicant(s) <b>Theken, et al.</b>				
		Examiner <b>Eduardo C. Robert</b>	Group Art Unit <b>3732</b>	Page 1 of 1			
<b>U.S. PATENT DOCUMENTS</b>							
		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	
	A	4,401,112	08/1983	Rezaian	606	61	
	B	4,599,086	07/1986	Doty	606	61	
	C	4,892,545	01/1990	Day, et al.	606	61	
	D	5,176,680	01/1993	Vignaud, et al.	606	60	
	E	5,344,421	09/1994	Crook	606	70	
	F	5,405,391	04/1995	Hednerson, et al.	606	61	
	G	5,458,641	10/1995	Ramirez Jimenez	623	17	
	H	5,462,722	10/1995	Liu, et al.	423	311	
	I	5,534,031	07/1996	Matsuzaki, et al.	606	61	
	J	5,648,097	07/1997	Nuwayser	424	489	
	K	5,681,310	10/1997	Yuan, et al.	606	61	
	L	5,800,433	09/1998	Benzel, et al.	606	60	
	M	5,904,683	05/1999	Pohndorf, et al.	606	61	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
	N	179,695	04/1986	E.P.O.	Kehr	623	17
	O	1,526,673	12/1989	Soviet Union	Omsk Med. Inst.	606	60
	P	9,417,744	08/1994	W.I.O.P.	Lowery, et al.	606	61
	Q	9,426,193	11/1994	W.I.O.P.	Nilsson, et al.	606	61
	R						
	S						
	T						
<b>NON-PATENT DOCUMENTS</b>							
		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)				DATE	
	U						
	V						
	W						
	X						

GP 3732

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF :

FOR

SERIAL NO.

FILED

EXAMINER

ART UNIT :

ATTORNEY DOCKET NO. :

Randall Theken et al

BONE FIXATION SYSTEM

09/114,996

July 18, 1998

Eduardo C. Robert

3732

72258/95945



RECEIVED

NOV 29 1999

Group 3700

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

1. Pursuant to 37 C.F.R. 1.97 and 1.98, and in compliance with 37 C.F.R. 1.56, the Office's attention is directed to the patents, publications and other information listed on the attached form PTO-1449. A copy of each listed document is enclosed *except for* documents previously cited by or submitted to the Office in a prior application(s) relied upon for an earlier filing date under 35 U.S.C. 120, said prior application(s) identified below:

Serial No.

Filing Date

2. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made.

3. Pursuant to 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed as an admission that the information cited in this Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

4. Regarding each listed document that is not in the English language, an English-language translation accompanies this Statement as indicated on the attached PTO-1449 or a concise explanation of the relevance of the document is set forth in the following document(s):

(X) Copy of each English language version of a search report by a foreign patent office in a counterpart foreign application, indicating the degree of relevance found by the foreign office of each document being submitted from the search report.

- ☐ Attachment entitled "Concise Explanation of Relevance of Non-English Language Documents."
  - ☐ English-language abstract.
  - ☐ 5. Pursuant to 37 C.F.R. 1.97(b) this Statement is being filed:
    - ☐ within 3 months of the filing date of a national application; or
    - ☐ within 3 months of the date of the entry of the national stage as set forth in 37 CFR 1.491 in an international application; or
    - ☐ before the mailing date of a first Office Action on the merits.
- {NOTE: Statements filed within the foregoing periods require neither a fee nor a Certification}
- ☒ 6. Pursuant to 37 C.F.R. 1.97(c) this Statement is being filed *after* the mailing date of a first Office Action on the merits but *before* the mailing date of either: a Final Office Action under 37 C.F.R. 1.113 or a Notice of Allowance under 37 C.F.R. 1.311, whichever occurs first. Accordingly, this Statement is accompanied by:
    - ☒ Certification as specified in 37 C.F.R. 1.97(e); OR
    - ☐ the fee set forth in 37 C.F.R. 1.17(p). Enclosed is a check covering the fee set forth in 37 C.F.R. 1.17(p) for consideration of this Statement
  - ☐ 7. Pursuant to 37 C.F.R. 1.97(d) this Statement is being filed *after* the period specified in 37 C.F.R. 1.97(c), but *before or concurrent with* payment of the Issue Fee. Accordingly, this Statement is accompanied by:
    - A. Certification as specified in 37 C.F.R. 1.97(e); AND
    - B. Petition requesting consideration of this Statement; AND  
 {NOTE: The IDS should be addressed to the ATTN. of appropriate Group Director of the examining group handling the application.}
    - C. The petition fee set forth in 37 C.F.R. 1.17(i). Enclosed is a check covering the fee set forth in 37 C.F.R. 1.17(i) for consideration of this Statement.
  - ☐ 8. Statement filed *after* payment of Issue Fee, but *before* patent grant:
 

This Statement is being filed *after* payment of the Issue Fee, but *before* grant of the patent; accordingly it is understood that this Statement will *not* be considered. However, it is respectfully requested that this Information Disclosure Statement be placed in the application file. {NOTE: no fees, certification or petition are required}

(X) 9. CERTIFICATION (if applicable):

(X) The undersigned hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than 3 months prior to the filing of this Statement, OR

() The undersigned hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the undersigned's knowledge, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c), more than 3 months prior to the filing of this Information Disclosure Statement.

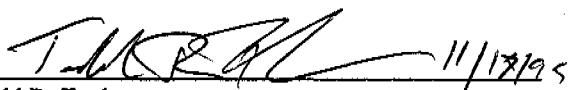
() 10. Petition required under 37 C.F.R. 1.97(d) (if applicable):

() Petition is hereby made for consideration of this Information Disclosure Statement.

The Commissioner is hereby authorized to charge any additional fees required for consideration of this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 50-0902, identifying our Docket No. 72258/95945.

Respectfully Submitted,

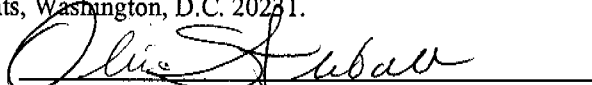
ARTER & HADDEN LLP

  
Todd R. Tucker  
Registration No. 40,850  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475  
(216) 696-3483

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Assistance Commissioner for Patents, Washington, D.C. 20231.

Date: Nov. 17, 1999

  
Name:

Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No.

PCT/US 99/15825

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:

1-4, 9, 14, 15, 17

2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

NOV 29 1999

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 616 144 A (R.A.YAP AND C.B.WORRICK) 1 April 1997 (1997-04-01) column 1, line 19 - column 2, line 62 figures	1, 9, 14, 15, 17 2
A		
X	FR 2 747 034 A (SCIENT'X) 10 October 1997 (1997-10-10) abstract; figure 3 page 2, line 28 - line 29	1-3
X	EP 0 179 695 A (P.KEHR) 30 April 1986 (1986-04-30) page 3, line 38 - page 4, line 22 figures 3, 4	1, 2, 4
X	FR 2 726 755 A (G.KEHYAYAN) 15 May 1996 (1996-05-15) abstract; figure 1	1, 2
A	US 4 445 513 A (B.ULRICH AND G.H.SLOT) 1 May 1984 (1984-05-01) abstract; figures 1, 3	1, 2
A	US 5 395 372 A (R.T.HOLT ET AL.) 7 March 1995 (1995-03-07) figure 2	1

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



Patent family members are listed in annex.

\* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

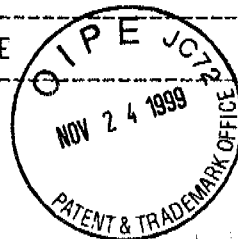
# Patent Family Annex

Information on patent family members

International Application No

PCT/US 99/15825

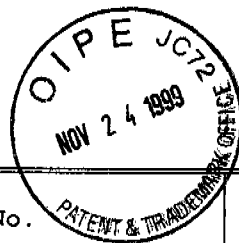
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5616144 A	01-04-1997	BR 9304828 A CA 2109907 A DE 69320593 D DE 69320593 T EP 0599640 A ES 2124288 T JP 6277228 A US 5549612 A	16-08-1994 26-05-1994 01-10-1998 04-03-1999 01-06-1994 01-02-1999 04-10-1994 27-08-1996
FR 2747034 A	10-10-1997	CA 2250804 A EP 0891169 A WO 9737620 A	16-10-1997 20-01-1999 16-10-1997
EP 0179695 A	30-04-1986	FR 2570594 A AT 41737 T	28-03-1986 15-04-1989
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Group 3700



Page # 9

Page 1 of 1

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Attorney Docket No. 72258/95945	Serial No.: 09/114,996
	Applicant: Randall R. Theken, et al	
	Filing Date: 7/14/1998	Group Art Unit: 3732

U.S. PATENT DOCUMENTS

INITIAL*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	4,445,513	5/1/84	Ulrich et al	<del>128</del>	<del>69</del>	
	AB	5,395,372	3/7/95	Holt, et al	<del>606</del>	<del>61</del>	
	AC	5,616,144	4/1/97	Yapp, et al	<del>606</del>	<del>61</del>	
	AD						
	AE						
	AF						
	AG						
	AH						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION? (YES/NO)
	AI	2 747 034	4/3/96	France			No
	AJ	2 726 755	11/10/94	France			No
	AK	0 179 695	9/26/84	Europe			No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AL	
	AM	
	AN	

EXAMINER:

DATE CONSIDERED:

3/27/00

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF : Randall Theken, et al  
 FOR : BONE FIXATION SYSTEM  
 SERIAL NO. : 09/114,996  
 FILED : July 18, 1998  
 EXAMINER : Eduardo C. Robert  
 ART UNIT : 3732  
 ATTORNEY DOCKET NO. : 72258/95945



Handwritten: 3732, J-L, 2-3-00

Handwritten: #10/Suppl IDS

SUPPLEMENT INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
 Washington, DC 20231

Sir:

1. Pursuant to 37 C.F.R. 1.97 and 1.98, and in compliance with 37 C.F.R. 1.56, the Office's attention is directed to the patents, publications and other information listed on the attached form PTO-1449. A copy of each listed document is enclosed *except for* documents previously cited by or submitted to the Office in a prior application(s) relied upon for an earlier filing date under 35 U.S.C. 120, said prior application(s) identified below:

Serial No.

Filing Date

2. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made.

3. Pursuant to 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed as an admission that the information cited in this Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

4. Regarding each listed document that is not in the English language, an English-language translation accompanies this Statement as indicated on the attached PTO-1449 or a concise explanation of the relevance of the document is set forth in the following document(s):

- ( ) Copy of each English language version of a search report by a foreign patent office in a counterpart foreign application, indicating the degree of relevance found by the foreign office of each document being submitted from the search report.



- ☐ Attachment entitled "Concise Explanation of Relevance of Non-English Language Documents."
  - ☐ English-language abstract.
  - ☐ 5. Pursuant to 37 C.F.R. 1.97(b) this Statement is being filed:
    - ☐ within 3 months of the filing date of a national application; or
    - ☐ within 3 months of the date of the entry of the national stage as set forth in 37 CFR 1.491 in an international application; or
    - ☐ before the mailing date of a first Office Action on the merits.
- {NOTE: Statements filed within the foregoing periods require neither a fee nor a Certification}
- ☒ 6. Pursuant to 37 C.F.R. 1.97(c) this Statement is being filed *after* the mailing date of a first Office Action on the merits but *before* the mailing date of either: a Final Office Action under 37 C.F.R. 1.113 or a Notice of Allowance under 37 C.F.R. 1.311, whichever occurs first. Accordingly, this Statement is accompanied by:
    - ☐ Certification as specified in 37 C.F.R. 1.97(e); OR
    - ☒ the fee set forth in 37 C.F.R. 1.17(p). Enclosed is a check covering the fee set forth in 37 C.F.R. 1.17(p) for consideration of this Statement
  - ☐ 7. Pursuant to 37 C.F.R. 1.97(d) this Statement is being filed *after* the period specified in 37 C.F.R. 1.97(c), but *before or concurrent with* payment of the Issue Fee. Accordingly, this Statement is accompanied by:
    - A. Certification as specified in 37 C.F.R. 1.97(e); AND
    - B. Petition requesting consideration of this Statement; AND  
 {NOTE: The IDS should be addressed to the ATTN. of appropriate Group Director of the examining group handling the application.}
    - C. The petition fee set forth in 37 C.F.R. 1.17(i). Enclosed is a check covering the fee set forth in 37 C.F.R. 1.17(i) for consideration of this Statement.
  - ☐ 8. Statement filed *after* payment of Issue Fee, but *before* patent grant:
 

This Statement is being filed *after* payment of the Issue Fee, but *before* grant of the patent; accordingly it is understood that this Statement will *not* be considered. However, it is respectfully requested that this Information Disclosure Statement be placed in the application file. {NOTE: no fees, certification or petition are required}



9. CERTIFICATION (if applicable):

- ( ) The undersigned hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than 3 months prior to the filing of this Statement, OR
- ( ) The undersigned hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the undersigned's knowledge, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c), more than 3 months prior to the filing of this Information Disclosure Statement.

10. Petition required under 37 C.F.R. 1.97(d) (if applicable):

( ) Petition is hereby made for consideration of this Information Disclosure Statement.

The Commissioner is hereby authorized to charge any additional fees required for consideration of this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 50-0902, identifying our Docket No. 72258/95945.

Respectfully Submitted,

ARTER & HADDEN LLP

Todd R. Tucker  
Registration No. 40,850  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475  
(216) 696-3483

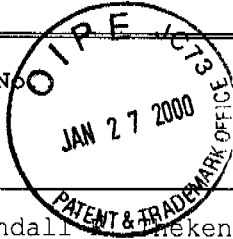
**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Assistance Commissioner for Patents, Washington, D.C. 20231.

Date: 1/24/2000

  
Name: Olivia Steuball

Supplemental Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. 72258/95945	Serial No.: 09/114,996
	Applicant: Randall Breken, et al	
	Filing Date: 07/14/98	Group Art Unit: 3732



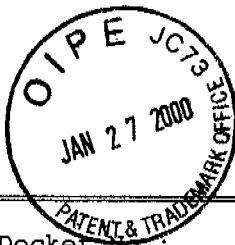
U.S. PATENT DOCUMENTS							
INITIAL*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
<i>AM</i>	AA	5,192,327	03/09/93	Brantigan	<del>623</del>	<del>17</del>	
	AB	5,609,637	03/11/97	Biedermann, et al	<del>623</del>	<del>17</del>	
	AC	4,820,305	04/11/89	Harms, et al	<del>623</del>	<del>16</del>	
<i>AM</i>	AD	5,578,034	10/26/96	Estes	<del>606</del>	<del>61</del>	
	AE	5,800,433	09/01/98	Benzel, et al	<del>606</del>	<del>61</del>	
	AF	5,681,312	10/28/97	Yuan, et al	<del>606</del>	<del>61</del>	
	AG	5,713,900	02/03/98	Benzel, et al	<del>606</del>	<del>61</del>	
<i>AM</i>	AH	5,607,426	03/04/97	Ralph, et al	<del>606</del>	<del>61</del>	

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION? (YES/NO)
	AI						No
	AJ						No
	AK						No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AL						
	AM						
	AN						
	AO						

EXAMINER: <i>E. Aug</i>	DATE CONSIDERED: 3/28/00
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\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw/line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



Supplemental Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Atty. Docket No.: 72258/95945		Serial No.: 09/114,996			
		Applicant: Randall R. Theken, et al					
		Filing Date: 07/14/98		Group Art Unit: 3732			

U.S. PATENT DOCUMENTS							
INITIAL*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	BA	5,531,746	07/02/96	Errico, et al	<del>606</del>	<del>61</del>	
	BB	5,520,690	05/28/96	Errico, et al	<del>606</del>	<del>61</del>	
	BC	5,423,826	06/13/95	Coates, et al	<del>606</del>	<del>96</del>	
	BD	5,549,612	08/27/96	Yapp, et al	<del>606</del>	<del>69</del>	
	BE	5,676,666	10/14/97	Oxland, et al	<del>606</del>	<del>61</del>	
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION? (YES/NO)
	BI						
	BJ						
	BK						

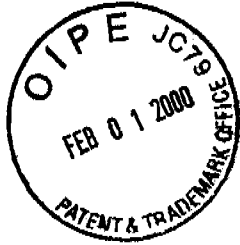
  

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BL						
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EXAMINER:	DATE CONSIDERED: 3/28/00
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\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF : Theken *et al.*  
FOR : BONE FIXATION SYSTEM  
SERIAL NO. : 09/114,996  
FILED : July 18, 1998  
EXAMINER : Eduardo C. Robert  
ART UNIT : 3732  
LAST OFFICE ACTION : September 23, 1999  
ATTORNEY DOCKET NO. : 72258/95945

TO 3110 JAL ROOM

Cleveland, Ohio 44115-1475  
January 24, 2000

**RESPONSE TO FIRST OFFICE ACTION**

Assistant Commissioner of Patents  
Washington, D.C. 20231

Dear Sir:

Enclosed with this response is a check in the amount of \$55.00 to cover the expense for a one-month extension of time.

(1mos)  
T.H.

In response to the Office Action dated September 23, 1999, applicants respond as follows:

02/03/2000 SARAYA 00000087 09114996  
01 FCB15 55.00 OP

### **Affirmation of Election**

During a telephone conversation with the Examiner on September 16, 1999 a provisional election was made with traverse to prosecute only claims 1-25 of the application. Applicants hereby affirm such election and withdraw claims 26-36 from further consideration by the Examiner as being drawn to a non-elected invention. The cancellation of these claims does not affect the inventorship related to the amended application.

### **Drawings**

Per the instructions of the Examiner, Applicants respectfully submit proposed drawing corrections to show the invention specified in the claims. The proposed drawing changes are shown in Figures 19, 20, and 21, attached to this Response. Figure 19 shows the ledge members connected together to form an intervertebral cage, as per claim 3. Figure 20 shows the embodiment wherein the window includes a plurality of holes, per claim 7, and Figure 21 shows the embodiment wherein the engagement structure includes at least one of: spikes and teeth, as per claim 23. No new matter is entered that is not supported by the claims or specification.

Since the drawings were not objected to by the Draftsman, the Applicants respectfully submit that it is not clear why the Examiner states that a separate letter to the Draftsman is necessary in accordance with MPEP § 608.02(r). This letter, however, has been included.

The attached drawings consist of sketches showing changes, in red ink, to the original drawings in accordance with MPEP § 608.02(v). New formal drawings to correct the noted objections will be submitted if and when the application is allowed by the Examiner.

### Claims Amendments

Please amend the claims as follows:

1. (amended) A bone fixation system comprising:
- an elongated plate [means] having a top portion, a bottom portion, and a bridge portion integrally spanning between the top portion and bottom portion, said bridge portion for connecting at least two bone structures;
- at least one support structure that engages external surfaces of bone structures at terminal ends of said bone structures; and
- a fastener [means] for fastening the plate [means] to said [at least two] bone structures.
2. (amended) A bone fixation system according to claim 1, wherein said at least one support [means] structure includes ledge members located adjacent to said top and bottom portions.
5. (amended) A bone fixation system according to claim 1, wherein said bridge [means] portion includes [a] at least one window [means] for observation of a graft area.
6. (amended) A bone fixation system according to claim 5, wherein said at least one window [means] includes an opening having a general shape of: an ellipse, rectangle, square, oval or parallelogram.
7. (amended) A bone fixation system according to claim 5, wherein said at least one window [means] includes a plurality of holes.

8. (amended) A bone fixation system according to claim 5, wherein said at least one window [means] has an irregular shape.

9. (amended) A bone fixation system according to claim 1, wherein said top and bottom portions each include at least one opening dimensioned to receive said fastener [means].

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10. (amended) A bone fixation system according to claim 9, wherein said at least one opening includes a first fastener receiving section having a tapered surface, said fastener [means] including a mating tapered surface, wherein said mating tapered surface generally matching the tapered surface of said first fastener receiving section.

11. (amended) A bone fixation system according to claim 10, wherein said fastener [means include] includes a set screw member having a threaded surface.

21  
12. (amended) A bone fixation system [according to claim 11,] comprising:  
an elongated plate means having a top portion, a bottom portion, and a bridge portion  
integrally spanning between the top portion and bottom portion, said bridge portion for  
connecting at least two bone structures; and  
a fastener means for fastening the plate means to said at least two bone structures; and  
wherein said top and bottom portions each include at least one opening dimensioned to  
receive said fastener means; and



wherein said at least one opening includes a first fastener receiving section having a tapered surface, said fastener means including a mating tapered surface, wherein said mating tapered surface generally matching the tapered surface of said first fastener receiving section; and  
wherein said fastener means includes a set screw member having a threaded surface; and  
wherein said at least one opening includes a second fastener receiving section having a mating threaded surface, said mating threaded surface generally matching the threaded surface of said set screw member.

42  
cancel 22  
13. (amended) A bone fixation system according to claim 12, wherein said set screw member includes an means for aligning said set screw with said at least one opening.

14. (amended) A bone fixation system according to claim 9, wherein said fastener [means] includes a head portion, said at least one opening dimensioned to receive at least a portion of said head portion.

03  
16. (amended) A bone fixation system according to claim 9, wherein said fastener [means] includes a head portion, said head portion having a diameter greater than said at least one opening.

24 12  
18. (amended) A bone fixation system according to claim 9, wherein said at least one opening includes a section dimensioned to receive a press fit fastener [means].

19. (amended) A bone fixation system according to claim 1, wherein said plate [means] has an anterior side said having a medial surface that generally matches an anterior profile of a vertebral body.

20. (amended) A bone fixation system according to claim 1, wherein said plate [means] has a posterior side having a medial surface that is generally flat in cross-section.

21. (amended) A bone fixation system according to claim 1, wherein said plate [means] has a medial side having a surface that is anatomically contoured to approximate the profile of lateral aspects of a vertebral body.

17/ 22. (amended) A bone fixation system according to claim 1, wherein said plate [means] has a medial side having engagement [means] structure for engaging with at least one of said bone structure.

18/ 23. (amended) A bone fixation system according to claim 22, wherein said engagement [means] structure includes at least one of: spikes and teeth.

19/ 24. (amended) A bone fixation system according to claim 1, wherein said plate [means] has a medial side having a surface treatment allowing bone ingrowth.

### Remarks

The Office Action states that claims 12 and 13 are allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in the Office Action and to include all of the limitations of the base claim and any intervening claims. It is submitted that claim 12 has been appropriately rewritten to meet the Examiner's specifications and is therefore patentable in its present form. As claim 13 depends from claim 12, it is submitted that claim 13 is also patentable.

The Office Action, together with the cited references, have been given careful consideration. Following such consideration, claims 1, 2, 5-14, 16, and 18-24 have been amended to more clearly define the patentable invention applicants believe is disclosed herein. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The present invention is directed to an internal bone fixation system for the treatment of bone anomalies. In addition, the fixation system includes a fastener which fastens the plate to the bone structures. Moreover, the present invention includes support structures located near both ends of the plate to support the bones.

Claims 2-8 and 9-18 were rejected in the Office Action as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The present amendment alters the form of claim 1 to read in relevant part "A bone fixation system comprising: elongated plate having a top portion, a bottom portion, and a bridge portion . . .; support structures that engage . . ." The present amendment alters claims 2 and 5 so that they no longer lack the proper antecedents.

The present amendment alters the forms of claim 2 to read in relevant part "A bone fixation system according to claim 1, wherein said support structures . . ." and claim 5 to read in relevant part "A bone fixation system according to claim 1, wherein said bridge portion . . ." The present amendment also alters the form of claim 9 to read in relevant part "A bone fixation system according to claim 1, wherein said top and bottom portions each include . . ." Accordingly, it is respectfully requested that the rejection of claims 2, 5, and 9, as well as the claims that depend on those claims, (*i.e.* claims 3, 4, 6-8, and 10-18) be withdrawn.

Claims 1-5, 9, 16, 17, 19-25 have been rejected in the Office Action as being anticipated by Matsuzaki, *et al.* The Office Action relies upon the disclosure of Matsuzaki, *et al.* for a system comprising an elongated plate means and fastener means for fastening the plate means. The Office Action also states that Matsuzaki, *et al.* discloses a plate means with a top portion, a bottom portion, and a bridge portion. It is respectfully submitted that Matsuzaki, *et al.* does not disclose the applicant's invention as set forth in the present claims.

With regard to independent claim 1, this claim recites:

A bone fixation system comprising:

elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between the top portion and bottom portion, said bridge portion for connecting at least two bone structures;

**support structures that engage the external surfaces of the two bone structures at the terminal ends of said at least two bone structures;** and  
fastener for fastening the plate to said at least two bone structures.

While Matsuzaki, *et al.* may disclose a system that includes members which are connected together to form an intervertebral cage device, Matsuzaki members are embedded in adjacent vertebrae. The system disclosed by Matsuzaki, *et al.* does not disclose the claimed support structures that engage external bone surfaces and support a load.

In view of the foregoing, it is respectfully submitted that claim 1 be patentable over the prior art. Claims 2-5, 9, 16, 17, 19-25 ultimately depend from claim 1, thus it is respectfully submitted that these claims are patentable over the prior art for the reasons set forth above in connection with claim 1.

Claims 1, 5, 6, 9, 16, and 20 have been rejected by the Office Action as being anticipated by Osmk Med. The Office Action states that Osmk Med. Inst. discloses a system comprising an elongated plate means and fastener means for fastening the plate means. The Office Action also states that the plate means has a top portion, a bottom portion, and a bridge portion.

First of all, Applicants respectfully submit that Omsk is non-analogous art which one of skill would not look to when attempting to solve the problems contemplated by applicants' invention. Specifically Osmk discloses a fixation device for a single long bone, namely, the mandible bone. Second, the above discussion regarding the present invention's patentability over Matsuzaki, *et al.* can also be applied analogously to Omsk Med. Inst. Omsk Med. Inst. does not disclose the support structures that are included in the present invention. Therefore, claim 1, in its present form, is patentable over Omsk Med. Inst. and claims 5, 6, 9, 16, and 20, as they ultimately depend from claim 1, are likewise patentable.

Claims 1-4, 9, 10, 14, 15, 17, 19-21, and 25 have been rejected by the Office Action as being anticipated by Kehr. The Office Action states that Kehr discloses a system comprising an elongated plate means and fastener means for fastening the plate means. Furthermore, the Office Action states that the plate means has a top portion, a bottom portion, and a bridge portion. Lastly, the Office Action states that the bridge portion comprises an insert, medial side, or artificial graft which includes ledge members.

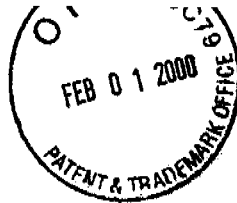
It is respectfully submitted that the determination that the bridge portion includes ledge members is incorrect. The artificial graft 16, that the Office Action references, is not a support structure, but rather an insert that serves to induce bone growth between the vertebrae. Clearly, this is a different structure from what is now claimed in claim 1 of the present invention.

Claims 1, 9-11, 14, 15, 17-21 have also been rejected as being anticipated by Nillson, *et al.* The Office Action states that Nillson, *et al.* discloses a system comprising an elongated plate means and fastener means for fastening the plate means. The Office Action goes on to further elaborate that the plate means has a top portion and a bottom portion. However, as with the previously addressed references, Nillson, *et al.* does not disclose support structures.

It is respectfully requested that the rejection based on Nillson, *et al.* be withdrawn. As currently written claim 1 is not anticipated by Nillson, *et al.* and is therefore allowable. As claims 9-11, 14, 15, 17-21 all depend from claim 1, it is submitted that they are also patentable.

Claims 7 and 8 have been rejected by the Office Action as being unpatentable over Osmk Med. Inst. The Office Action states that Osmk Med. Inst. discloses the claimed invention except for the window being a plurality of holes (claim 7) or having an irregular shape (claim 8). The Office Action concludes that it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the window of Osmk Med. Inst. as a plurality of holes or having an irregular shape.

As stated earlier in connection with the rejection of claim 1 as being anticipated by Osmk Med. Inst., as currently written, claim 1 is patentable over Osmk Med. Inst. Therefore, as claims 7 and 8 depend from claim 1, it is submitted that these claims are now patentable.



The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teach or suggest the present invention as defined by the present claims.

In accordance with the foregoing, the applicants request that the present application is in proper condition for allowance. If the Examiner believes that there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any further fees necessitated by the foregoing communication please charge such fees to our Deposit Account No. 50-0902, referencing our Docket No. 72258/95945.

Respectfully submitted,

ARTER & HADDEN LLP

Todd R. Tucker  
Reg. No. 40,850  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, OH 44115-1475  
(216) 696-3483

481956.1

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, DC 20231.

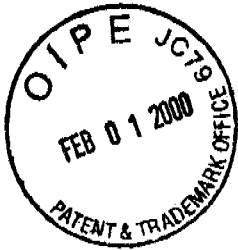
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1-24-00

Valerie A. Milam

(SIGNATURE)

Valerie A. Milam



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF : Theken *et al.*  
FOR : BONE FIXATION SYSTEM  
SERIAL NO. : 09/114,996  
FILED : July 18, 1998  
EXAMINER : Eduardo C. Robert  
ART UNIT : 3732  
LAST OFFICE ACTION : September 23, 1999  
ATTORNEY DOCKET NO. : 72258/95945

Cleveland, Ohio 44115-1475  
January 24, 2000

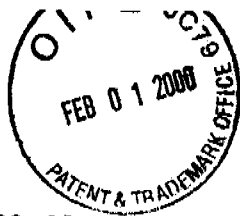
**LETTER TO DRAFTSMAN PURSUANT TO MPEP § 608.02(r)**

Assistant Commissioner of Patents  
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated September 23, 1999, Applicants respectfully submit proposed drawing corrections to show the invention specified in the claims. The proposed drawing changes are shown in Figures 19, 20, and 21, attached to this Letter. Figure 19 shows the ledge members connected together to form an intervertebral cage, as per claim 3. Figure 20 shows the embodiment wherein the window includes a plurality of holes, per claim 7, and Figure 21 shows the embodiment wherein the engagement structure includes at least one of:





spikes and teeth, as per claim 23. No new matter is entered that is not supported by the claims or specification.

The attached drawings consist of sketches showing changes, in red ink, to the original drawings in accordance with MPEP § 608.02(v). New formal drawings to correct the noted objections will be submitted if and when the application is allowed by the Examiner.

In accordance with the foregoing, the applicants request that the present application is in proper condition for allowance. If the Examiner believes that there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any further fees necessitated by the foregoing communication please charge such fees to our Deposit Account No. 50-0902, referencing our Docket No. 72258/95945.

Respectfully submitted,

ARTER & HADDEN LLP

Todd R. Tucker  
Reg. No. 40,850  
1100 Huntington Building  
925 Euclid Avenue  
Cleveland, OH 44115-1475  
(216) 696-3483

482539.1

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, DC 20231.

OR

1-24-00

Valerie A. Milan

(SIGNATURE)  
Valerie A. Milan

10/12/00  
 10/12/00  
 10/12/00

4/11

early approval 3/27/00  
 10/12/00

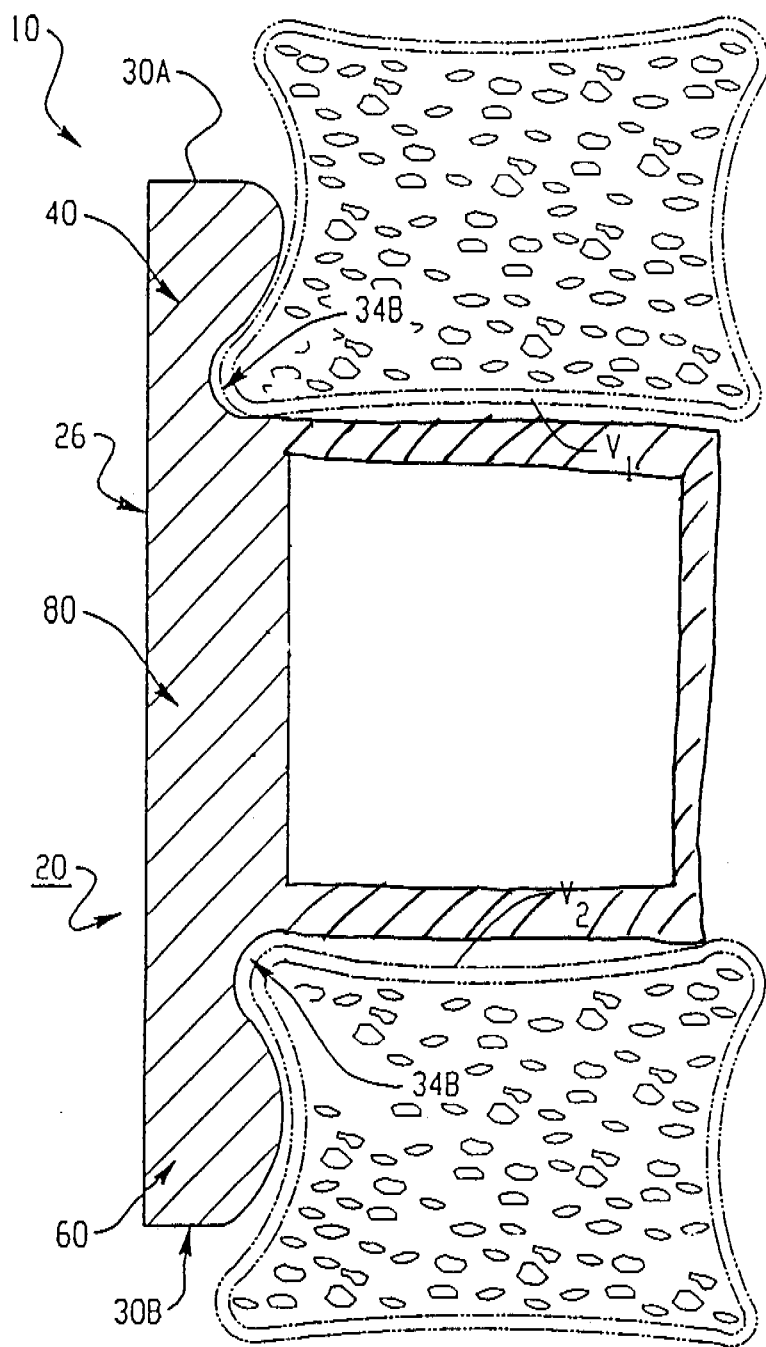


Fig. 19 A

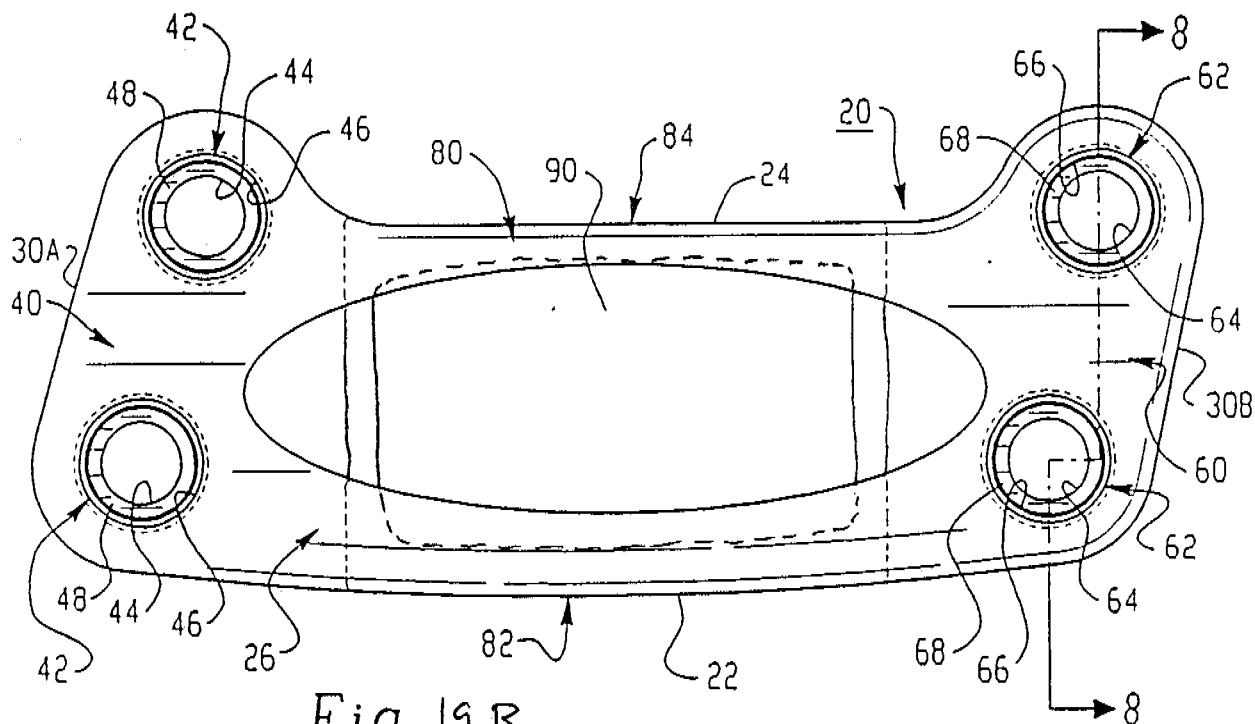


Fig. 19B

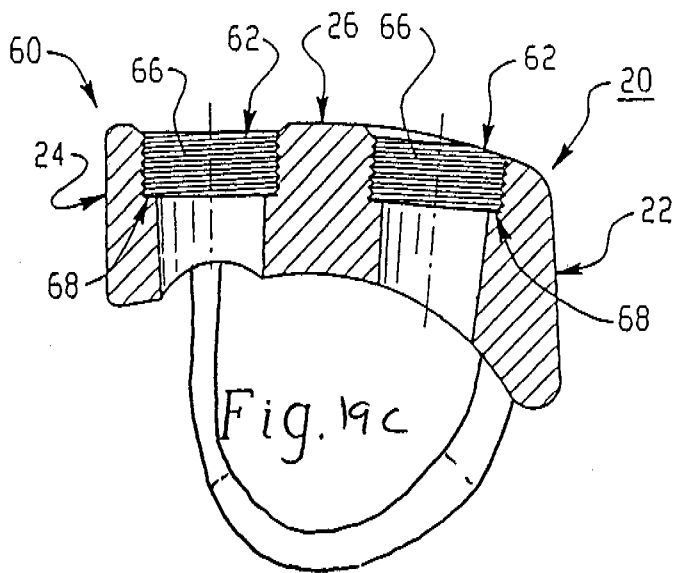


Fig. 19C

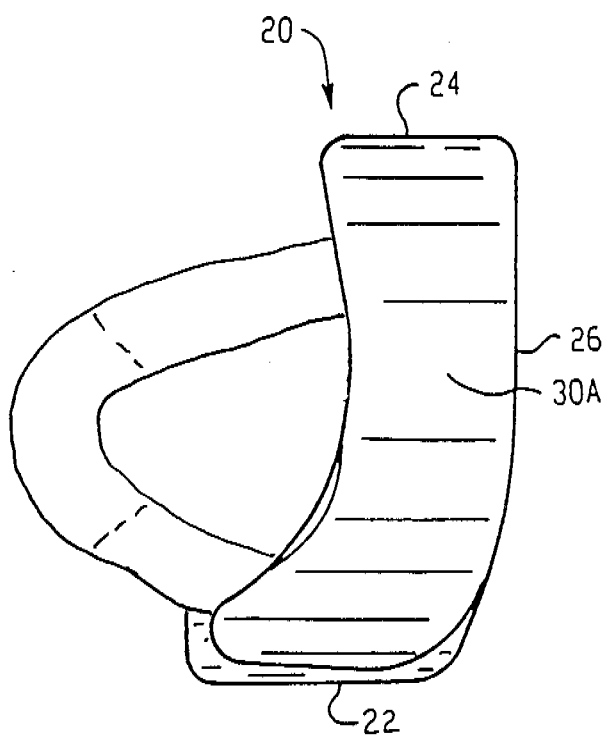
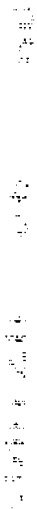


Fig. 19D



0116

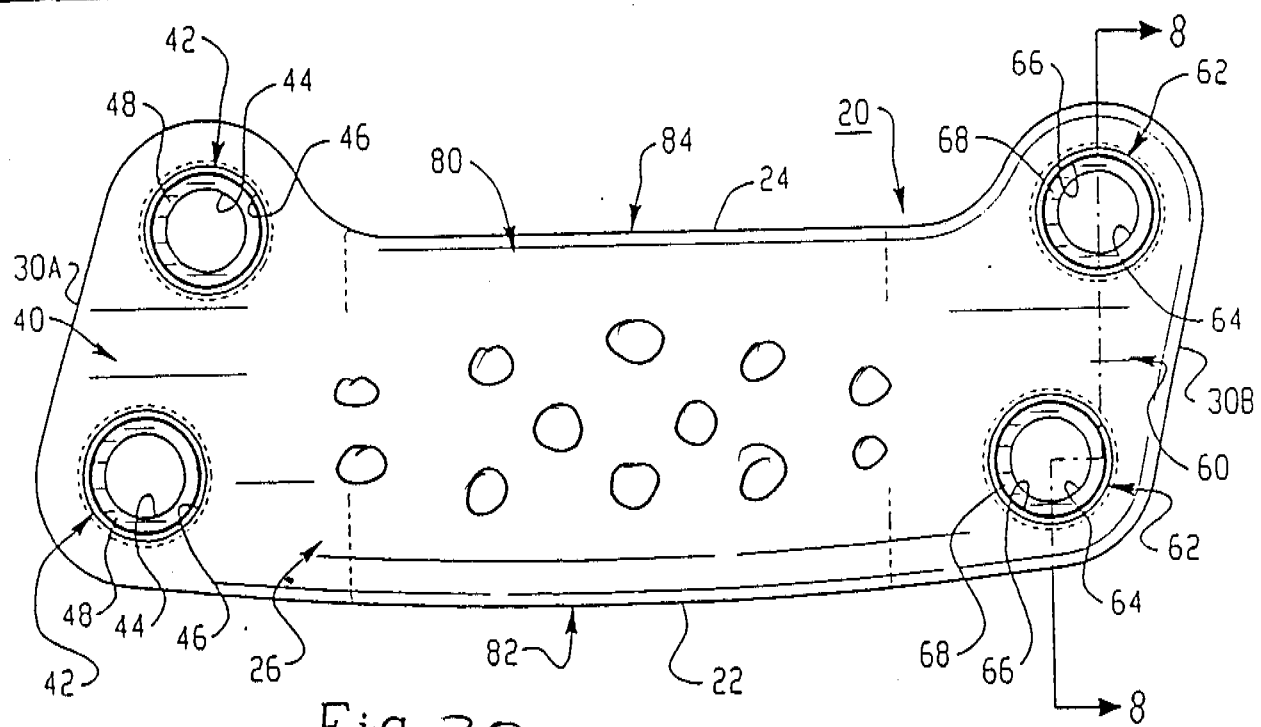


Fig. 20

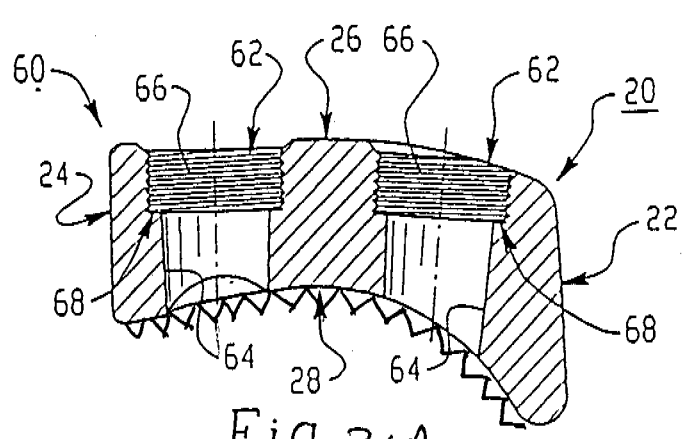


Fig. 21A

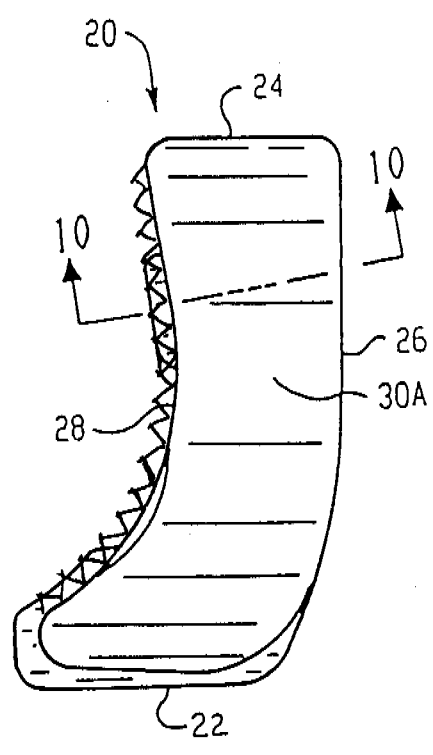
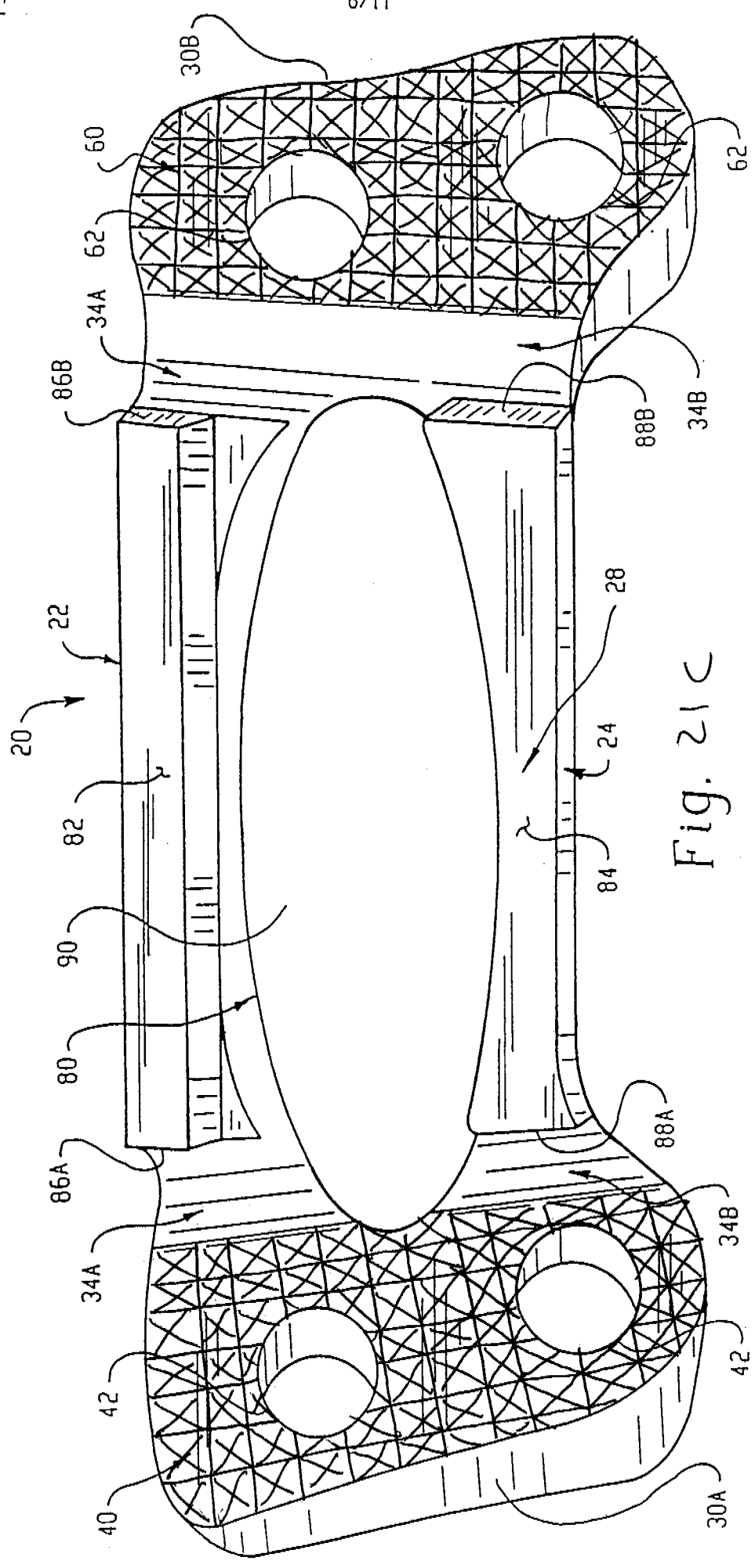
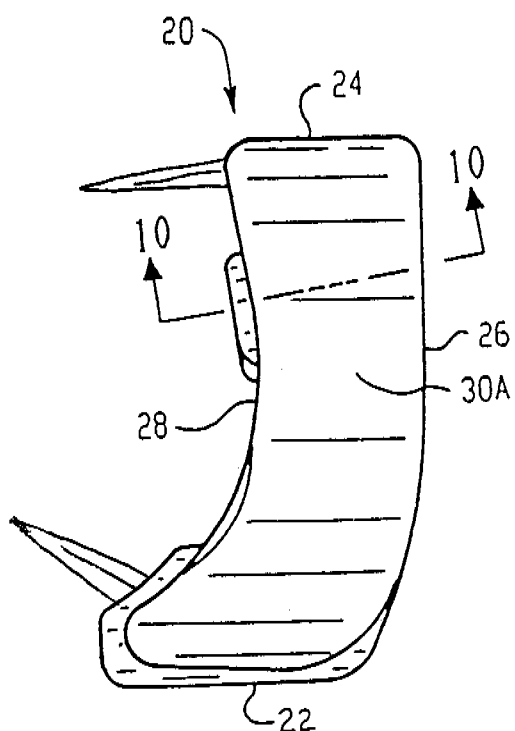
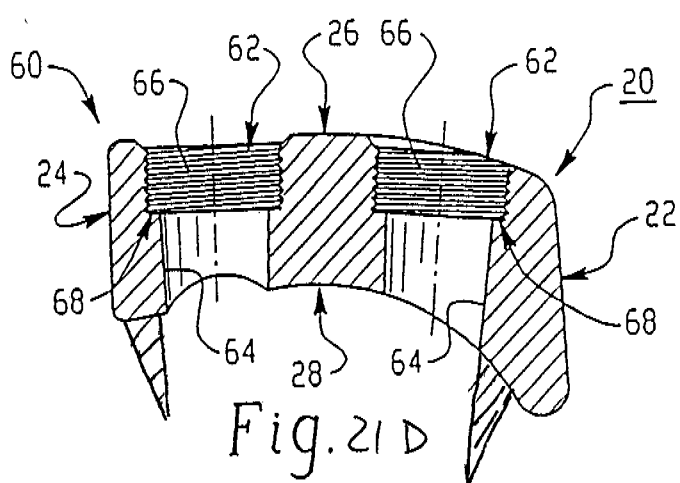
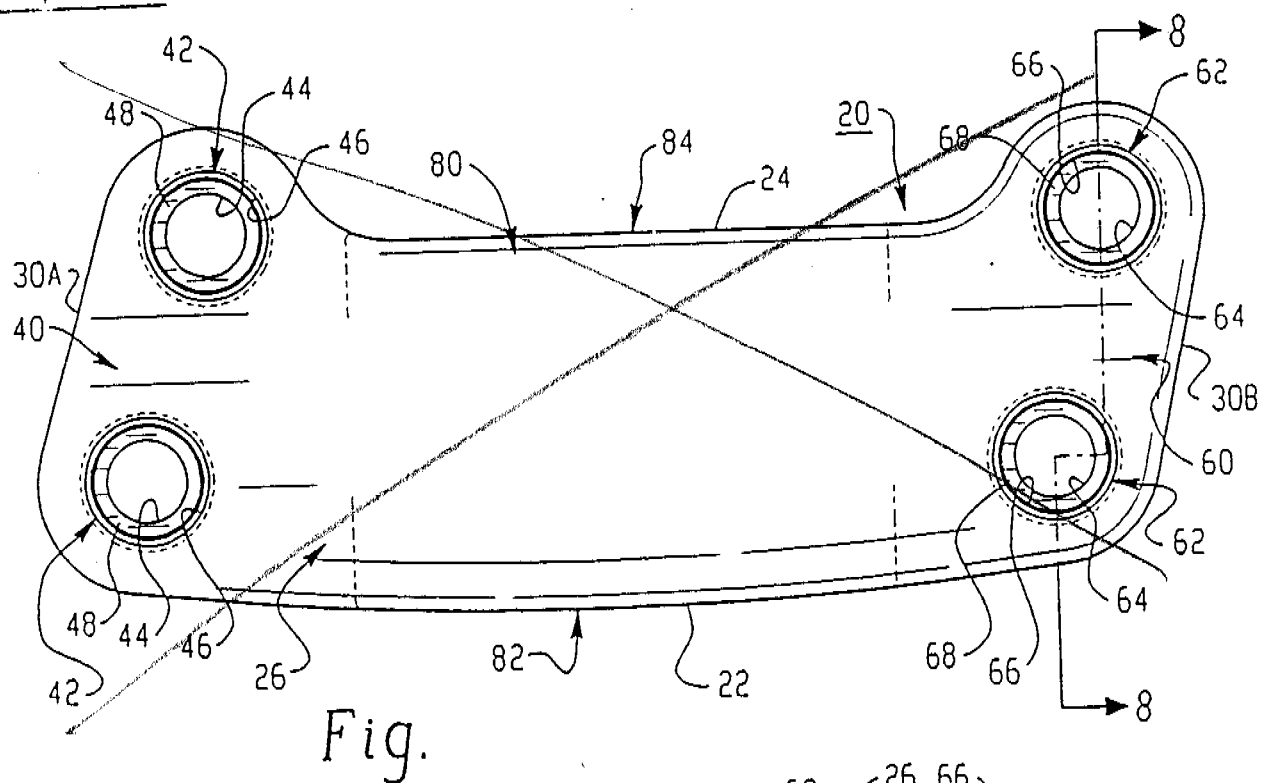


Fig. 21B







UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/114,996 07/14/98 THEKEN

R 23724-3

EXAMINER

QM12/0406

TODD R. TUCKER, ESQ.  
ARTER & HADDEN LLP  
1100 HUNTINGTON BUILDING  
925 EUCLID AVENUE  
CLEVELAND OH 44115-1475

ROBERT E

ART UNIT

PAPER NUMBER

3732

DATE MAILED:

04/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



## Office Action Summary

Application No.  
09/114,996

Applicant(s)  
Theken, et al.

Examiner  
Eduardo C. Robert

Group Art Unit  
3732



☒ Responsive to communication(s) filed on Feb 1, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

☒ Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 12 and 13 is/are allowed.

☒ Claim(s) 1-11 and 14-25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☒ The proposed drawing correction, filed on Feb 1, 2000 is ☒ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9, 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Drawings*

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on February 1, 2000 have been approved.

### *Specification*

The disclosure is objected to because of the following informalities: there is no brief description of figures 19, 19b, 19c, 19d, 19e, 20, 21a, 21b, 21c, 21d, and 21e. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 16, 17, 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuzaki, et al.

Matsuzaki, et al. disclose a system comprising an elongated plate having a top portion, a bottom portion, and a bridge portion (see Figure 9). The system further comprises at least one

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support structure (see Attachment A) and a fastener 29. The bridge portion comprises ledge members which are connected together to form an intervertebral cage device or medial side and that also are part of the support member (see Attachment A). The ledge members include a bioresorbable compound, i.e. a coating of calcium phosphate compound (see col. 6, lines 65-67). The bridge portion includes an aperture or window. Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener 29. The fastener 29 include a head portion which has a diameter greater than the at least one opening (see Figure 10). The plate has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section. The medial side has ribs or teeth for engaging with the bone structures.

Claims 1, 5, 6, 9, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Omsk Med. Inst.

Omsk Med. Inst. discloses a system comprising an elongated plate having a top portion, a bottom portion or base and a bridge portion. The system further comprises a fastener. The bottom portion or base can be considered a support structure. The bridge portion includes a window for observation. The window has an oval shape. The top and bottom portions, each includes at least one opening to receive the fastener which have a head portion. The plate has a posterior side having a medial surface that is flat in cross-section.

Claims 1-4, 9, 10, 14, 15, 17, 19-21, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kehr.

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Kehr discloses a system comprising an elongated plate, at least one support structure and a fastener (see Attachment B). The plate has a top portion, a bottom portion, and a bridge portion (see Figures 1, 2 and 4). The bridge portion comprises an insert, medial side, or artificial graft 16 which includes ledge members (see Attachment B). Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener. The at least one opening of each portions include a first fastener receiving section having a tapered surface and the fastener including a mating tapered surface (see Figure 4). The plate has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section.

Claims 1, 9-11, 14, 15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson, et al.

Nilsson, et al. disclose a system comprising an elongated plate 13 having a top portion, a bottom portion or base, and a bridge portion. The system further comprises a fastener (see Figure 2). The bottom portion or base can be considered a support structure. Each of the top and bottom portions include at least one opening, i.e. elongated slot, dimensioned to receive the fastener. The at least one opening of each portions includes a fastener receiving section having a gradual decrease in width along the section (see Figure 2) and the fastener has mating surfaces. The fastener includes a set screw member 18 having a threaded surface. The plate has an anterior side having a medial surface that matches an anterior profile of a vertebral body and it further has a posterior side having a medial surface that is flat in cross-section.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omsk Med. Inst.

Omsk Med. Inst. discloses the claimed invention except for the window being a plurality of holes (claim 7) or having an irregular shape (claim 8). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the window of Omsk Med. Inst. as a plurality of holes or having an irregular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an opening for observation. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

***Response to Arguments***

Applicant's arguments filed on February 1, 2000 have been fully considered but they are not persuasive.

In response to applicant's argument that Matsuzaki, et al. does not disclose the claimed support structure, it is noted that Matsuzaki, et al. disclose at least one support structure formed

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by a ledge member and a portion of the bottom portion of the plate (see Attachment A). The at least one support structure clearly engages surfaces or portions of a vertebrae. With regard to the functional language, i.e. "that engages external surface of bone structure at terminal end of said bone structure", it is noted that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In response to applicant's argument that Omsk Med. is non-analogous art, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In response to applicant's argument that Omsk Med. does not disclose a support structure, it is noted that Omsk Med. discloses a plate having a bottom portion or base. It is noted that "base" is defined by *The Webster's II New Riverside University Dictionary* as "The lower or bottom part", "A supporting layer or part : FOUNDATION", therefore the bottom portion or base can be considered the support structure. With regard to the functional language, i.e. "that engages external surface of bone structure at terminal end of said bone structure", it is noted that

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it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant's argument that in Kehr "the determination that the bridge portion includes ledge members is incorrect". It is noted that the term "ledge" is defined by *The Webster's II New Riverside University Dictionary* as "A narrow shelf projecting from a wall", "A cut or projection forming a shelf on a cliff or rock wall". Thus, with this definition in mind, applicant's attention is directed to Attachment B, wherein ledge members are clearly shown as a shelf projecting from a wall, i.e. the bottom portion. Furthermore, applicants argue that "The artificial graft 16 is not a support structure", it is noted that Kehr clearly discloses at least one support structure and that the at least one support structure is formed by a ledge and portion of the bottom portion (see Attachment B and Figure 4). With regard to the functional language, i.e. "that engages external surface of bone structure at terminal end of said bone structure", it is noted that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant's argument that Nilsson, et al. does not disclose at least one support structure, it is noted that Nilsson, et al. clearly disclose a plate having a bottom portion or base and this base can be considered a support structure.

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Applicant's arguments with regard to claims 7 and 8 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an opening for observation. Applicant has not provided any showing that such limitations are "critical". *In re Cole*, 140 USPQ 230 (CCPA 1964); *In re Kuhle*, 188 USPQ 7 (CCPA 1975); *In re Davies*, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of evidence. *In re Cole*, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); *In re Walters*, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

***Allowable Subject Matter***

Claims 12 and 13 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



Application/Control Number: 09/114,996

Page 9


Art Unit: 3732

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is (703) 305-7333.

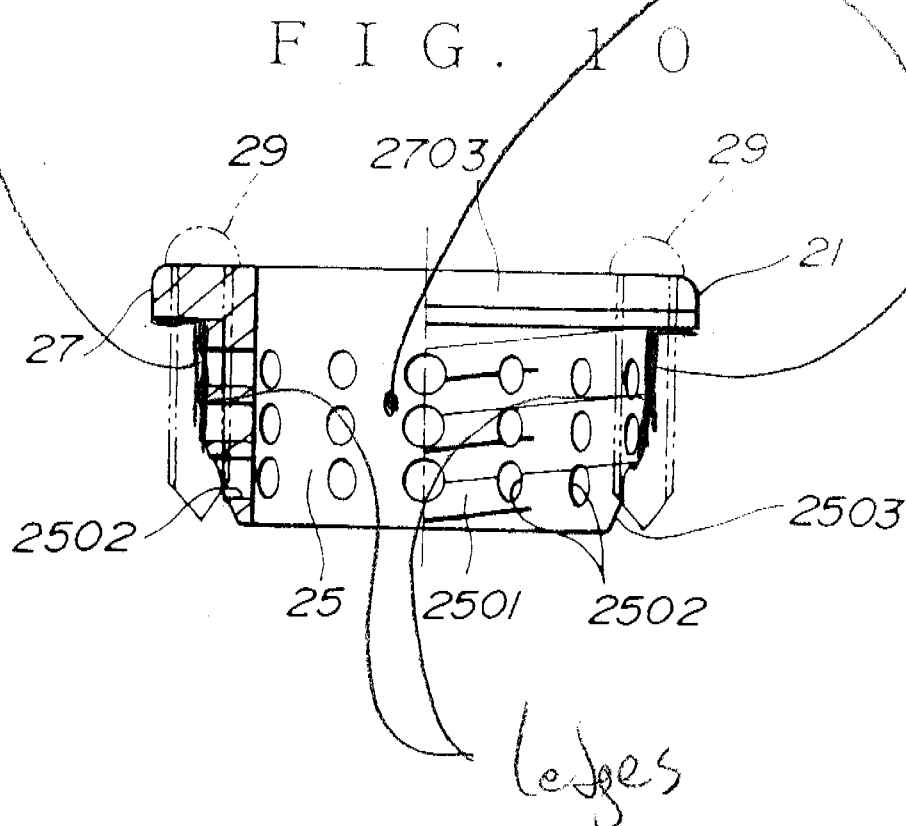
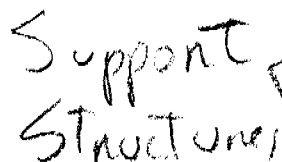


E.C. Robert  
March 28, 2000



Gene Mancene  
Supervisory Patent Examiner  
Group 3700

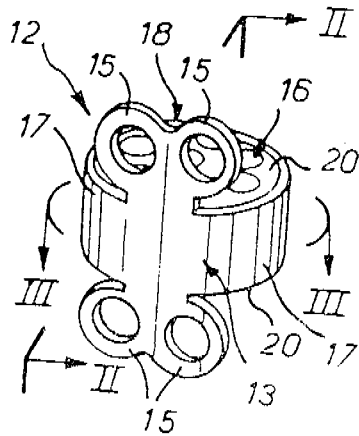
## FIG. 9



# Attachment B

0179695

FIG. 1



1/1  
one ledge

FIG. 2

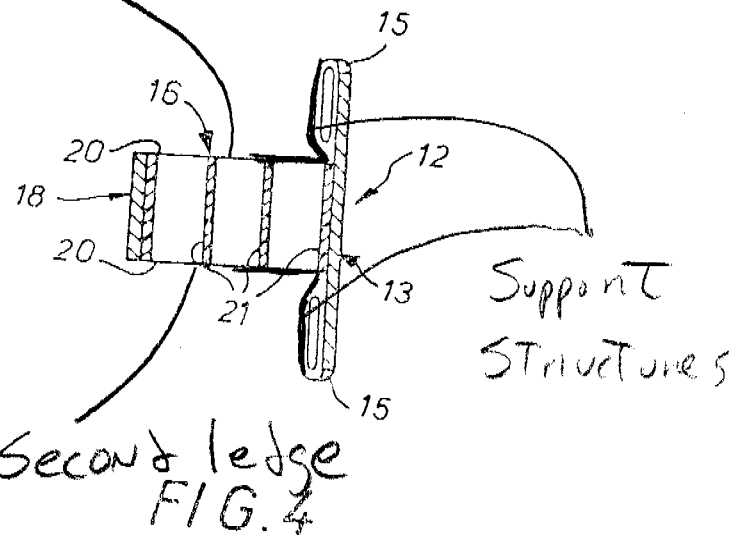


FIG. 3

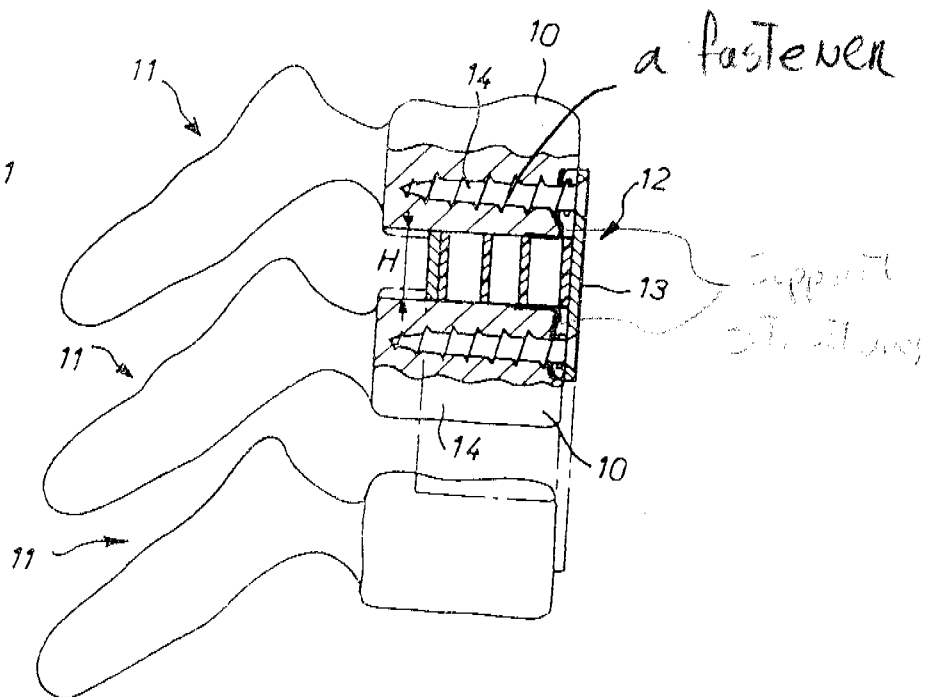
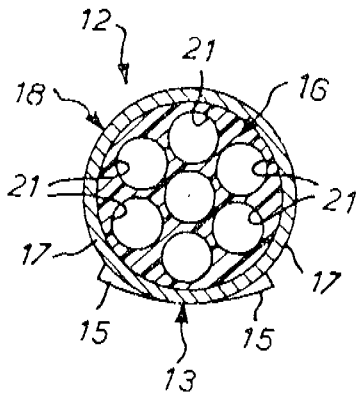


FIG. 5

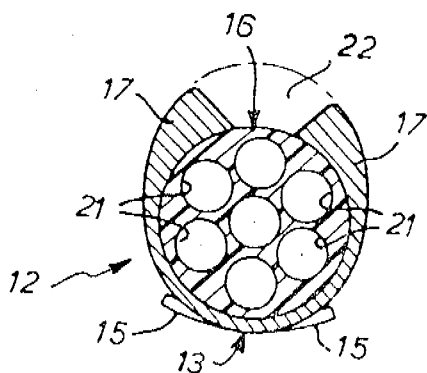
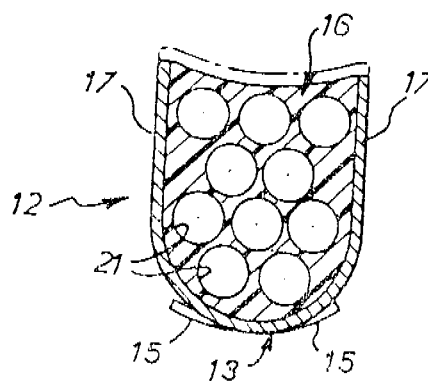


FIG. 6





S. Hill  
6-27-00

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<b>REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT</b>	Application Number	09/114,996
	Filing Date	July 17, 1998
	First Named Inventor	Randall R. Theken #1/skew patty
	Group Art Unit	3731
	Examiner Name	Eduardo Robert
	Attorney Docket Number	09337.114120

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

☒ A Power of Attorney or Authorization of Agent is submitted herewith.

OR

☐ Please change the correspondence address for the above-identified application to:

☐ Customer Number

OR

Place Customer  
Number Bar Code  
Label here

<input checked="" type="checkbox"/> Firm or Individual Name	Robert H. Eichenberger					
Address	120 West Spring Street					
Address	Suite 400					
City	New Albany					
Country	USA	State	Indiana	ZIP	47150	
Telephone	(812) 948-2800	Fax	(812) 948-7994			

I am the:

☐ Applicant.

☒ Assignee of record of the entire interest  
Certificate under 37 CFR 3.73(b) is enclosed

SIGNATURE of Applicant or Assignee of Record

Name	Randy Theken
Signature	
Date	6/6/00

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**POWER OF ATTORNEY OR  
AUTHORIZATION OF AGENT,  
NOT ACCOMPANYING  
APPLICATION**

Application Number	09/114,996
Filing Date	July 17, 1998
First Named Inventor	Randall R. Theken
Group Art Unit	3731
Examiner Name	Eduardo Robert
Attorney Docket Number	09337.114120

I hereby appoint:

☐ Practitioners at Customer Number

OR

☒ Practitioner(s) named below:

Name	Registration Number
Robert H. Eichenberger	42,509

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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the Patent and Trademark Office connected therewith.

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<input checked="" type="checkbox"/> Firm or Individual Name	Robert H. Eichenberger				
Address	120 West Spring Street				
Address	Suite 400				
City	New Albany	State	Indiana	ZIP	47150
Country	USA				
Telephone	(812) 948-2800	Fax	(812) 948-7994		

I am the:

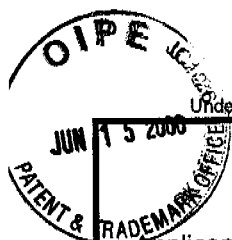
☐ Applicant.

☒ Assignee of record of the entire interest  
*Certificate under 37 CFR 3.73(b) is enclosed*

**SIGNATURE of Applicant or Assignee of Record**

Name	Randy Theken
Signature	
Date	6/6/00

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Theken Surgical

Application No./Patent No.: 09/114,996 Filed/Issue Date: July 17, 1998

Entitled: Bone Fixation System

Theken Surgical, a Limited Liability Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

- ☒ the assignee of the entire right, title, and interest; or
- ☐ an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

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☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the PTO. See MPEP 302-302.8]

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

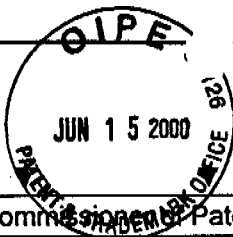
6/6/00  
Date

[Signature]  
Signature

Randy Theken  
Typed or printed name

\_\_\_\_\_  
President Title

**PATENTS ONLY**



To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

- (1) Randall R. Theken;
- (2) Lukas Eisermann; and
- (3) Ben Taylor

Additional names(s) of conveying party(ies)

☐ Yes ☒ No

3. Nature of conveyance:

- ☒ Assignment ☐ Merger
- ☐ Security Agreement ☐ Change of Name
- ☐ Other

(1) June 30, 1998, (2) June 30, 1998;

Execution Date: and (3) July 9, 1998

2. Name and address of receiving party(ies):

Name: Theken Surgical L.L.P.

Internal Address: \_\_\_\_\_

Street Address: 1100 Nola Avenue

City: Barberton State: OH ZIP: 44203

Additional name(s) & address(es)

☐ Yes ☒ No

4. Application number(s) or registration numbers(s):

If this document is being filed together with a new application, the execution date of the application is: June 30, 1998

A. Patent Application No.(s)

B. Patent No.(s)

Additional numbers

☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Michael A. Jaffe, Esq.

Internal Address: BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP

Street Address: 2300 BP America Building

200 Public Square

City: Cleveland State: OH ZIP: 44114

6. Total number of applications and patents involved:

1

7. Total fee (37 CFR 3.41):.....\$ 40.00

☒ Enclosed

☐ Authorized to be charged to deposit account

8. Deposit account number:

02-2051, Docket No. 23724-3

(Attach duplicate copy of this page if paying by deposit account)

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Michael A. Jaffe

Name of Person Signing

Signature

REG. NO.  
36,326

7/14/98

Date

Total number of pages including cover sheet, attachments, and

6



Docket No. 23724-3

ASSIGNMENT

In consideration of the payment by ASSIGNEES to ASSIGNOR of the sum of Ten Dollars (\$10.00), the receipt of which is hereby acknowledged, and for other good and valuable consideration,

ASSIGNORS:	Name:	Randall R. Theken
	Address:	1100 Nola Avenue Barberton, Ohio 44203
	County:	Summit
	Name:	Lukas Eisermann
	Address:	2490 East 126th Street Cleveland, Ohio 44120
	County:	Cuyahoga
	Name:	Ben Taylor
	Address:	The Farmhouse Marshcroft Lane Tring Hertfordshire, England HP235QN

hereby sell, assign and transfer to

ASSIGNEE:	Name:	Theken Surgical L.L.P.
	Principal Place Of Business:	1100 Nola Avenue Barberton, Ohio 44203
	State of Incorporation:	Ohio



and the successors, assigns and legal representatives of the ASSIGNEE the entire right, title and interest for the United States and its territorial possessions, and in all foreign countries, including all rights to claim priority in and to any and all improvements which are disclosed in the invention entitled:

BONE FIXATION SYSTEM

and which is found in (37 C.F.R. § 3.21)

X U.S. patent application executed on the X 30 day of X JUNE, 1998

X U.S. patent application executed on the X 30 day of X JUNE, 1998

X U.S. patent application executed on the X 30 day of X JUNE, 1998

To comply with 37 C.F.R. § 3.21 for recordal of this assignment, we, as ASSIGNORS signing below, hereby authorize and request our attorney to insert below the filing date and application number when they become known:

and any legal equivalent thereof in a foreign country, including the right to claim priority and, in and to, all Letters Patent to be obtained for such invention by the above application or any continuation, division, renewal, or substitute thereof, and as to letters patent, any reissue or re-examination thereof.

ASSIGNORS hereby covenant that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

ASSIGNORS further covenant that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said invention and said Letters Patent and legal equivalents as may be known and accessible to ASSIGNORS and will testify as to the same in any interference, litigation or proceeding related thereto and will promptly execute and deliver to ASSIGNEE or its legal representatives any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said invention and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof.



Signed at X Barberton, X Ohio on this  
(City) (State)

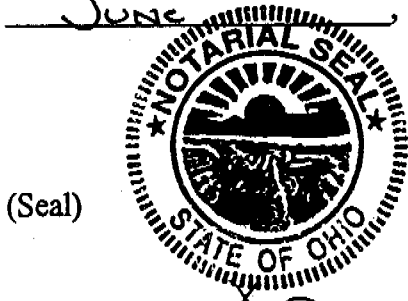
X 30 day of X JUNE, 1998.  
(Month)

X [Signature]  
Randall R. Theken

STATE OF OHIO )  
 ) : SS  
COUNTY OF SUMMIT )

Personally appeared before me this day, the above named Randall R. Theken, to me personally known, who acknowledged that he signed the foregoing instrument for the uses and purposes therein mentioned, and that the same is his free act and deed.

In testimony whereof, I have hereunto set my hand and affixed my seal, this 30 day of JUNE, 1998.



Notary Public

Michael L. Weigand  
MICHAEL L. WEIGAND, Attorney at Law  
NOTARY PUBLIC, State of Ohio  
My Commission Has No Expiration Date  
Section 147-03 R. C.

Signed at X Barberton, X Ohio on this  
(City) (State)

X 30 day of X JUNE, 1998.  
(Month)

X [Signature]  
Lukas Eisermann

Received Jul-12-98 05:10pm

from 44 01442 891318 → 7530 15

page 3



Sent by:

Jun-24-98 05:28pm

from 753992544 81442 891318 page 4

Full name of second inventor: Lukas Eisermann

Inventor's signature *[Signature]*

Date : *X* JUNE 24, 1998

Residence : Cleveland, Ohio

Citizenship : ~~United States of America~~ GERMANY *LS 6/24/98*

Post Office Address : 2490 East 126th Street  
Cleveland, Ohio 44120

Full name of third inventor: Bob Taylor

Inventor's signature *X* *[Signature]*

Date : *X* 9th July 1998

Residence : Hertfordshire, England

Citizenship : United Kingdom

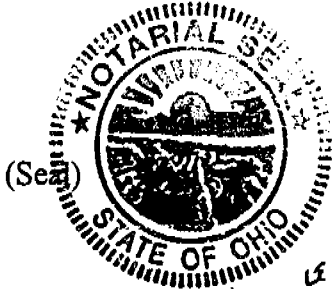
Post Office Address : The Farmhouse  
Marshcroft Lane  
Tring  
Hertfordshire, England  
HP235QN



STATE OF OHIO )  
 ) : SS  
COUNTY OF CUYAHOGA )

Personally appeared before me this day, the above named Lukas Eisermann, to me personally known, who acknowledged that he signed the foregoing instrument for the uses and purposes therein mentioned, and that the same is his free act and deed.

In testimony whereof, I have hereunto set my hand and affixed my seal, this 30 day of JUNE, 1998.



Notary Public

*Michael L. Wengand*  
MICHAEL L. WENGAND, Attorney at Law  
NOTARY PUBLIC, State of Ohio  
My Commission Has No Expiration Date  
Section 147-03 R. C.

Signed at X BARBERTON X on this

(City)

(Country)

X day of X, 1998.

(Month)

X  
Ben Taylor

X  
Witness

Address: X  
X  
X

X  
Date

Received Jul-12-98 05:10pm

from 44 01442 891318 → 7536 5

page 2

Sent by:

Jun-24-98 05:21pm

from 7539925+44 01442 891318 page 8/8



STATE OF OHIO )  
 )SS  
COUNTY OF CUYAHOGA )

Personally appeared before me this day, the above named Lukas Eisermann, to me personally known, who acknowledged that he signed the foregoing instrument for the uses and purposes therein mentioned, and that the same is his free act and deed.

In testimony whereof, I have hereunto set my hand and affixed my seal, this \_\_\_\_ day of \_\_\_\_\_, 1998.

Notary Public

(Seal)

Signed at X \_\_\_\_\_, X \_\_\_\_\_ on this  
(City) (County)

X day of X \_\_\_\_\_, 1998.  
(Month)

x Ben Taylor  
Ben Taylor

x Witness  
Witness

Address: X 36 Chiltem Ave  
X Edelsborn  
X Breda AUG 02H/  
ENGLAND.

x 9/07/98  
Date



## CERTIFICATE OF MAILING

I hereby certify that the following documents:

Transmittal Letter  
Revocation of Power of Attorney Form PTO/SB/82  
Power of Attorney Form PTO/SB/81  
Statement Under 37 C.F.R. 3.73(b) Form PTO/SB/96  
Copy of Assignment documents (7 pages)  
Return Postcard

are being deposited with the United States Postal Service as First Class Mail, postpaid in an envelope addressed to:

Assistant Commissioner for Patents  
Washington, DC 20231

on June 12, 2000.

Printed name of person signing this certificate: Linda L. Gardner

Signature:



GAU 373

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Lukas G. Eisermann, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SERIAL NO. : 09/114,996  
FILING DATE : July 17, 1998  
EXAMINER : Eduardo C. Robert  
ATTORNEY DOCKET NO. : 09337.114120 (formerly 72258/95945)

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

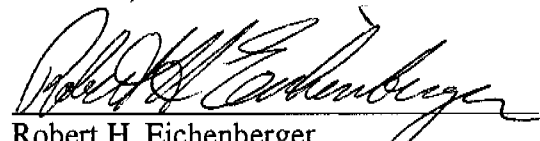
June 12, 2000

Dear Sir:

1. Attached are the following:
  - a) Revocation of Power of Attorney Form PTO/SB/82;
  - b) Power of Attorney Form PTO/SB/81;
  - c) Statement Under 37 C.F.R. 3.73(b) Form PTO/SB/96; and
  - d) Copy of Assignment documents (7 pages).
2. If anything further is required in order to effectuate the appointment of the undersigned as attorney of record, please contact the undersigned.

Respectfully submitted,

BROWN, TODD & HEYBURN PLLC

  
Robert H. Eichenberger  
Reg. No. 42,509  
120 West Spring Street, Suite 400  
New Albany, IN 47150  
(812) 948-2800 (phone)  
(812) 948-7994 (fax)

0520  
09337.114120  
\\NA2\SYSTEMS\USERS\520\Theken Surgical\BodyForm Bone Fixation System\114120\US Prosecution\Transmittal for Power of Attorney.doc

RECEIVED  
JUN 19 2000  
TC 3700 MAIL ROOM



\*OC000000005205378\*



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENT AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/114,996	07/14/1998	RANDALL R. THEKEN	23724-3

ROBERT H. EICHENBERGER  
120 WEST SPRING STREET  
SUITE 400  
NEW ALBANY, IN 47150

Date Mailed: 06/27/2000

**NOTICE REGARDING POWER OF ATTORNEY**

This is in response to the Power of Attorney filed 06/15/2000.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Customer Service Center  
Initial Patent Examination Division (703) 308-1202

ATTORNEY/APPLICANT COPY





\*OC000000005205264\*



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENT AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/114,996	07/14/1998	RANDALL R. THEKEN	23724-3

TODD R. TUCKER, ESQ.  
ARTER & HADDEN LLP  
1100 HUNTINGTON BUILDING  
925 EUCLID AVENUE  
CLEVELAND, OH 441151475

Date Mailed: 06/27/2000

**NOTICE REGARDING POWER OF ATTORNEY**

This is in response to the Power of Attorney filed 06/15/2000.

The Power of Attorney to you in this application has been revoked by the assignee who has intervenered as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Customer Service Center  
Initial Patent Examination Division (703) 308-1202  
FORMER ATTORNEY/AGENT COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SERIAL NO. : 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert  
ATTORNEY DOCKET NO. : 09337.114120 (formerly 72258/95945)

T.H.  
9-21-00  
#16/Ext  
of  
time  
(2mos)

37 C.F.R. § 1.136(a) PETITION FOR EXTENSION OF TIME

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 6, 2000

Dear Sir:

This is a petition to extend the time for filing a response to the Office Action dated April 6, 2000 in the above-identified patent application. Said response takes the form of a submission in support of a Request for Continued Examination pursuant to 37 C.F.R. § 1.114, which accompanies this petition. The examiner set a three-month shortened statutory period for reply. As this response is being filed within two months after the shortened statutory period, an extension of time of two months is requested, and has not yet been granted.

A check for the total amount of this reply includes the following fees, as identified on the attached Fee Transmittal:

Extension of time fee (within second month)	\$190.00
Submission of Information Disclosure Statement	\$240.00
Request for Continued Examination	\$345.00
TOTAL	\$775.00

(2mos)

09/08/2000 YPOLITE1 00000048 09114996

02 FC:216

190.00 OP

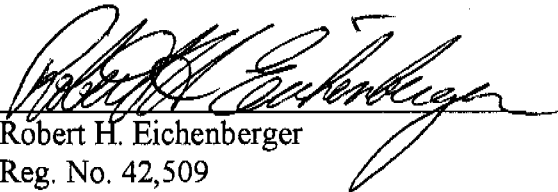
APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SER. NO.: 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert

---

It is believed that this petition complies with the requirements of 37 C.F.R. §§1.136, 1.114, and 1.17. If for some reason the examiner considers otherwise, it is respectfully requested that the undersigned be called so that any deficiencies can be remedied.

September 6, 2000

Respectfully submitted,

  
Robert H. Eichenberger  
Reg. No. 42,509  
Attorney for Applicants

BROWN, TODD & HEYBURN PLLC  
120 West Spring Street, Suite 400  
New Albany, IN 47150  
Phone: 812-948-2800  
Fax: 812-948-7994

0520  
09337.114120  
\\NA2\SY\USERS\520\Theken Surgical\BodyForm Bone Fixation System114120\US Prosecution\203 Petition for Extension of Time.doc



9-07-00

RCE/3732/114

9-22-00  
#17/114  
Key  
RCE

PTO/SB/30 (5/2000)

Approved for use through xx/xx/xxxx. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000,  
provides for continued examination of an utility or plant application  
filed on or after June 8, 1995.  
See The American Inventors Protection Act of 1999 (AIPA).

Application Number	09/114,996
Filing Date	July 14, 1998
First Named Inventor	Theken
Group Art Unit	3732
Examiner Name	E. Robert
Attorney Docket Number	09337.114120

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

**NOTE:** 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

## 1. Submission required under 37 C.F.R. § 1.114

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on \_\_\_\_\_  
(Any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_
- iii. ☐ Other \_\_\_\_\_
- b. ☒ Enclosed
- i. ☒ Amendment/Reply Including New Figures 22, 23, 24, 25
- ii. ☐ Affidavit(s)/Declaration(s)
- iii. ☒ Information Disclosure Statement (IDS)
- iv. ☐ Other \_\_\_\_\_

## 2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)
- b. ☒ Other Return postcard \_\_\_\_\_

## 3. Fees

The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed.

- a. ☐ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. \_\_\_\_\_
- i. ☒ RCE fee required under 37 C.F.R. § 1.17(e)
- ii. ☒ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
- iii. ☒ Other Submission of Information Disclosure Statement
- b. ☒ Check in the amount of \$ 775.00 \_\_\_\_\_ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Robert H. Eichenberger	Registration No. (Attorney/Agent)	42,509
Signature	<i>Robert H. Eichenberger</i>	Date	09/06/2000

## CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on:

Name (Print/Type)	SEE ATTACHED CERTIFICATE OF EXPRESS MAILING		
Signature		Date	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Commissioner for Patents, Box RCE, Washington, DC 20231.

09/08/2000 YPOLITE1 00000048 09114996  
01 FC:279 345.00 OP



PTO/SB/17 (12/99)  
Approved for use through 09/30/2000. OMB 0651-0032  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.  
Small Entity payments must be supported by a small entity statement,  
otherwise large entity fees must be paid. See Forms PTO/SB/09-12.  
See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT (\$775.00)

## Complete if Known

Application Number 09/114,996  
Filing Date July 14, 1998  
First Named Inventor Theken  
Examiner Name E. Robert  
Group / Art Unit 3732  
Attorney Docket No. 09337.114120

## METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number

Deposit Account Name

☐ Charge Any Additional Fee Required  
Under 37 CFR §§ 1.16 and 1.17

2. ☒ Payment Enclosed:

☒ Check ☐ Money Order ☐ Other

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
101	690	201	345	Utility filing fee	
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) (\$)

### 2. EXTRA CLAIM FEES

		Extra Claims		Fee from	Fee Paid
				below	
Total Claims	<input type="text"/>	-20**	= <input type="text"/> X	<input type="text"/>	= <input type="text"/>
Independent Claims	<input type="text"/>	-3**	= <input type="text"/> X	<input type="text"/>	= <input type="text"/>
Multiple Dependent	<input type="text"/>			<input type="text"/>	= <input type="text"/>

\*\*or number previously paid, if greater; For Reissues, see below

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
103	18	203	9	Claims in excess of 20	
102	78	202	39	Independent claims in excess of 3	
104	260	204	130	Multiple dependent claim, if not paid	
109	78	209	39	** Reissue independent claims over original patent	
110	18	210	9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$)

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	190
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,210	241	605	Petition to revive - unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Statement	240
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) Continuing Examination

Other fee (specify)

\* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$775.00)

## SUBMITTED BY

Name (Print/Type) Robert H. Eichenberger  
Signature

Registration No. 42,509  
(Attorney/Agent)

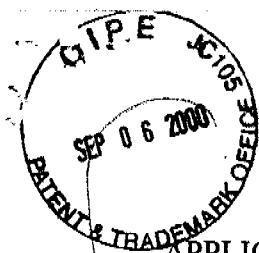
## Complete (if applicable)

Telephone 812-948-2800  
Date 09/06/2000

## WARNING:

Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SERIAL NO. : 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert  
ATTORNEY DOCKET NO. : 09337.114120 (formerly 72258/95945)

*T.H.*  
*9-22-00*  
*#18/ Supply*  
*And*  
*B*  
*4pt.*  
RECEIVED  
SEP 11 2000  
TECHNOLOGY CENTER

**AMENDMENT AND REPLY IN SUPPORT OF SUBMISSION FOR  
37 C.F.R. 1.114 REQUEST FOR CONTINUED EXAMINATION**

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 6, 2000

Dear Sir:

In response to the office action dated April 6, 2000, and in conjunction with a Request for Continued Examination pursuant to 37 C.F.R. § 1.114, a petition for extension of time, and an information disclosure statement, all of which are attached hereto, applicants respond as follows:

**IN THE SPECIFICATION**

At page 5, line 5, cancel the second occurrence of "and"

At page 5, line 7, cancel "." and insert --;--

Per the instructions of the examiner, please insert the following at page 5 line 8 of the specification:

*B*  
-- Fig. 19A is a posterior sectional view of the bone fixation system, as affixed to a pair of vertebral bodies, showing the ledge members connected together to form an intervertebral cage;

Fig. 19B is a top plan view of the lateral side of the bone plate, showing the ledge members connected together to form an intervertebral cage;

APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SER. NO.: 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert

---

Fig. 19C is a sectional view of the bone plate, taken along line 8-8 of Fig. 19B, showing the ledge members connected together to form an intervertebral cage;

Fig. 19D is an end view of the bone plate, showing the ledge members connected together to form an intervertebral cage;

Fig. 19E is a lateral side view of the bone fixation system, as affixed to a pair of vertebral bodies, showing the ledge members connected together to form an intervertebral cage;

Fig. 20, is a top plan view of the lateral side of the bone plate, showing a window having a plurality of holes;

*B' cited.*  
Fig. 21A is a sectional view of the bone plate, taken along line 8-8 of Fig. 20, showing an engagement structure comprising teeth;

Fig. 21B is an end view of the bone plate, showing an engagement structure comprising teeth;

Fig. 21C is a medial side view of the bone plate shown in Fig. 5, showing an engagement structure comprising teeth;

Fig. 21D is a sectional view of the bone plate, taken along line 8-8 of Fig. 20, showing an engagement structure comprising spikes;

Fig. 21E is an end view of the bone plate, showing an engagement structure comprising spikes.--

( In addition, please insert the following at the end thereof: )

APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SER. NO.: 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert

--Fig. 22 is a perspective view of a bone plate, taken from an anterior side perspective, showing the three-dimensional medial surface contours at top and bottom portions of the preferred embodiment and showing an alternative embodiment of support structure;

Fig. 23 is the perspective view of Figure 22 shown as a three-dimensional surface model;

B' C' 1.  
Fig. 24 is a perspective view of a bone plate, taken from a posterior side perspective, showing the three-dimensional medial surface contours at top and bottom portions of the preferred embodiment and showing an alternative embodiment of support structure; and

Fig. 25 is the perspective view of Figure 24 shown as a three-dimensional surface model.—

#### IN THE CLAIMS

Please amend the claims as follows:

1. (Twice amended) A bone fixation system comprising:

B' 2.  
[an] a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between [the] said top portion and said bottom portion, [said bridge portion for connecting at least two bone structures; and], said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion, and said bottom portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion, said medial side of



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said top and bottom portions being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;

at least one support structure [that engages] having medial surface contours extending substantially from an anterior surface of said three-dimensionally contoured elongated plate to a posterior surface of said three-dimensionally contoured elongated plate, said medial surface contours engaging external surfaces of bone structures [at terminal ends of said bone structures];  
and

a fastener for fastening [the] said plate to said bone structures.

2. (Twice amended) A bone fixation system according to claim 1, wherein said at least one support structure includes [ledge members] contoured gaps located adjacent to said top and bottom portions.

3. (~~1~~ amended) A bone fixation system according to claim 2, wherein said [ledge members] contoured gaps have support surfaces that are connected together to form an intervertebral cage device.

4. (~~1~~ amended) A bone fixation system according to claim 2, wherein said [ledge members] contoured gaps include at least one of: bioresorbable compound, bone graft, or bone graft substitute material.

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B<sup>4</sup>  
5. (Twice amended) A bone fixation system according to claim 1, wherein said bridge portion includes at least one window extending from a lateral side through a medial side of said bridge portion for observation of a graft area.

B<sup>5</sup>  
10. (Twice amended) A bone fixation system according to claim 9, wherein said at least one fastener opening includes a first fastener receiving section having a tapered surface, said fastener including a mating tapered surface, wherein said mating tapered surface generally [matching] matches the tapered surface of said first fastener receiving section.

Please cancel claims 19-21 without prejudice. ✓

In addition, please add the following claims:

B<sup>6</sup>  
~~23~~ / ~~21~~  
~~37~~. A bone fixation system according to claim ~~12~~, wherein said fastener means includes a head portion and wherein said at least one opening is dimensioned to receive at least a portion of said head portion.--

~~24~~ / ~~23~~  
~~38~~. A bone fixation system according to claim ~~37~~, wherein said head portion is generally spherical, oval, hex, or flat.--

~~25~~ / ~~21~~  
~~39~~. A bone fixation system according to claim ~~12~~, wherein said fastener means includes a head portion, said head portion having a diameter greater than said at least one opening.--

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26  
21  
~~40.~~ A bone fixation system according to claim 12, wherein said at least one opening is an elongated slot.--

27  
21  
~~41.~~ A bone fixation system according to claim 12, wherein said at least one opening includes a section dimensioned to receive a press fit fastener.--

28  
36  
Central  
~~42.~~ A bone fixation system comprising:

a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between said top portion and said bottom portion, said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion, and said bottom portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion, said medial side of said top and bottom portions being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;

C  
at least one support structure <sup>capable of</sup> engaging external surfaces of bone structures at terminal ends of said bone structures; and

a fastener for fastening said plate to said bone structures.--

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30  
~~43.~~ A bone fixation system according to claim 42, wherein said at least one support structure includes ledge members located adjacent to said top and bottom portions.--

31  
~~44.~~ A bone fixation system according to claim 43, wherein said ledge members are connected together to form an intervertebral cage device.--

32  
~~45.~~ A bone fixation system according to claim 43, wherein said ledge members include at least one of: bioresorbable compound, bone graft, or bone graft substitute material.--

29  
~~46.~~ A bone fixation system according to claim 42, wherein said bridge portion includes at least one window extending from a lateral side through a medial side of said bridge portion for observation of a graft area.--

33  
~~47.~~ A bone fixation system comprising:

a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between said top portion and said bottom portion along the longitudinal axis of said three-dimensionally contoured elongated plate, said three-dimensionally contoured elongated plate further having a lateral-medial axis and an anterior-posterior axis, said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion wherein said three dimensional surface contours further comprise contours about said

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longitudinal and said anterior-posterior axes, and said bottom portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion wherein said three dimensional surface contours further comprise contours about said longitudinal and said anterior-posterior axes, said three-dimensional surface contours of said top portion and bottom portion being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;

*By C. Robert*  
at least one support structure having medial surface contours extending substantially from an anterior surface of said three-dimensionally contoured elongated plate to a posterior surface of said three-dimensionally contoured elongated plate, said medial surface contours engaging external surfaces of bone structures; and

a fastener for fastening said plate to said bone structures.--

#### REMARKS

By this Amendment, claims 1-5 and 10 have been amended; claims 19, 20, and 21 have been canceled without prejudice; and claims 37 through 47 have been added. Therefore, claims 1-18, 22-25, and 37-47 are pending. As this Amendment is being made in conjunction with a request for continued application, all the applicants' arguments in previous amendments are deemed to be incorporated by reference herein. Reconsideration and allowance of the amended claims is respectfully requested.

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1. GENERAL COMMENTS

Additional drawings 22, 23, 24, and 25 have been submitted to further assist in describing the structure of the bone fixation system plate of the preferred and alternative embodiments.

Figure 22 is a perspective view, from an anterior vantage point, of a plate according to the amended claims. Figure 23 is the same view as Figure 22, but shown in solid form. Figure 24 is a perspective view, from a posterior vantage point, of a plate according to the amended claims. Figure 25 is the same view as Figure 24, but shown in solid form. These figures are basically a combination of Figures 4, 6, 8, and 9, and have been included to more clearly depict the three-dimensional surface contours of the amended claims. No new matter has been added as a result of these figures. Support for new Figures 22-25 is found at the following locations in the application: page 2, lines 13-14; page 3, lines 4-5; page 8, line 20 to page 9, line 6; page 10, lines 1-11; page 17, lines 15-21; page 18, lines 5-9. Further support is found in Figures 1-10, 15, 16, and 18.

Claim 1 has been amended to highlight the structural differences of the claimed system from any known prior art reference. Specifically, claim 1 has been amended to further describe the fact that the top and bottom portions 40, 60 of the plate 20 have an outer surface that is anatomically contoured to match **both** the lateral and anterior profile of bone structures. None of the prior art references are contoured in this fashion. It should be noted that the plate 20 of the preferred embodiment is designed for **lateral placement** along vertebrae of the thoraco-lumbar spine—not anterior placement as described in the references cited by the examiner. As a result of this lateral placement, the three-dimensional surface contours on the medial side 28 of the claimed system provide the desired close anatomical fit.

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Claim 1 has likewise been amended to further describe the support structure of the plate, with its medial side 28 contours also assisting in providing the proper anatomical fit. In particular, the medial side 28 contours allow the system plate 20 to sit "down into" rather than "on top of" the bone. This arrangement allows the plate to engage external surfaces of bone structures in addition to terminal ends of said bone structures. Support for these changes is found at the following locations in the application: Page 2, lines 3-8 and lines 12-14; Page 3, lines 4-9; and Page 10, lines 1-11. Further support is found in Figures 1-10.

Claims 2-4 have been amended to further describe the support structure as including contoured gaps 34A, 34B located adjacent to said top and bottom portions. Support for this language is found at the following locations in the application: Page 3, lines 4-9; Page 8 line 20 to page 9 line 21; Page 10, lines 3-11. Further support is found in Figures 1-10.

Claim 5 has been amended to further describe the recess 90, or observation window, as being located on the lateral side 26 of said bridge portion 80. Support for this language is found at the following locations in the application: Page 8, lines 5-19. Further support is found in Figures 1-3, 5-7, and 15-17. No new matter has been added by the amended claims

## **2. ALLOWABLE SUBJECT MATTER**

The Office Action states that claims 12 and 13 are allowable. As a result, new claims 37-41 are deemed allowable as they depend from and further limit claim 12, and because they add no new matter. Applicants respectfully request such allowance.

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3. **35 U.S.C. §102 REJECTIONS: CLAIMS 1-5, 9, 16, 17, 19-25**

Claims 1-5, 9, 16, 17, and 19-25 stand rejected under §102(b) as being anticipated by Matsuzaki, et al. (U.S. Patent No. 5,534,031). Applicants respectfully submit that the amended claims overcome the rejections noted for the following reasons.

First and foremost, amended claims 1-5 claim a three-dimensionally contoured plate 20 that closely conforms to **both** an anterior and a lateral aspect of bone structures. In particular, the applicants direct the examiner's attention to Figures 2, 3, and 4 of the application, and new Figures 22-25 of this amendment, to most clearly show how the three dimensional surface contours in the medial side 28 of the plate 20 "anatomically fit" both aspects of the bone structures.

Figure 22 accompanying this amendment contains a system of axes that facilitates a description of the required contours. The x-axis is the longitudinal axis, the y axis is the anterior-posterior axis; and the z-axis is the lateral-medial axis. The amended claims define a bone fixation system plate wherein curvatures, or surface contours, are present on the medial side 28 about at least two of these axes: in the preferred embodiment, these are the longitudinal axis and the anterior-posterior axis. Depending on the type of bone structure to which the claimed bone fixation system is applied, curvatures could exist about other axes or combinations of axes. This multiaxial curvature of the top and bottom portions 40, 60 of the plate 20 allows the plate to closely conform to both an anterior and a lateral aspect of the bone structures.

This is in stark contrast to the device described in Matsuzaki, where the surface that engages the bone is either **flat** (see Figure 7 of Matsuzaki) or has but a single radius of curvature about a single axis (see Figure 8 of Matsuzaki). Likewise, in Figure 10 of Matsuzaki, the flange



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beneath reference numeral 27 clearly depicts a flat surface. As a result, Matsuzaki clearly does not describe a system that provides the anatomical fit provided in the amended claims.

Because claim 1 has been amended to overcome prior art, dependent claims 2-4 are likewise deemed allowable. In addition, however, claims 2-4 are allowable because Matsuzaki clearly provides no teaching of a support structure having the contoured gaps 34A, 34B of these amended claims.

Because claim 1 has been amended to overcome prior art, dependent claim 3 is likewise deemed allowable. In addition, however, claim 3 is allowable because the intervertebral cage device likewise maintains the multiaxial anatomical fit of the bone fixation system of amended claim 1 (discussed above). This means that the cage device is positioned between adjacent vertebrae which are supported by the support structure contours. This is in stark contrast to the Matsuzaki cage, which is completely embedded into adjacent vertebrae. Such embedding actually requires harvesting portions of the bone for proper placement: "an annular groove 301 which is of such a size as to snugly receive the hollow cylindrical member 501 is formed jointly in the two adjacent vertebrae 3." (Matsuzaki, col. 4, lines 37-39).

Because claim 1 has been amended to overcome prior art, dependent claim 5 is likewise deemed allowable. In addition, amended claim 5 is deemed allowable because it further clarifies that the window for observation is disposed along the lateral-medial axis.

Because claim 1 has been amended to overcome the prior art, dependent claims 9, 16, 17, and 22-25 are likewise deemed allowable as they further limit claim 1. Claims 19-21 have been canceled without prejudice.

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In summary, Matsuzaki neither describes nor suggests the type of bone fixation system of the amended claims having multiaxial surface contours on top and bottom portions. Allowance of the amended claims is respectfully requested.

4. **35 U.S.C. §102 REJECTIONS: CLAIMS 1, 5, 6, 9, 16, 20**

Claims 1, 5, 6, 9, 16, and 20 stand rejected under §102(b) as being anticipated by Omsk Med. Inst. (SU 1,526,673). Applicants respectfully submit that the amended claims overcome the rejections noted for the following reasons.

All of the remarks regarding claims 1, 5, 9, 16, and 20 which were discussed above in Section 3 with respect to Matsuzaki are applicable to the Omsk reference, and, for the sake of brevity are incorporated herein by reference. Like Matsuzaki, Omsk does not disclose a device having the multiaxial contours of the amended claims. Indeed, Omsk has no contours at all—both sides of the Omsk device being flat. As a result, the Omsk device is devoid of any teaching of a contoured plate providing close anatomical fit in **either** the anterior aspect or the lateral aspect.

By contrast, the plate 20 of the amended claims has multiaxial surface contours about at least the longitudinal and the anterior-posterior axes, thus providing proper anatomical fit in **both** lateral and anterior aspects of the spine. In addition, Omsk does not disclose a support structure comprising contoured gaps as recited in the amended claims, and therefore does not disclose the contours associated with the support structure used to engage the bone structures at terminal ends thereof. As a result, claims 1, 5, 9, 16, and 20 are also allowable over Omsk.

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Because claim 1 has been amended to overcome the prior art, remaining dependent claim 6 is likewise deemed allowable.

In summary, Omsk neither describes nor suggests the type of bone fixation system of the amended claims having multiaxial surface contours on top and bottom portions. Allowance of the amended claims is respectfully requested.

**5. 35 U.S.C. §102 REJECTIONS: CLAIMS 1-4, 9, 10, 14, 15, 17, 19-21, 24, 25**

Claims 1-4, 9, 10, 14, 15, 17, 19-21, 24, and 25 stand rejected under §102(b) as being anticipated by Kehr (EU 0,179,695). Applicants respectfully submit that the amended claims overcome the rejections noted for the following reasons.

All of the remarks regarding claims 1-4, 9, 17, 19-21, 24, and 25 which were discussed above in Section 3 with respect to Matsuzaki are applicable to the Kehr reference, and, for the sake of brevity are incorporated by reference herein. Like Matsuzaki, Kehr does not disclose or suggest a device having the claimed surface contours on the top and bottom portions 40, 60 of the device. Instead, Kehr clearly depicts a plate section that is flat on both sides. Figures 1, 2, and 4 of Kehr indicate that the surface of the plate that engages the bone is flat and has no contours whatsoever. As a result, applicants respectfully traverse the examiner's statement that the Kehr plate "has an anterior side having a medial surface that matches an anterior profile of a vertebral body . . . ." Figures 1 and 2 of Kehr clearly show that the anterior side of the Kehr plate is flat and therefore does not "match" the anterior profile of a vertebral body.

Figures 5 and 6 of Kehr show a plate having a curvature, but this is merely a curvature about the longitudinal axis. This uniaxial curvature of Kehr is in direct contrast to the multiaxial

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curvatures of the amended claims that allow the claimed system to match **both** the lateral and anterior aspects of the bone structure. As a result, Kehr does not provide the anatomical fit of the amended claims, and therefore neither describes nor suggests the bone fixation system of the amended claims. Therefore, claims 1-4, 9, 17, 24, and 25 are also allowable over Kehr, claims 19-21 having been canceled without prejudice.

Because claim 1 has been amended to overcome the prior art as discussed above, remaining dependent claims 10, 14, and 15 are likewise deemed allowable.

In summary, Kehr neither describes nor suggests the type of bone fixation system of the amended claims having multiaxial surface contours on top and bottom portions. Allowance of the amended claims is respectfully requested.

6. **35 U.S.C. §102 REJECTIONS: CLAIMS 1, 9-11, 14, 15, 17-21**

Claims 1, 9-11, 14, 15, 17-21 stand rejected under §102(b) as being anticipated by Nilsson, et al. (WO 9,426,193). Applicants respectfully submit that the amended claims overcome the rejections noted for the following reasons.

All of the remarks regarding claims 1, 9, 17, and 19-21 which were discussed above in Section 3 with respect to Matsuzaki are applicable to the Nilsson reference, and, for the sake of brevity are incorporated herein by reference. Like Matsuzaki, Nilsson does not disclose or suggest a bone fixation system having multiaxial surface contours on top and bottom portions that closely match **both** the lateral and anterior aspects of bone structures. As in both Matsuzaki and Kehr, Figure 3 of Nilsson appears to depict a bottom surface having a curvature, but again this curvature is uniaxial only—there is no disclosure of multiaxial contours as provided in the

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amended claims. Furthermore, Nilsson clearly sits atop the bone structures. This is in stark contrast to the plate 20 of the amended claims which utilize contoured gaps 34A, 34B to engage the external surfaces of the bone structures. By using contoured gaps 34A, 34B to engage the external surfaces of the bone structures as claimed, the applicants' invention "sits down into," rather than "on top of" the bone. (Application, Page 10, Lines 8-9). This provides a lower profile plate than that described in the Nilsson reference. As a result, Nilsson does not describe the system of the amended claims. Therefore, claims 1, 9, and 17 are also allowable over Nilsson, claims 19-21 having been canceled without prejudice.

Because claim 1 has been amended to overcome the prior art as discussed above, remaining dependent claims 10, 11, 14, 15, and 18 are likewise deemed allowable.

In summary, Nilsson neither describes nor suggests the type of bone fixation system of the amended claims having multiaxial surface contours on top and bottom portions. Allowance of the amended claims is respectfully requested.

**7. 35 U.S.C. §103 REJECTIONS: CLAIMS 7, 8**

Claims 7-8 stand rejected under §103(a) as being unpatentable over Omsk Med. Inst. (SU 1,526,673). Specifically, the examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the window of Omsk as a plurality of holes or having an irregular shape. Applicants respectfully submit that the amended claims overcome the rejections noted for the following reasons.

Claims 7 and 8 depend from claims 1 and 5 which have been amended to overcome the §102 rejections (discussed in detail above). These amendments include three-dimensional

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multiaxial surface contours on top and bottom portions 40, 60 that closely match **both** lateral and anterior aspects of bone structures. In addition, amended claims 7 and 8 require a support structure likewise having surface contours for conforming to bone structures. Claims 7 and 8 therefore incorporate all the limitations of amended claims 1 and 5. Because Omsk neither teaches nor suggests **any** of these claim limitations, it is respectfully submitted that the §103 rejections have likewise been overcome by the amendments.

8. NEW CLAIMS 42-47

Claim 42 is nearly identical to amended claim 1, except for one minor distinction. In claim 1 the "at least one support structure" described refers to the medial side 28 contours near the union of the top portion 40 and the bridge portion 80, and near the union of the bottom portion 60 and the bridge portion 80. By contrast, the "at least one support structure" of new claim 42 refers to the embodiment that includes medial side ledges 86A and 86B. Because new claim 42 refers to the ledges 86A and 86B, the "at least one support structure" is described as engaging external surfaces of bone structures "at terminal ends of bone structures." Whereas the support structure of claim 42 engages the terminal ends of bone structures, the support structure of claim 1 is not so limited. In particular, note that the specification teaches that "all of the ledges could be omitted" (see specification at page 9, lines 19-21) for the plate. Claim 1 therefore describes a plate requiring no ledges; claim 42 describes a plate having ledges. Therefore, claim 42 is deemed more restrictive than claim 1.

Support for claim 42 is found at the following locations in the specification: Page 2, lines 3-8; Page 3, lines 4-9; Page 8 line 20 to Page 9 line 21; and Page 10, lines 1-11. Further support

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is found in Figures 1-10. No new matter has been added by new claim 42. Applicants respectfully submit that claim 42 is therefore allowable.

Claims 43-46 further limit claim 42 in the same manner as dependent claims 2-5 further limit claim 1. Support for claims 43-46 is found at the following locations in the specification: Page 3, lines 4-9; Page 8, line 5 to Page 9 line 21; Page 10, lines 3-11. Further support is found in Figures 1-10. No new matter has been added by claims 43-46. Because claims 43-46 further limit claim 42, which is deemed allowable, claims 43-46 are likewise deemed allowable.

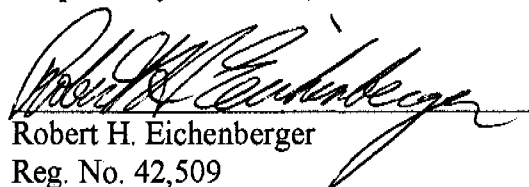
Claim 47 incorporates all the limitations of claim 1. In addition, claim 47 further describes the contours for the plate according to the amended claims. As a result, applicants respectfully submit that claim 47 is likewise allowable, and applicants request such allowance.

### CONCLUSION

For all of the foregoing reasons, it is believed that the amended claims warrant allowance, and such allowance is respectfully requested.

September 6, 2000

Respectfully submitted,

  
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**RULE 1.10 CERTIFICATE OF EXPRESS MAILING**



I hereby certify that the following documents:

Request for Continued Examination Transmittal  
Rule 114 Submission (Amendment and Reply) (18 pages)  
Additional drawing sheets (4 sheets)  
Information Disclosure Statement  
Form PTO/SB/08A  
One copy each of patents listed on Form PTO/SB/08A  
Rule 136(a) Petition for Extension of Time  
Fee Transmittal  
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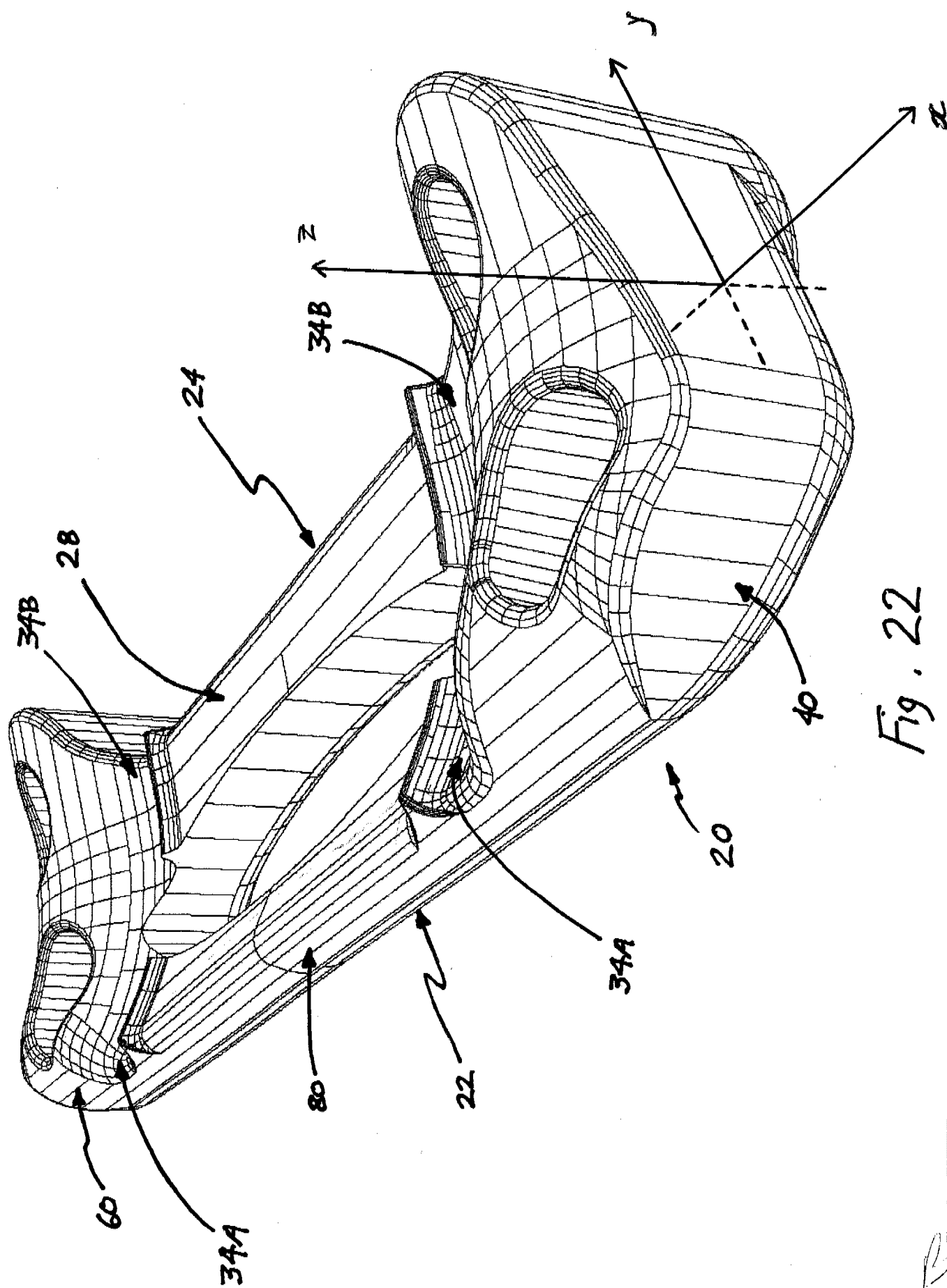
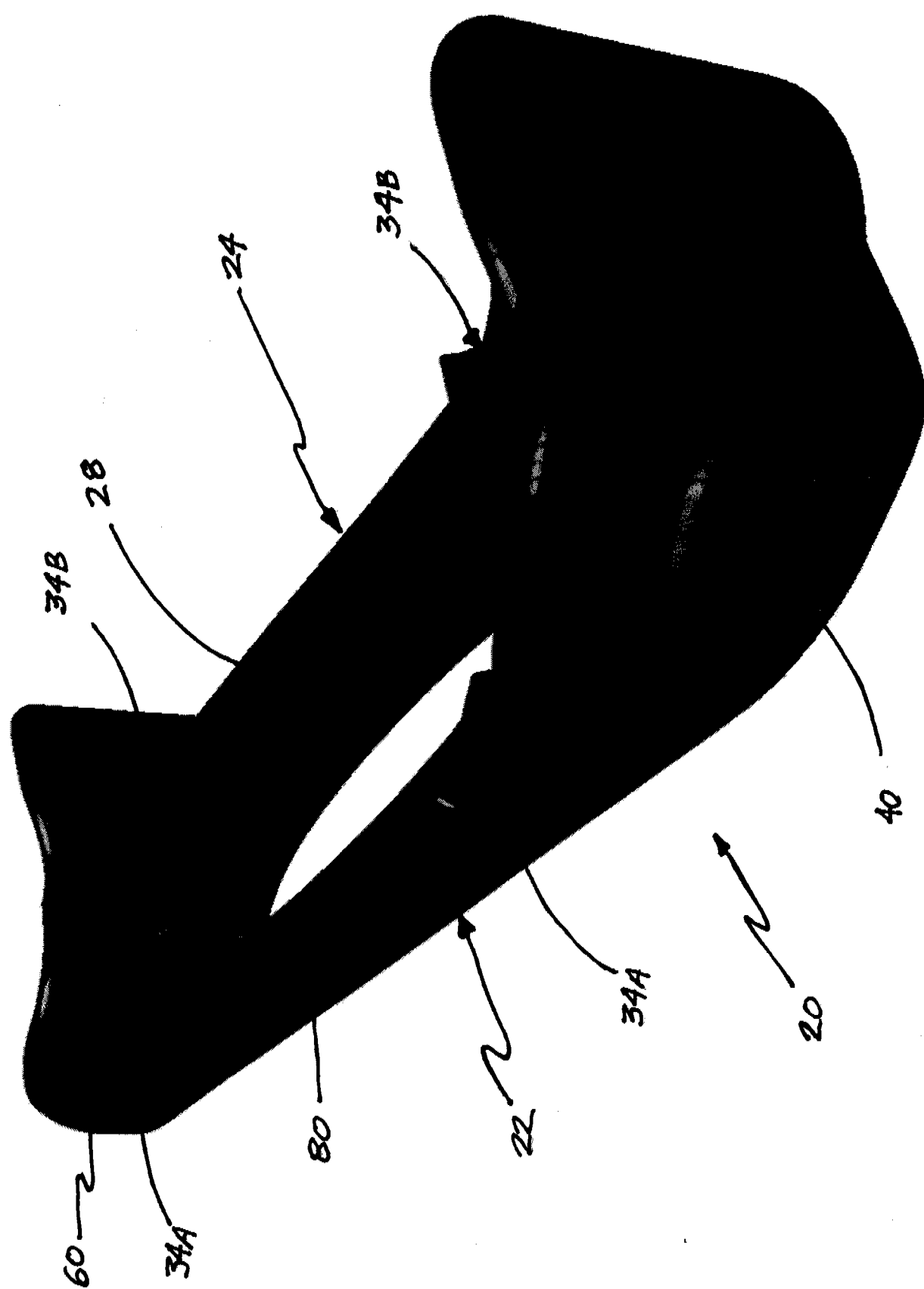


Fig. 22



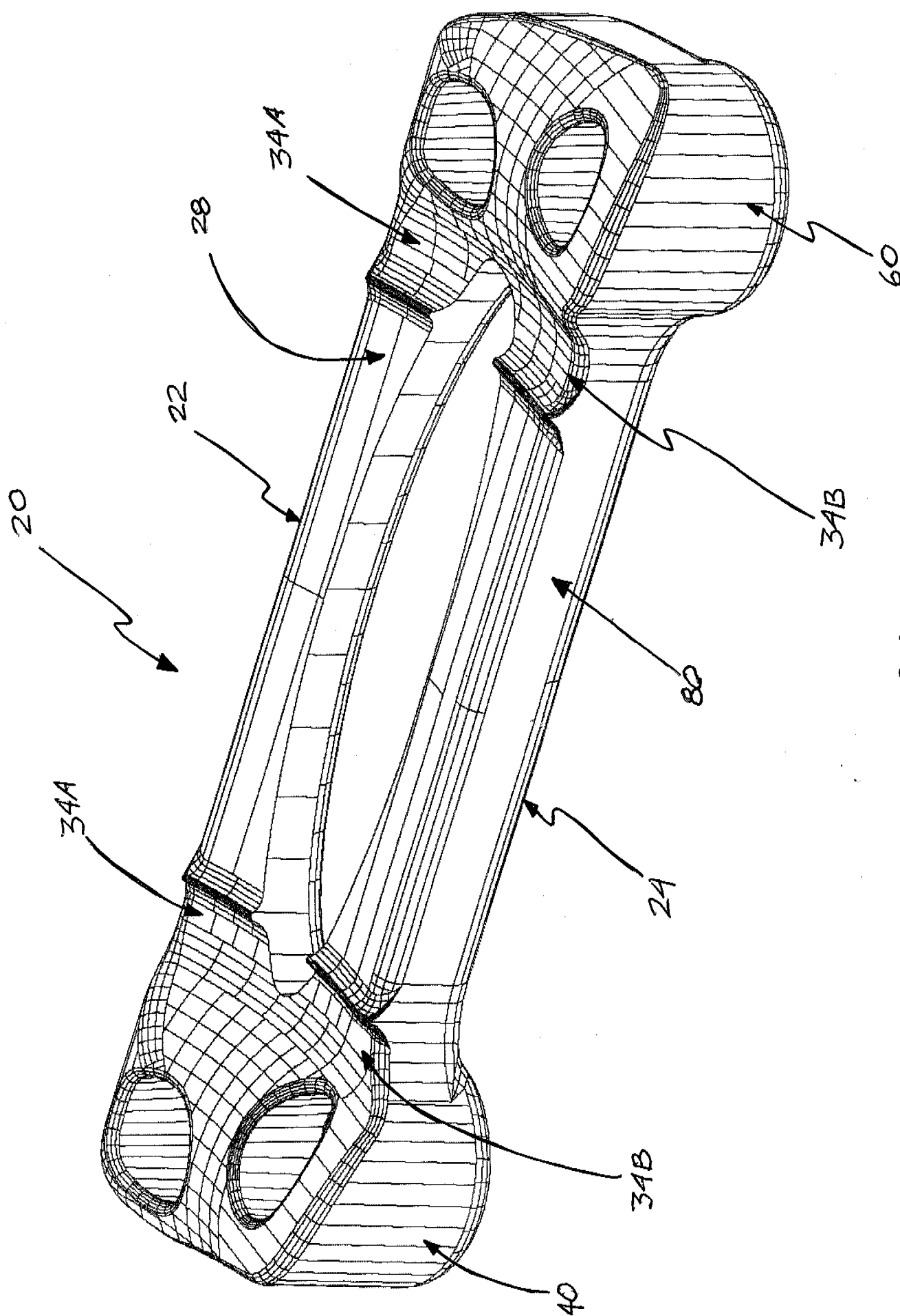


Fig. 24

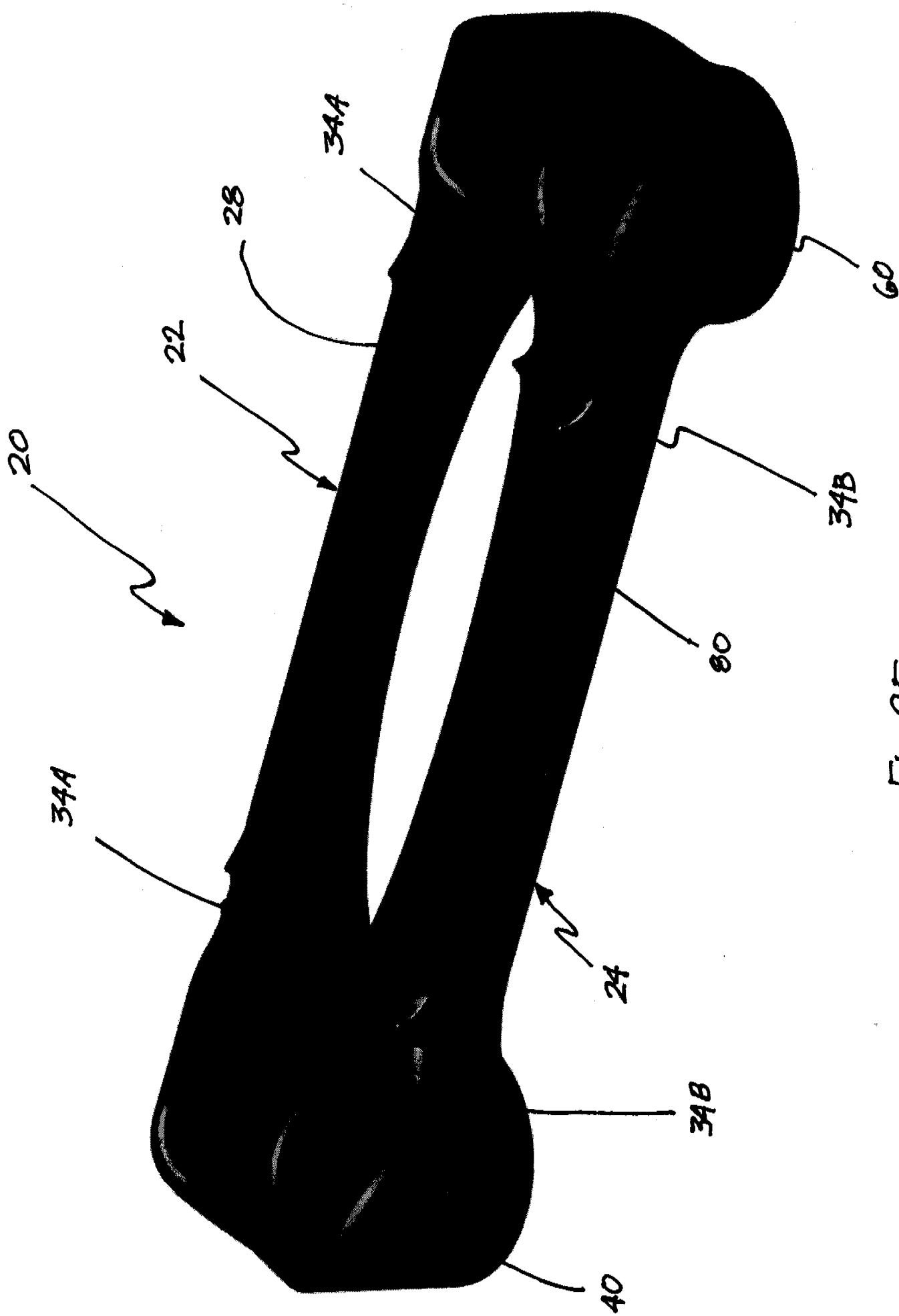


Fig. 25

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ATTORNEY DOCKET NO. : 09337.114120 (formerly 72258/95945)



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 6, 2000

Dear Sir:

Applicants submit this Statement in accordance with their duty of disclosure under 37 C.F.R. §§1.56 and 1.97-1.98. This statement is filed in accordance with 37 C.F.R. §1.97(b), before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114. Said Request accompanies this Statement.

Attached hereto is Form PTO/SB/08A, a substitute for 1449A/PTO, listing documents which may be relevant to the subject application. In accordance with MPEP § 609, it is respectfully requested that these documents be considered by the examiner, cited of record, and initialed by the examiner.

In accordance with §1.97(g), this Statement should not be construed as a representation that a search has been made. Similarly, in accordance with §1.97(h), this Statement should not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in §1.56(b).

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Information Disclosure Statement

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A copy of each reference is enclosed. Pursuant to 37 C.F.R. § 1.98(a)(3), the following concise explanations of the foreign references cited in this Statement is provided below.

Reference E: This reference is an osteosynthesis plate usable for the lower end of a femur. The plate has a curved main shaft with boss near the lower end above a pair of oppositely cambered apertured sections.

Reference F: This reference appears to disclose an implantable device with bone screws having tapered head portions matching the tapered openings in the implantable device.

Reference G: This reference appears to disclose an implantable fracture plate that is movable longitudinally relative to locators screwed to a bone. It appears the screw heads are tapered to match the screw openings.

Reference H: This reference appears to disclose an implantable connecting plate for a fractured bone.

Reference I: This reference appears to disclose an implantable bone positioning device having parallel rails of circular cross section. From C-shaped openings, a bore widens in a cone in both directions.

Reference J: This reference appears to disclose an implantable device for bones such as femurs.

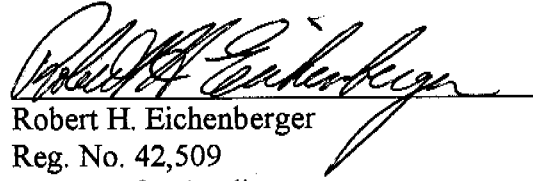
It is believed that this disclosure complies with the requirements of 37 C.F.R. §§ 1.56, 1.97, and 1.98, and the Manual of Patent Examining Procedures § 609. If for some reason the examiner considers otherwise, it is respectfully requested that the undersigned be called so that any deficiencies can be remedied.

APPLICANT : Theken, et al.  
TITLE OF INVENTION : BONE FIXATION SYSTEM  
APPLICATION SER. NO.: 09/114,996  
FILING DATE : July 14, 1998  
EXAMINER : Eduardo C. Robert

---

September 6, 2000

Respectfully submitted,

  
Robert H. Eichenberger  
Reg. No. 42,509  
Attorney for Applicants

BROWN, TODD & HEYBURN PLLC  
120 West Spring Street, Suite 400  
New Albany, IN 47150  
Phone: 812-948-2800  
Fax: 812-948-7994

0520  
09337.114120  
\\NA2\SY\USERS\520\Theken Surgical\BodyForm Bone Fixation System114120\US Prosecution\202 Information Disclosure Statement.doc

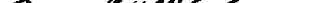
Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	09/114,996
		Filing Date	July 14, 1998
		First Named Inventor	Theken
		Group Art Unit	3732
		Examiner Name	E. Robert
Sheet 1 of 1		Attorney Docket Number	09337.114120

[illegible][illegible]

Examiner Signature		Date Considered	12/7/00
-----------------------	---	--------------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



DEC-11-2000 MON 01:45 PM BROWN, TODD, & HEYBURN

FAX NO.

P. 01

# 19/34/8  
1200

**FROST BROWN TODD LLC**

120 West Spring Street, Suite 400  
New Albany, Indiana 47150-3655  
(812) 948-2800 Telephone  
(502) 581-1087 Facsimile

DRAFT  
plans

**FACSIMILE TRANSMISSION COVER SHEET**

The information contained in this facsimile transmission is confidential and intended for the use of the individual or entity named below. If the reader of this message is not the intended recipient (or the employee or agent responsible to deliver it to the intended recipient), you are notified that any dissemination, distribution or copying of this communication is prohibited. If you have received this communication in error, please notify us by collect telephone and return the original facsimile transmission to us at our expense to the above address.

DATE: December 11, 2000

TO: Eduardo Robert

COMPANY/FIRM: USPTO

CITY/STATE: \_\_\_\_\_

FAX NUMBER: (703) 308 - 2708

CONFIRM NUMBER: \_\_\_\_\_

FROM: Robert Eichenberger

SUBJECT: DRAWINGS

NUMBER OF PAGES (Including Cover) 5 If you do not receive all pages please call Ext. 8361

MESSAGE: \_\_\_\_\_

\_\_\_\_\_

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Original <b>WILL</b> Follow By:		
<input type="checkbox"/> First Class Mail	<input type="checkbox"/> Certified Mail	<input type="checkbox"/> Registered Mail
<input type="checkbox"/> Overnight Delivery	<input type="checkbox"/> Hand Delivery	<input type="checkbox"/> Interoffice Mail
<input type="checkbox"/> Original <b>WILL NOT</b> Follow		

CLIENT/MATTER NO: 09337, 114120

RETURN TO: B

Recommend entry. Ref. 12/11/00  
July 2000  
12/12/00

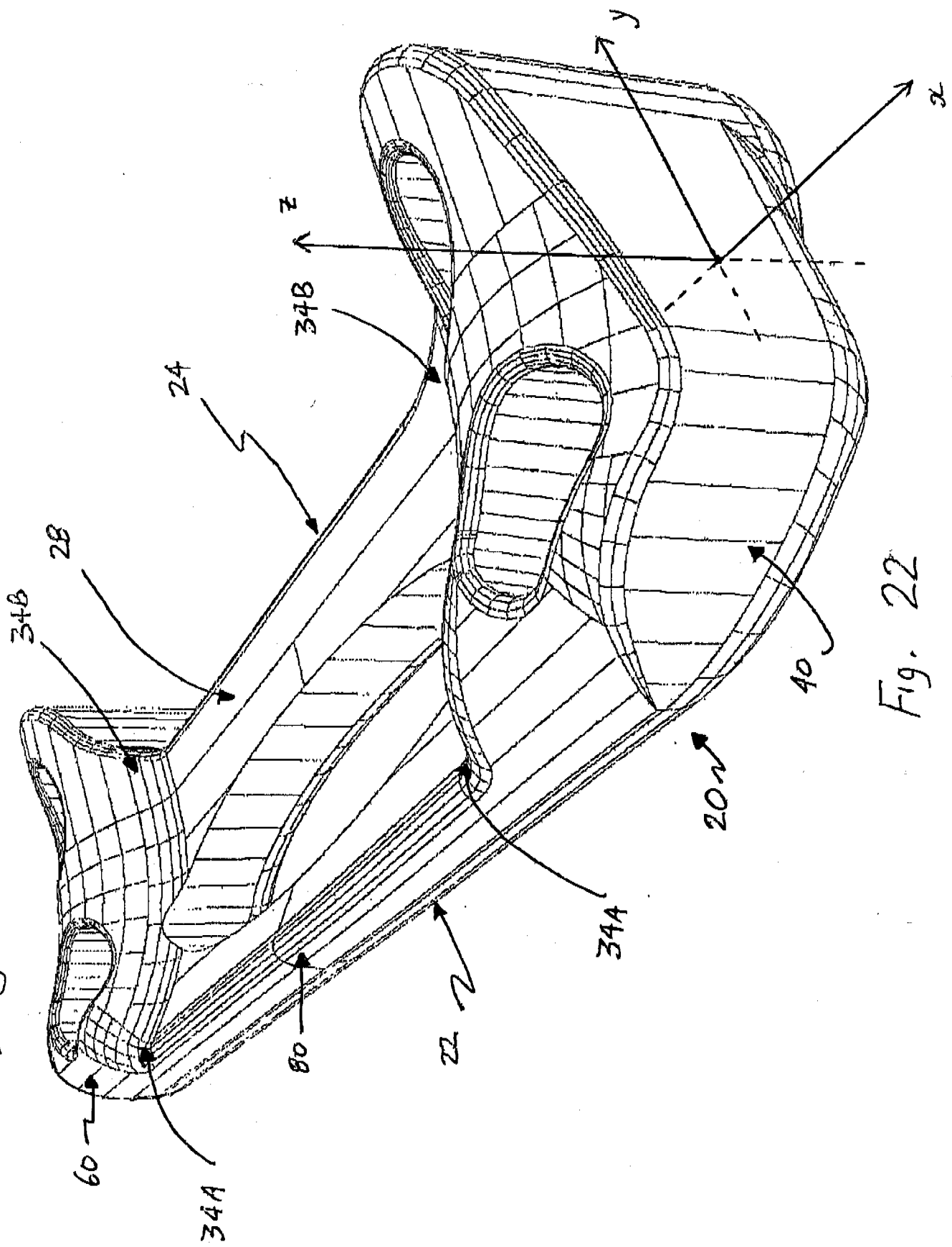
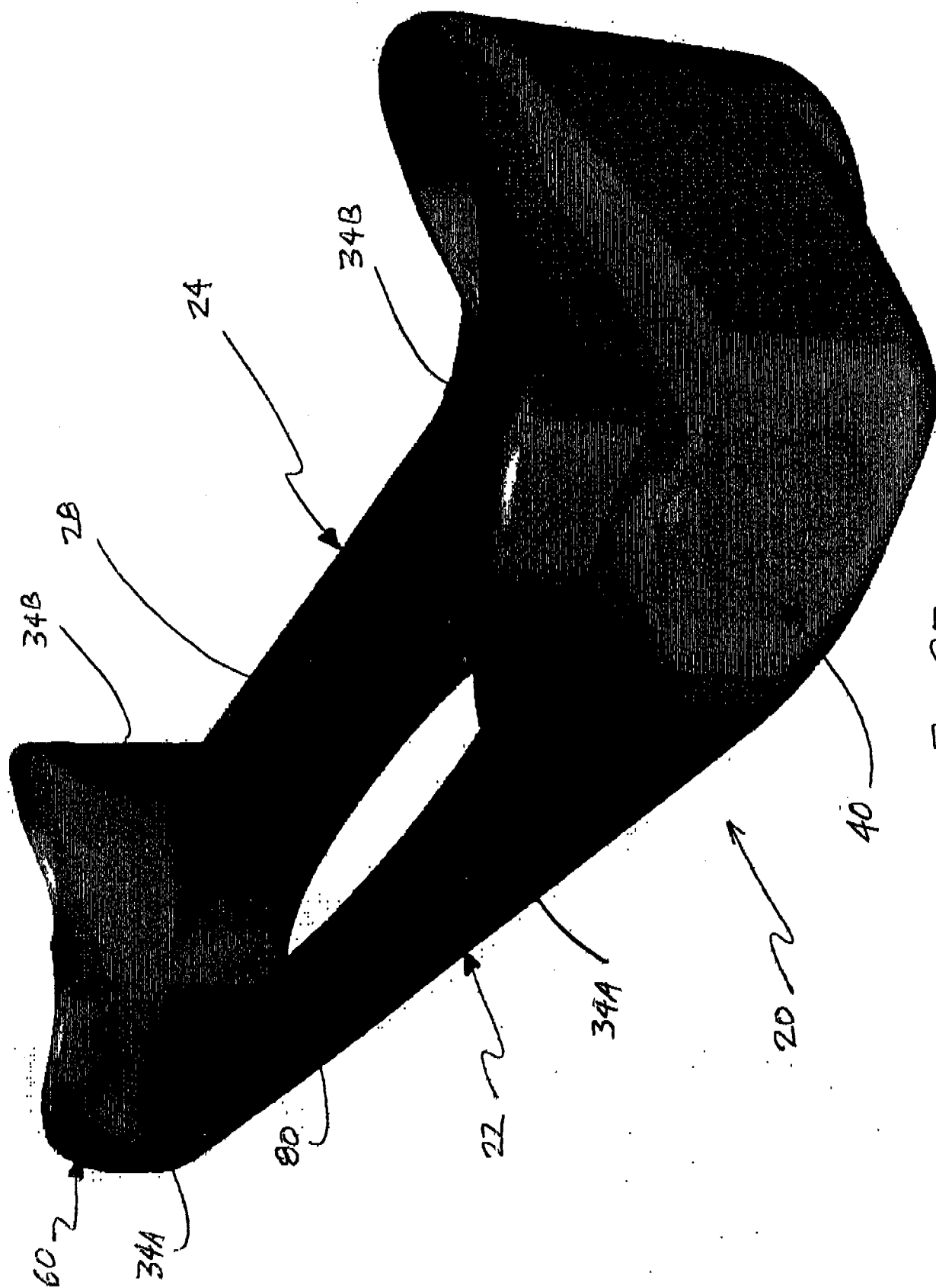


Fig. 22



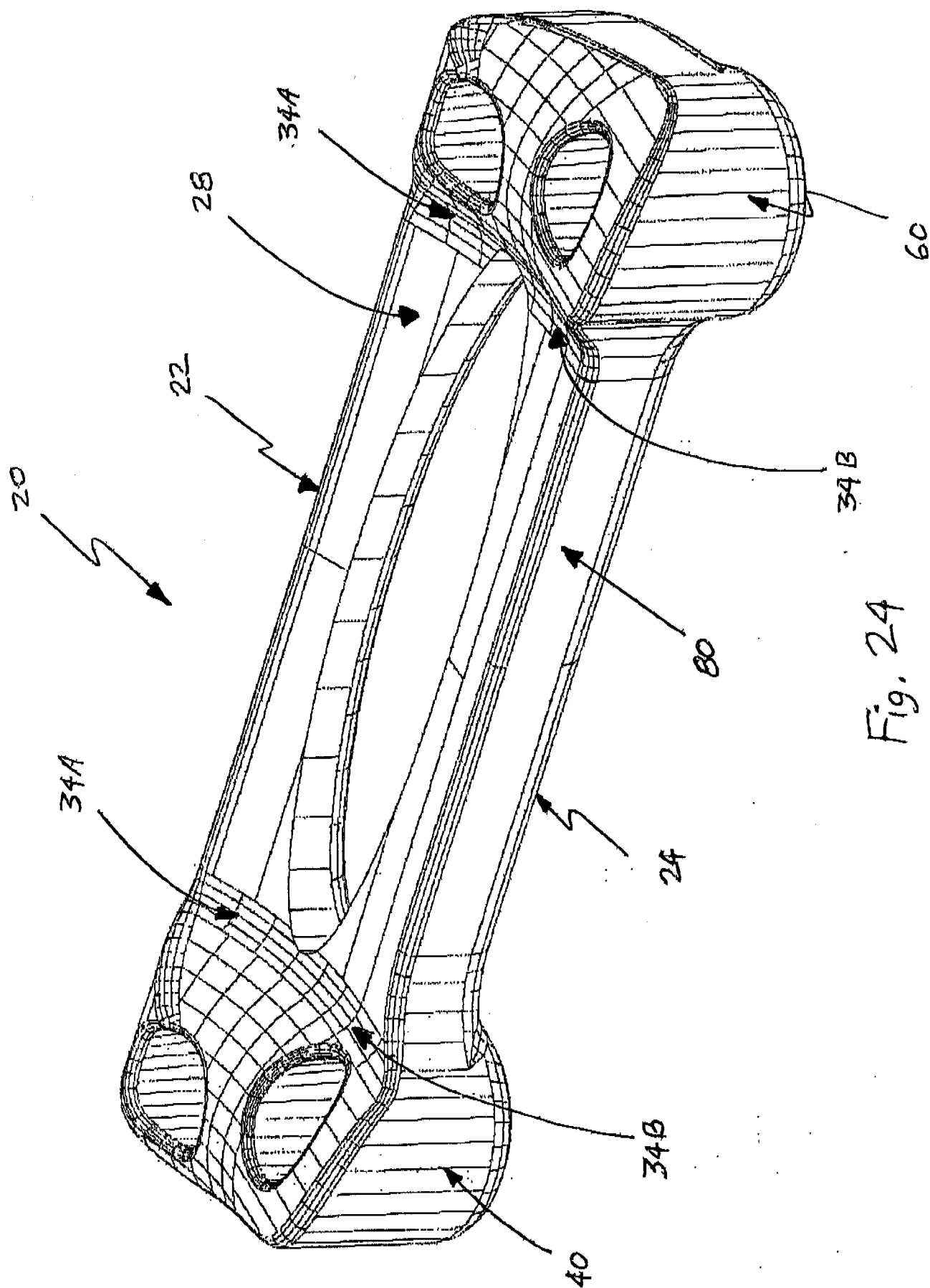


Fig. 24

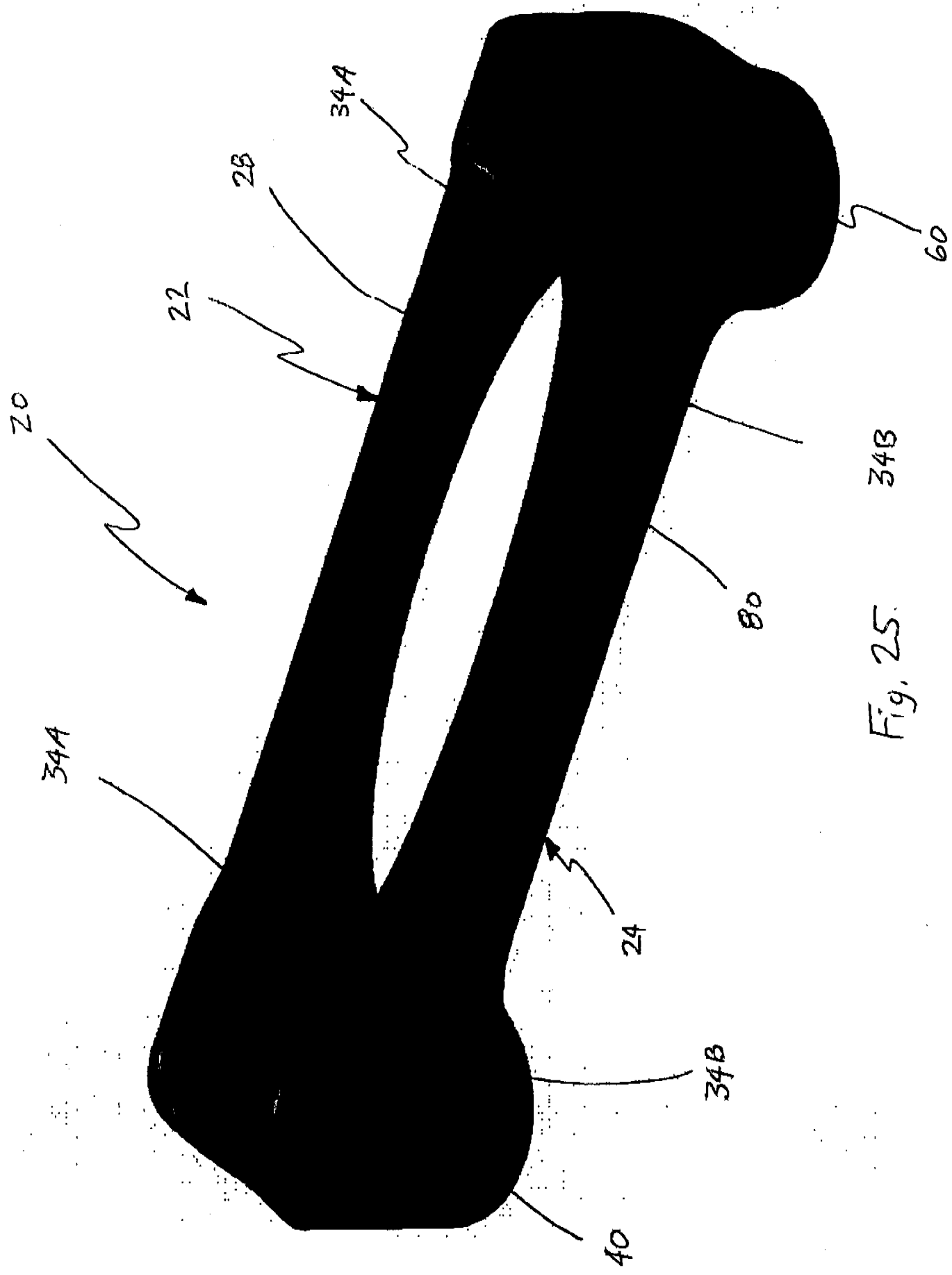


Fig. 25.

34B

## Interview Summary

Application No.

09/114,996

Applicant(s)

Theken, et al.

Examiner

Eduardo C. Robert

Group Art Unit

3732



All participants (applicant, applicant's representative, PTO personnel):

(1) Eduardo C. Robert

(3) \_\_\_\_\_

(2) Mr. Robert H. Eichenberger

(4) \_\_\_\_\_

Date of Interview Dec 11, 2000Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:Agreement ☒ was reached. ☐ was not reached.Claim(s) discussed: 1, 42, and 47

Identification of prior art discussed:

None

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Claims 1, 42, and 47 have been amended to place the case in condition for allowance (see examiner's amendment attached hereto). Also, the examiner explained to applicant's representative that proposed drawings 22-25, filed on 9/6/00, were disapproved because they introduce new matter. Applicants re-filed new drawings 22-25, on 12/11/00, which were approved by the examiner.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/114,996 07/14/98 THEKEN

R 23724-3

EXAMINER

QM12/1213

ROBERT H. EICHENBERGER  
120 WEST SPRING STREET  
SUITE 400  
NEW ALBANY IN 47150

ROBERT, E	
ART UNIT	PAPER NUMBER

3732  
DATE MAILED:

12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

#21/C

# **Notice of Allowability**

Application No.  
09/114,996

Applicant(s)  
Theken, et al.

Examiner  
Eduardo C. Robert

Group Art Unit  
3732



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to amendment filed on 9/6/00 and interview on 12/11/00

☒ The allowed claim(s) is/are 1-18, 22-25, and 37-47

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_

☒ including changes required by the proposed drawing correction filed on 2/1/00 + 12/11/00, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## **Attachment(s)**

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance

*Gene Mancene*  
Gene Mancene  
Supervisory Patent Examiner  
Group 3700



Art Unit: 3732

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Robert h. Eichenberger on December 11, 2000.

The application has been amended as follows:

In claim 1, line 16, -- capable of -- has been inserted after "contours".

In claim 42, line 12, -- capable of -- has been inserted after "structure".

In claim 47, line 19, -- capable of -- has been inserted after "contours".

### *Drawings*

The proposed drawing, filed on September 6, 2000 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of a plate having protruding ledges and no anterior and posterior walls.


The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on December 11, 2000 have been approved.

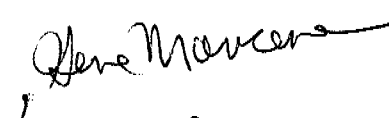
Application/Control Number: 09/114,996

Page 3

Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is (703) 305-7333.

  
E.C. Robert  
December 11, 2000

  
Gene Mancena  
Supervisory Patent Examiner  
Group 3700  
Supervisory Patent Examiner  
Group 3700



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM12/1213

ROBERT H. EICHENBERGER  
120 WEST SPRING STREET  
SUITE 400  
NEW ALBANY IN 47150

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP/ART UNIT	DATE MAILED
09X114,926	07/14/98	033	ROBERT, E	3732 12/13/00
First Named Applicant	THEKEN, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION BONE FIXATION SYSTEM

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 23724-3	606-061.000	W31	UTILITY	YES	\$620.00	03/13/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

If the SMALL ENTITY is shown as NO:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or  
B. If the status is the same, pay the FEE DUE shown above.

- A. Pay FEE DUE shown above, or  
B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.  
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

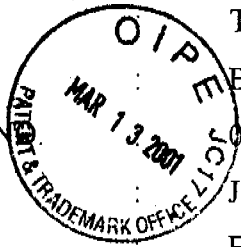
**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

PATENT AND TRADEMARK OFFICE COPY

03-14-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT Theken, et al.  
TITLE OF INVENTION BONE FIXATION SYSTEM  
APPLICATION SERIAL NUMBER 09/114,996  
FILING DATE July 14, 1998  
EXAMINER Eduardo C. Robert  
ATTORNEY DOCKET NUMBER : 09337.114120



#22m  
B  
March & Return

LETTER TO DRAFTSPERSON PURSUANT TO MPEP § 608.02(r)

Assistant Commissioner for Patents  
Washington, D.C. 20231

March 13, 2001

Dear Sir:

In response to the Notice of Allowance dated December 13, 2000, and in conjunction with the issue fee being transmitted on even date herewith, applicants respectfully submit the final drawings to show the invention specified in the claims. The final drawings are shown in Figures 1-18, 19A-19E, 20, 21A-21E, and 22-25 attached to this letter. No new matter is entered that is not supported by the claims or specification.

The attached drawings reflect the amended drawings which were filed January 24, 2000 and December 11, 2000 in accordance with the provisions of MPEP §§ 608.02 (h), (r), and (v).

Applicants respectfully point out the following minor changes to certain of the informal drawings, said changes having been made in order to adhere to 37 C.F.R. § 1.84:

- ◆ Figure 19B: The direction of the cutting line 19C has been corrected. As originally filed, the cutting line direction was to the right of the page, which would not have produced Figure 19C showing the cage. Only a cutting line to the left of the page would render Figure 19C.
- ◆ Figure 19C: As a result of the above-referenced change to Figure 19B, the point of connection for the cage has been corrected accordingly.
- ◆ Figure 23: As filed on December 11, 2000, informal Figure 23 was depicted as a solid surface-shaded model. Since Rule 1.84(m) prohibits the type of solid black shading depicted in the informal drawing, thin contour lines have been added instead. No other change has been made to this figure.

12/00

APPLICANT: Theken, et al.  
TITLE: BONE FIXATION SYSTEM  
SERIAL NO.: 09/114,996  
EXAMINER: Eduardo C. Robert  
FILING DATE: July 14, 1998

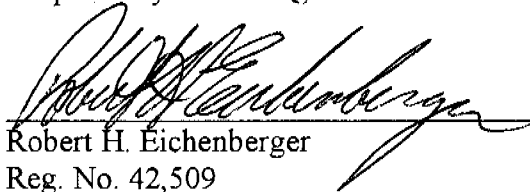
- ◆ Figure 25: As filed on December 11, 2000, informal Figure 25 was depicted as a solid surface-shaded model. Since Rule 1.84(m) prohibits the type of shading depicted in the informal drawing, thin contour lines have been added instead. No other change has been made to this figure.

In accordance with the foregoing, the applicants submit that the present application is in proper condition for issuance. If any further matters need to be discussed in order to expedite the issuance of the present application, please contact the undersigned.

If any further fees are necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 02-4275, referencing our Docket No. 09337.114120.

March 13, 2001

Respectfully submitted,

  
Robert H. Eichenberger  
Reg. No. 42,509  
Attorney for Applicants

FROST BROWN TODD LLC  
120 West Spring Street, Suite 400  
New Albany, IN 47150  
Phone: 502-568-0361  
Fax: 502-581-1087

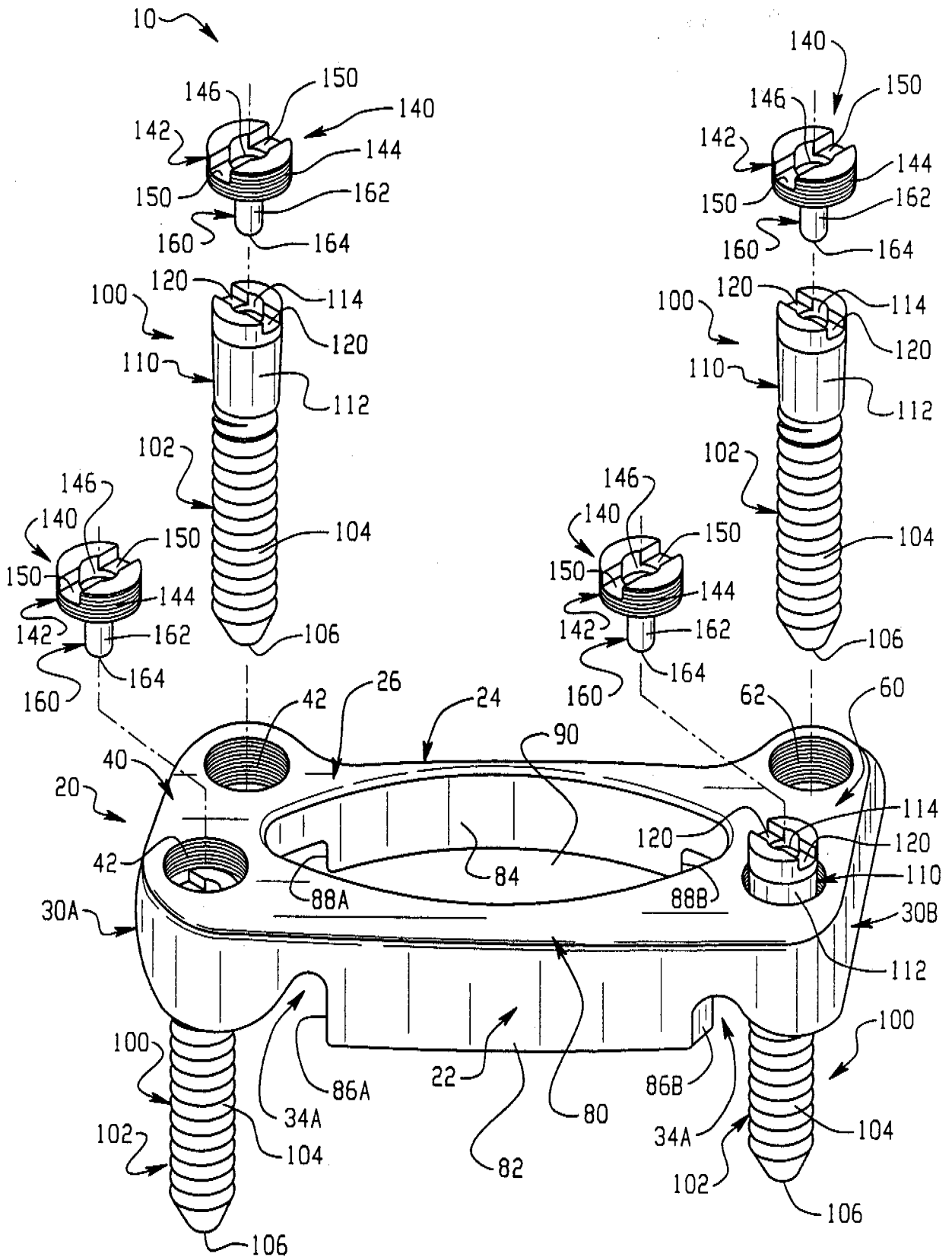
**Rule 1.10 Certificate of Express Mailing**

I hereby certify that this Letter to Draftsperson Pursuant to MPEP §608.02(r) and the accompanying drawings 1-18, 19A-19E, 20, 21A-21E, and 22-25 are being deposited with the United States Postal Service with sufficient postage paid for Express Mail "Post Office to Addressee" in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on the date indicated below.

Ellen L. Crandall (Depositor's Name) Ellen L. Crandall (Signature)  
March 13, 2001 (Date)

09337.114120  
NWAIMDMS/140.1

**6228085**



*Fig. 1*



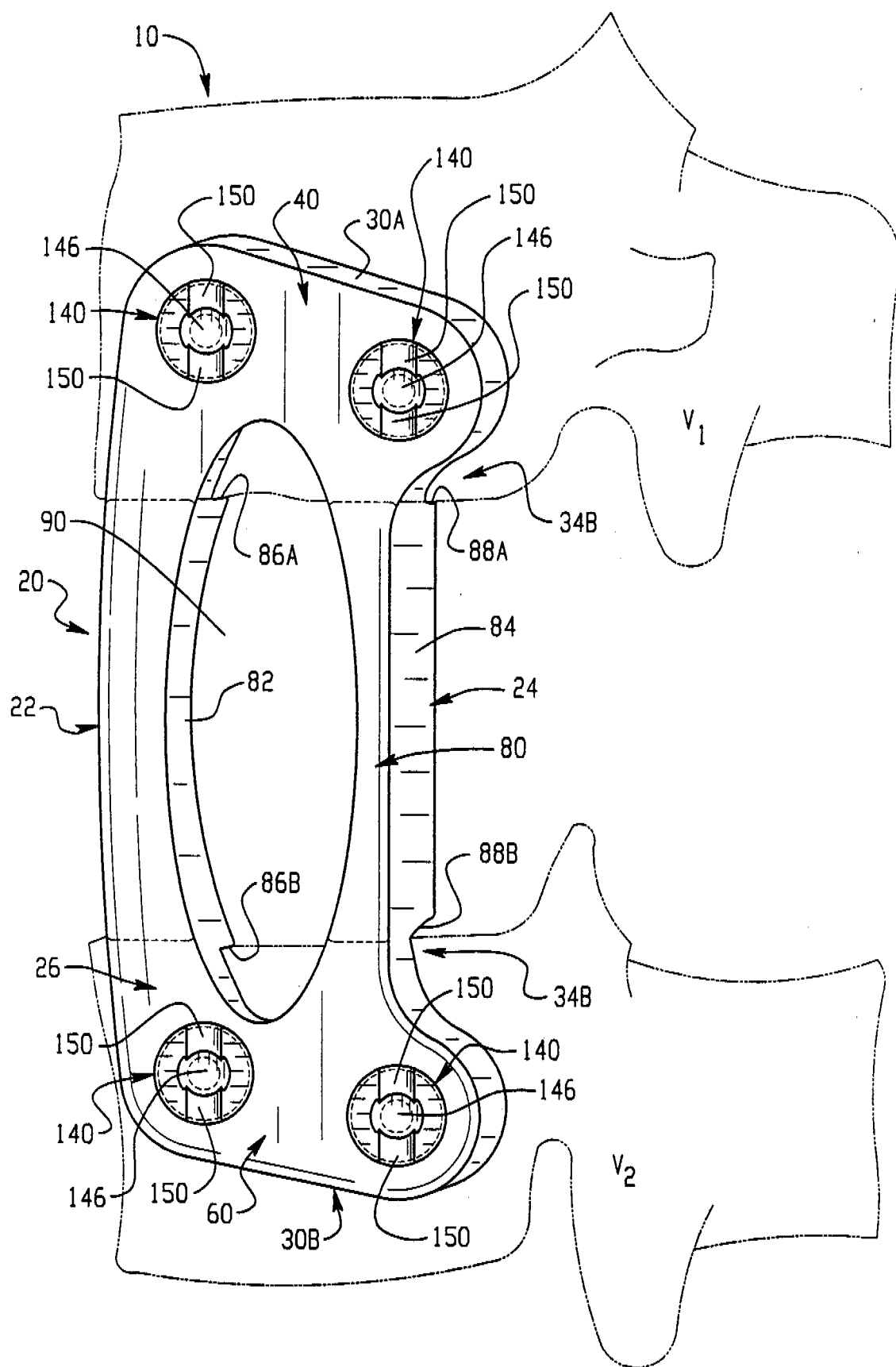


Fig. 3



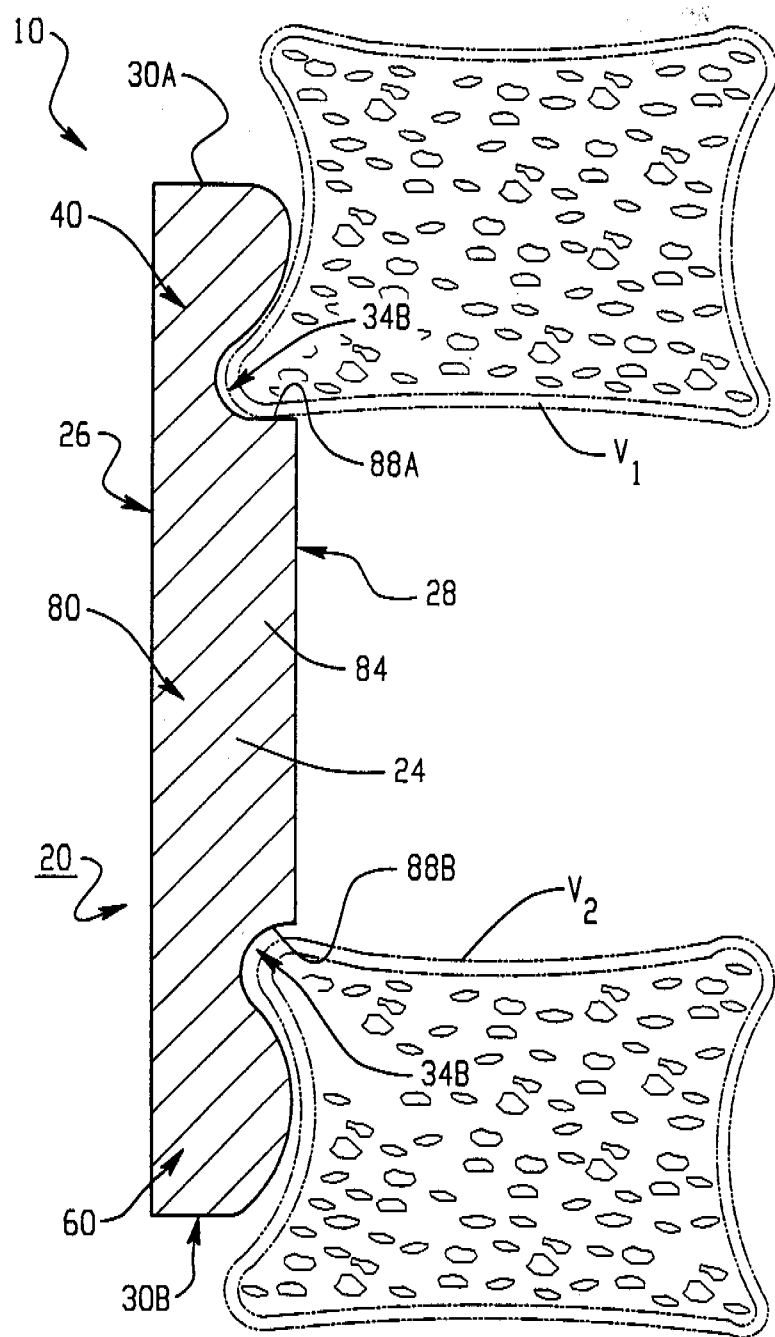


Fig. 4

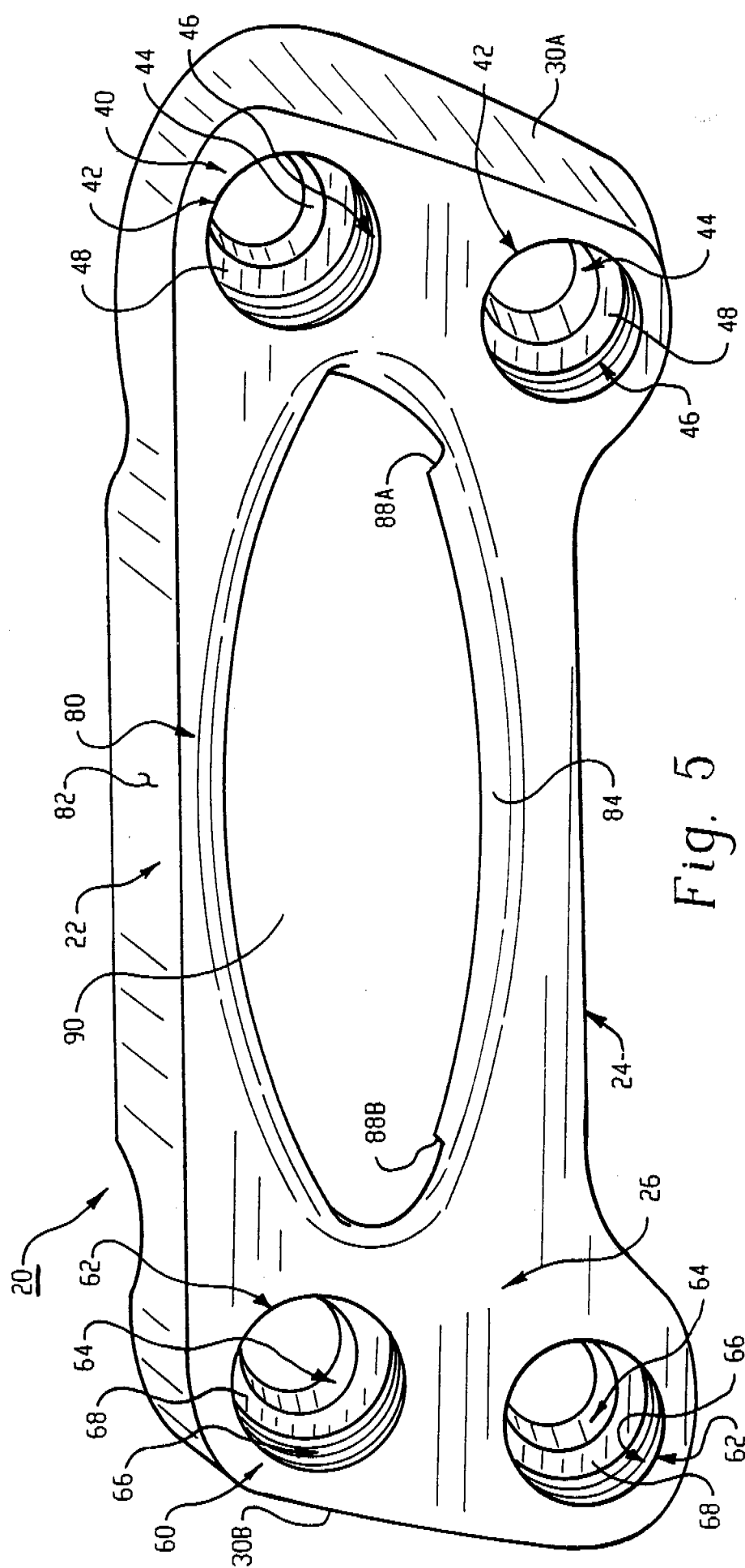


Fig. 5

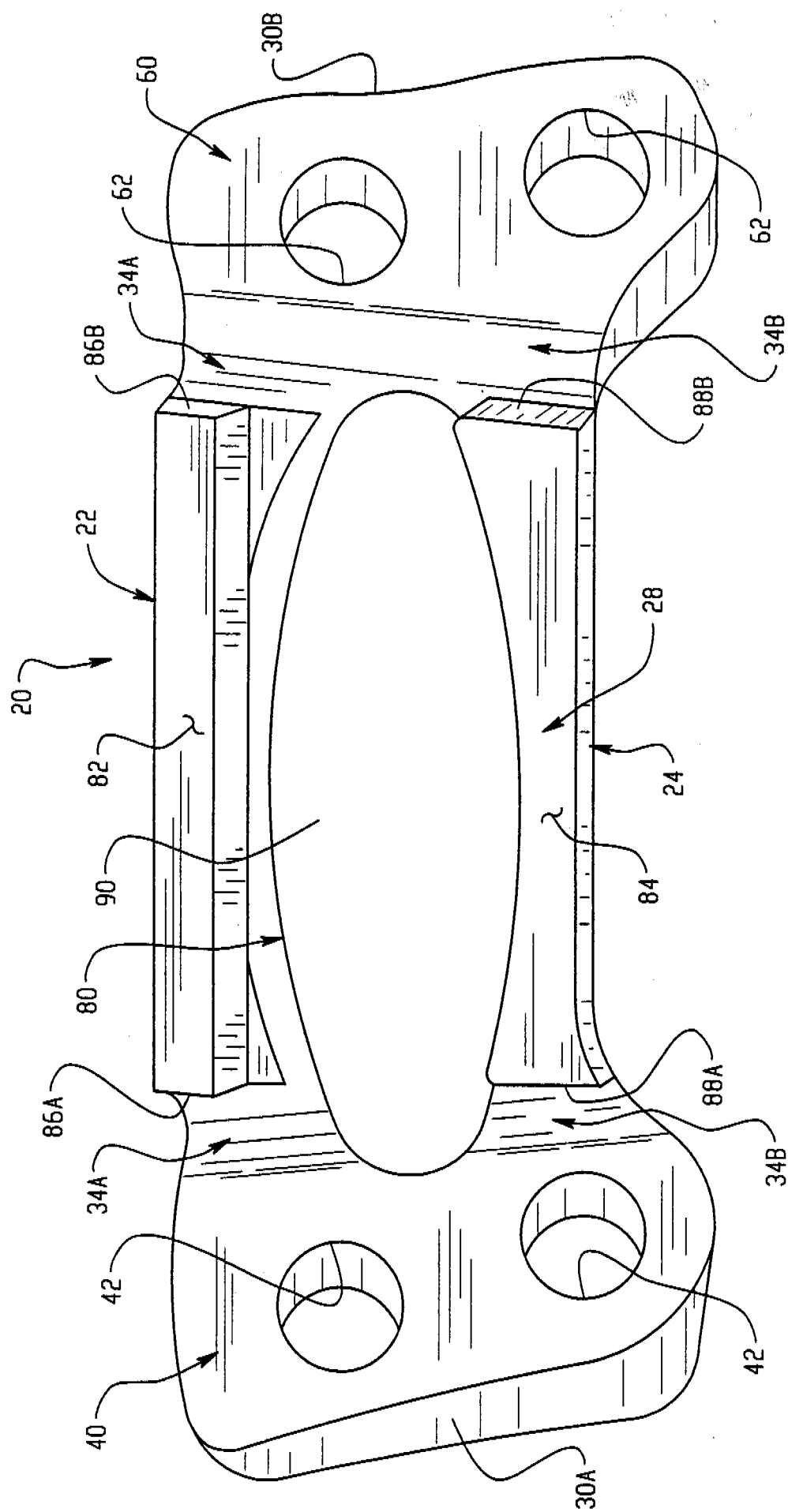


Fig. 6

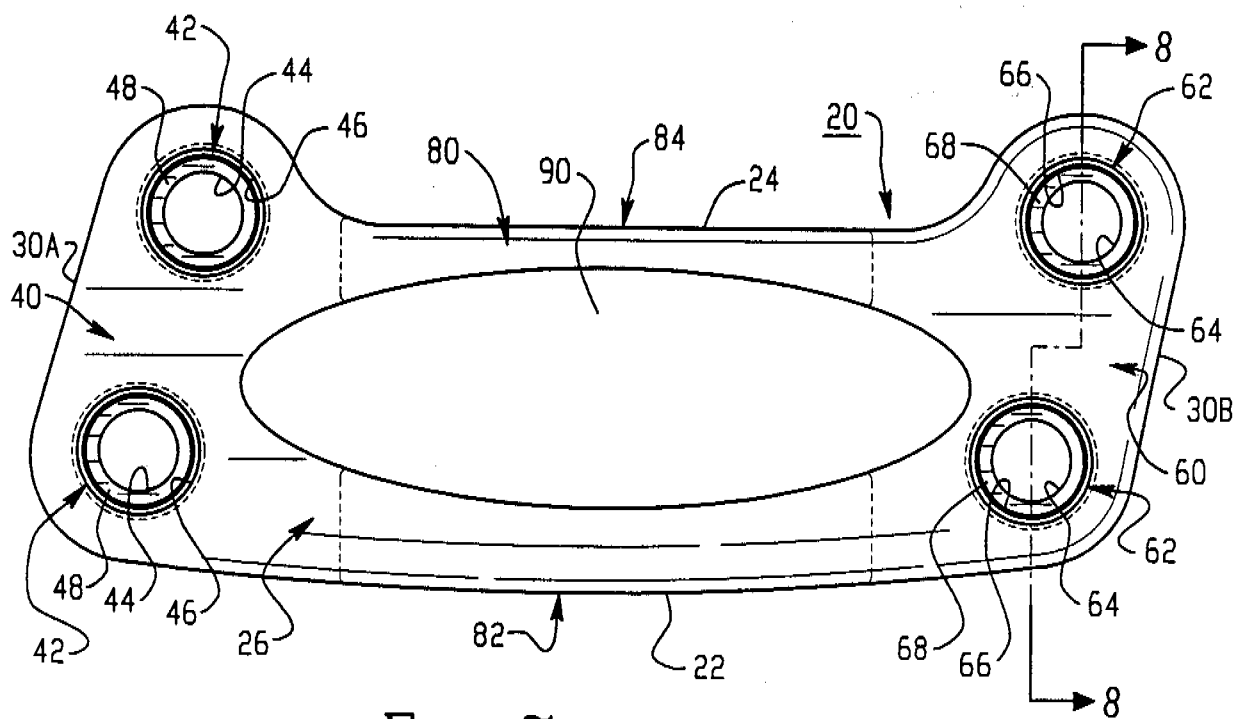


Fig. 7

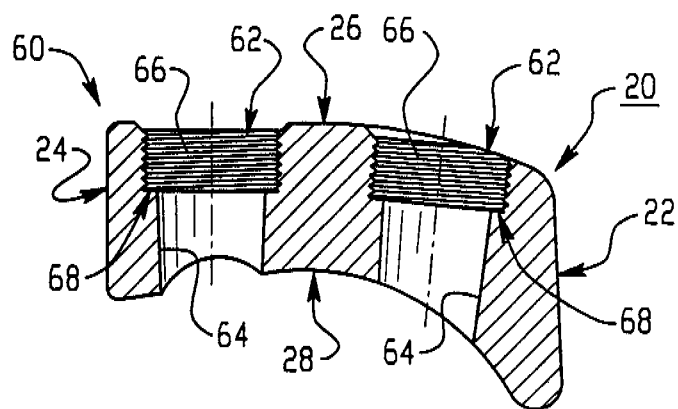


Fig. 8

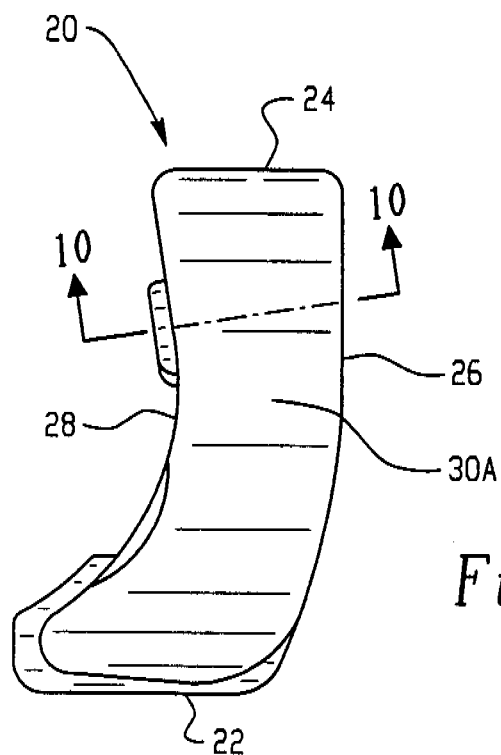
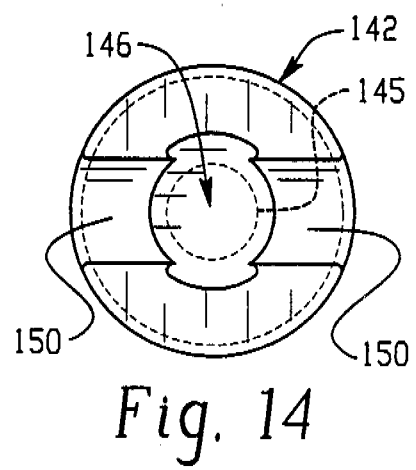
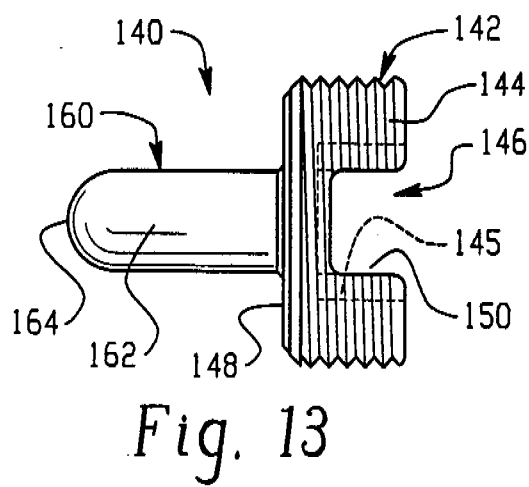
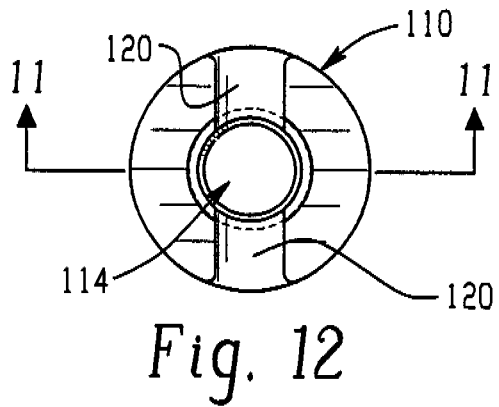
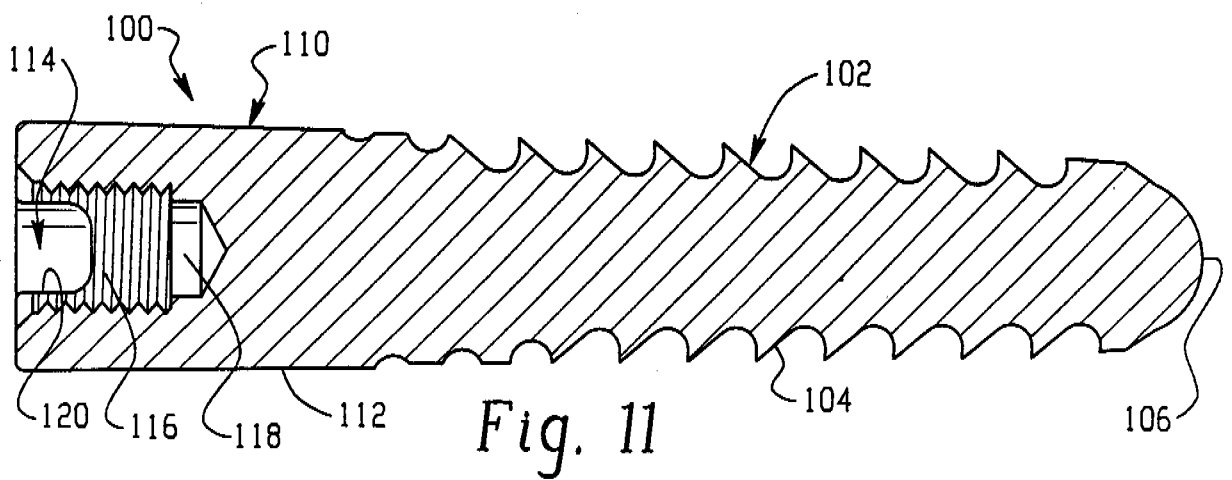
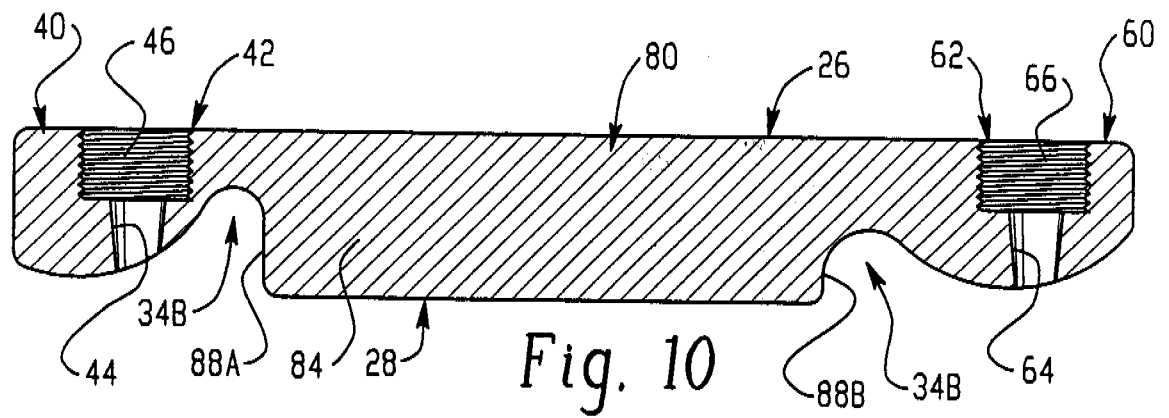


Fig. 9



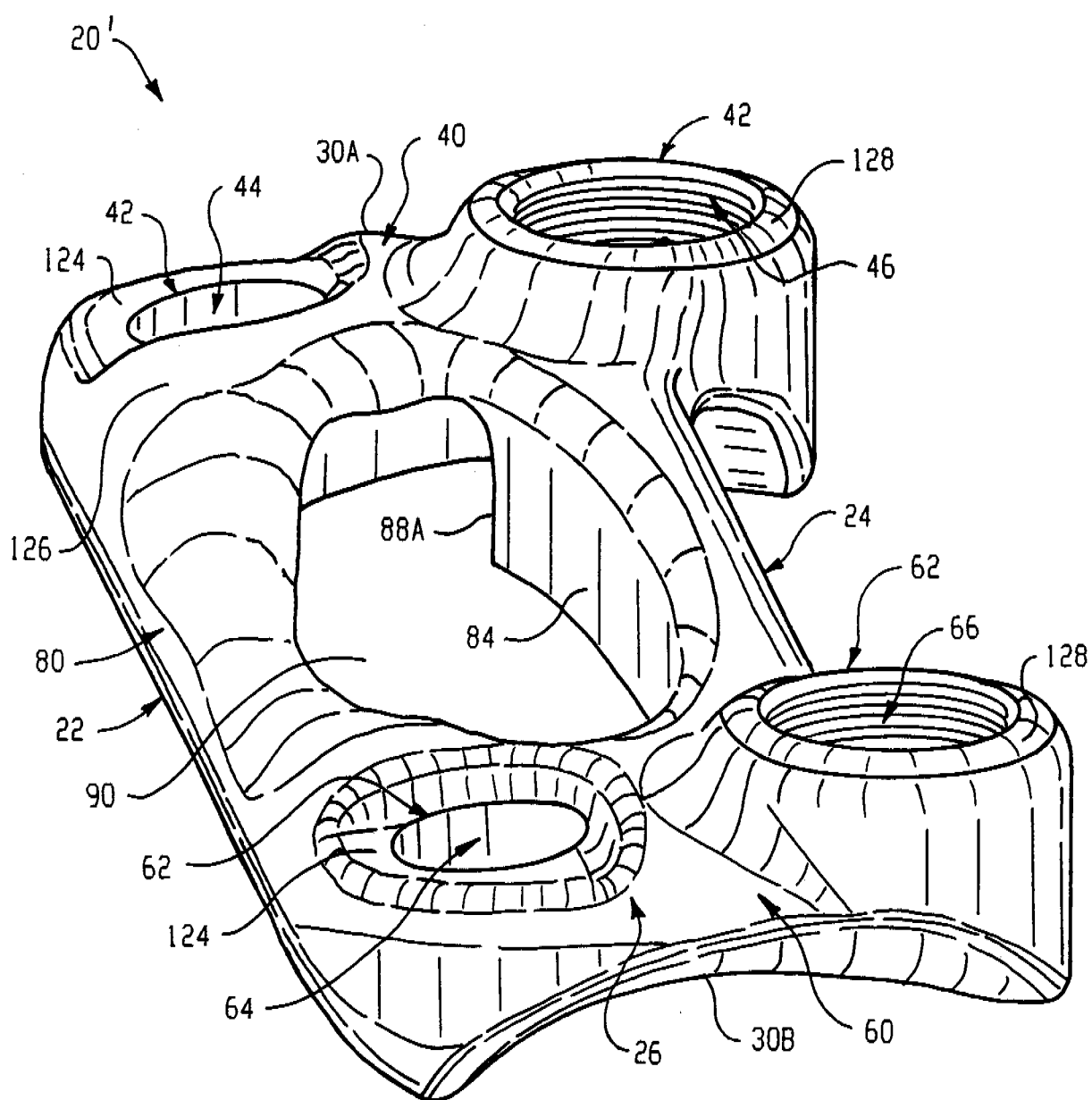


Fig. 15

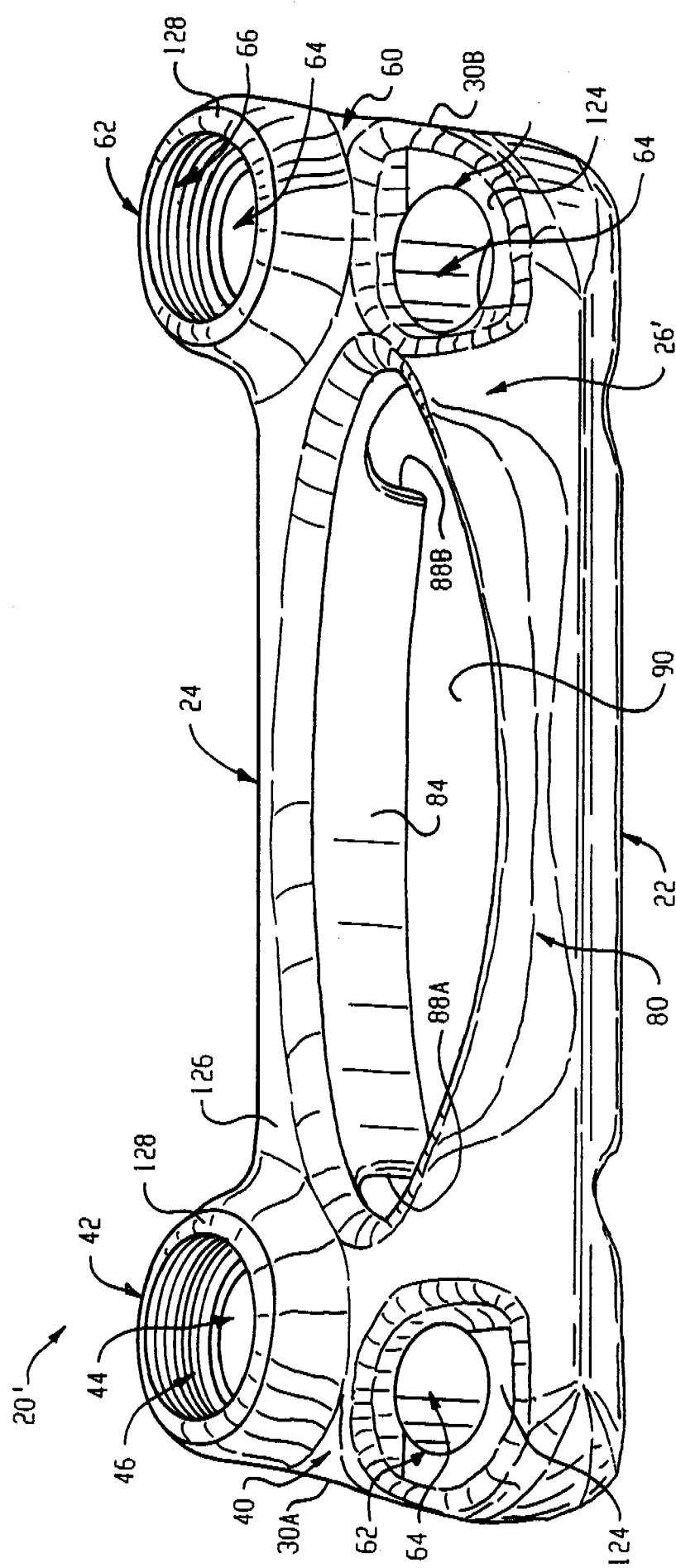


Fig. 16

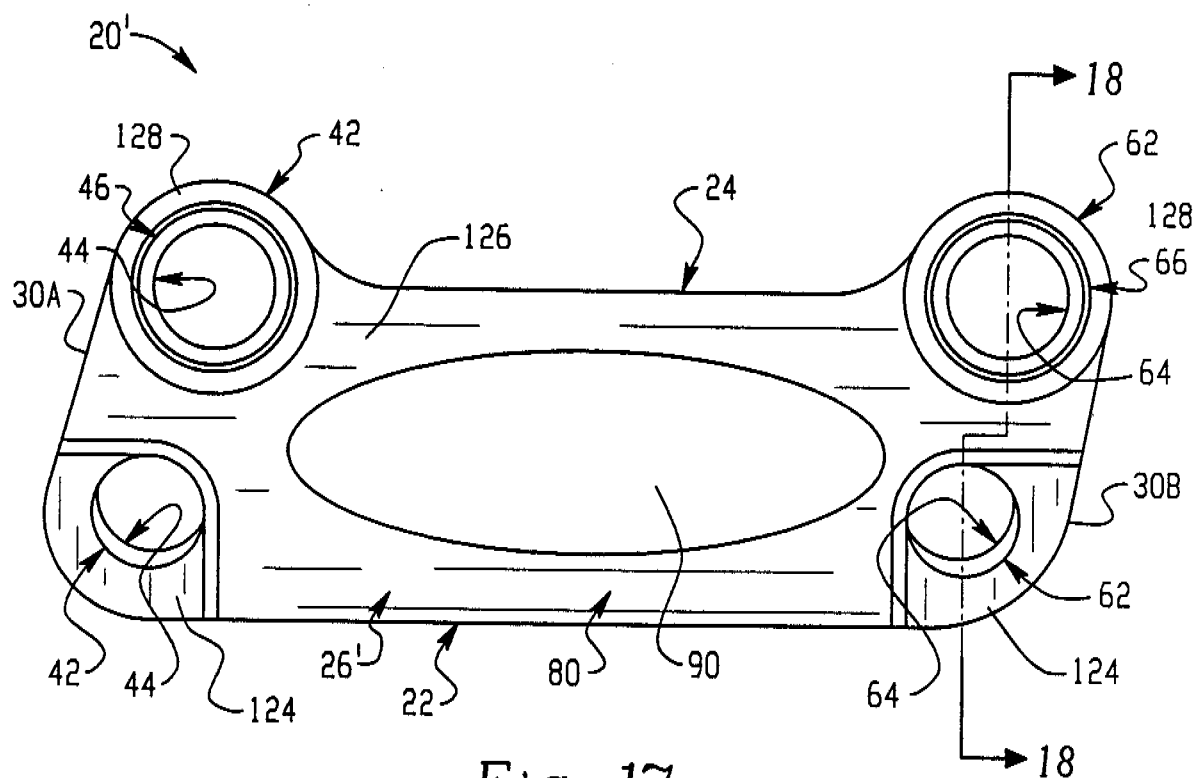


Fig. 17

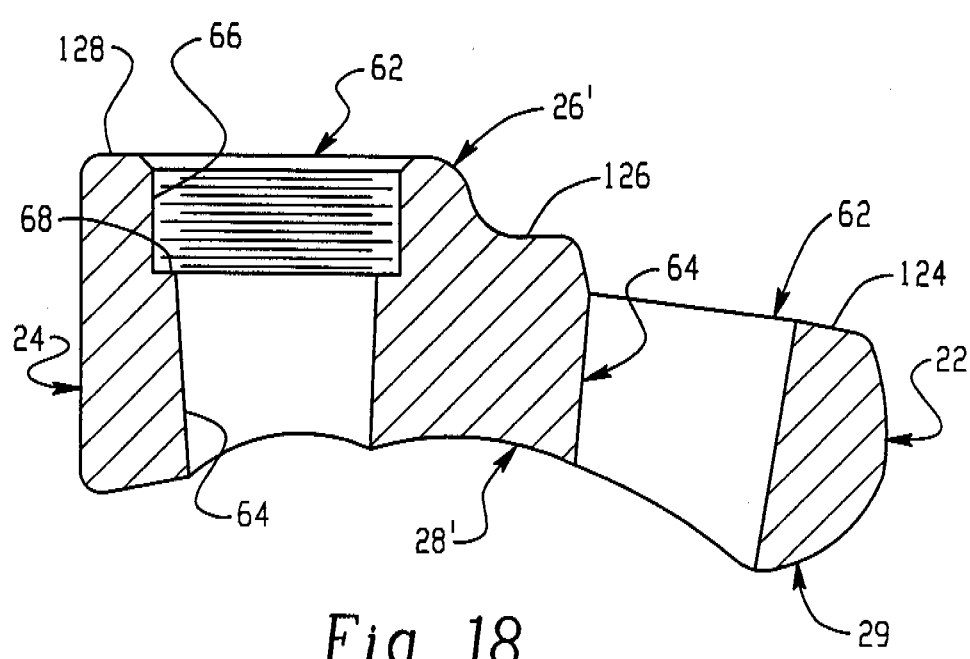


Fig. 18



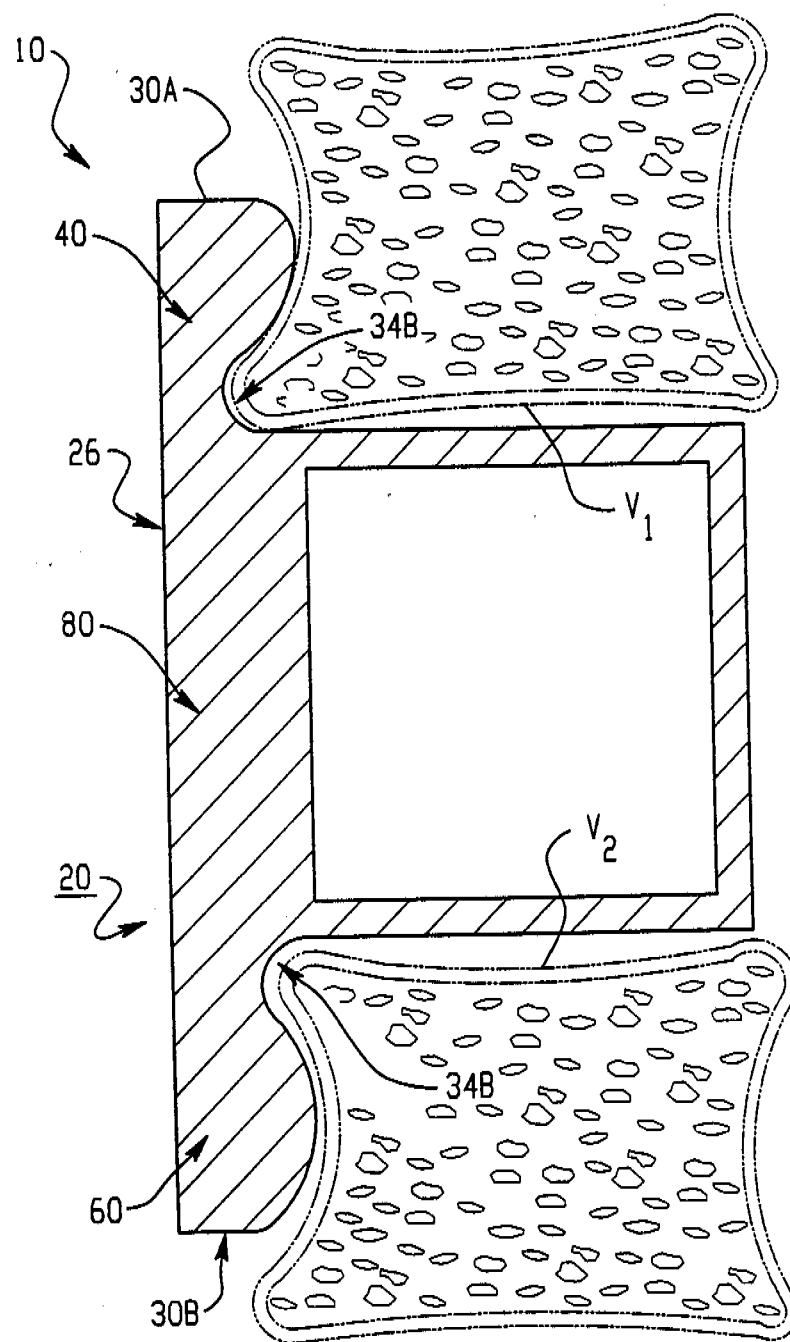


Fig. 19A

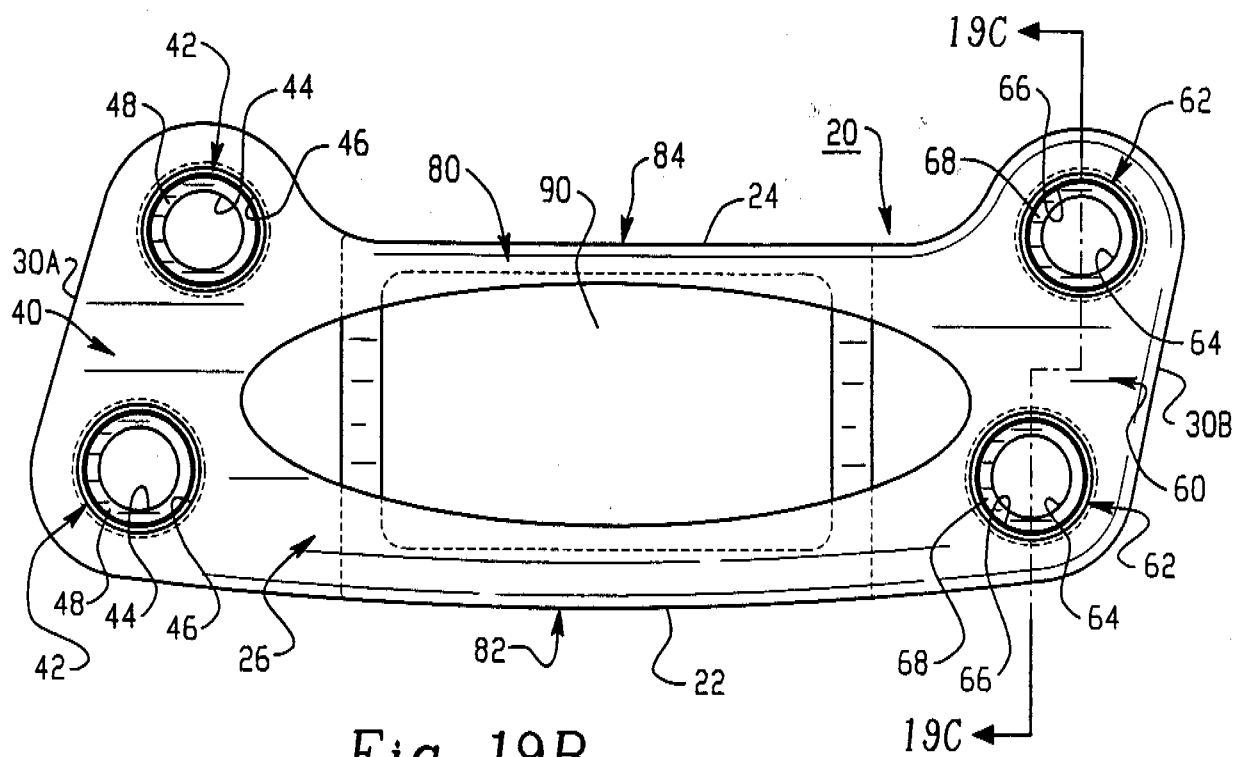


Fig. 19B

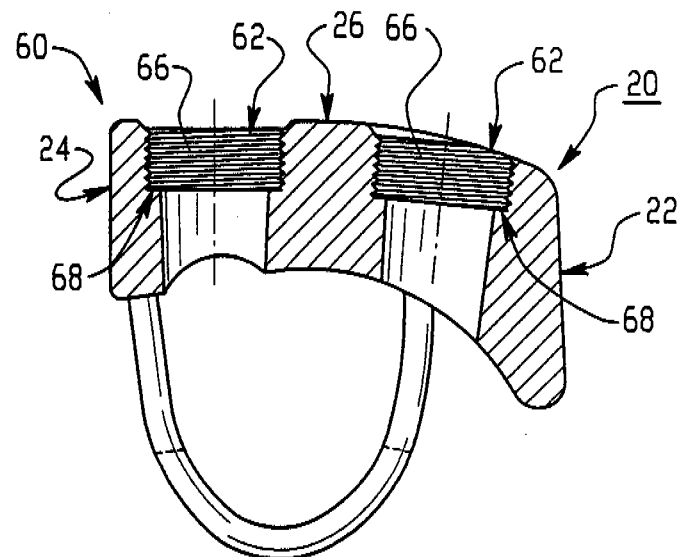


Fig. 19C

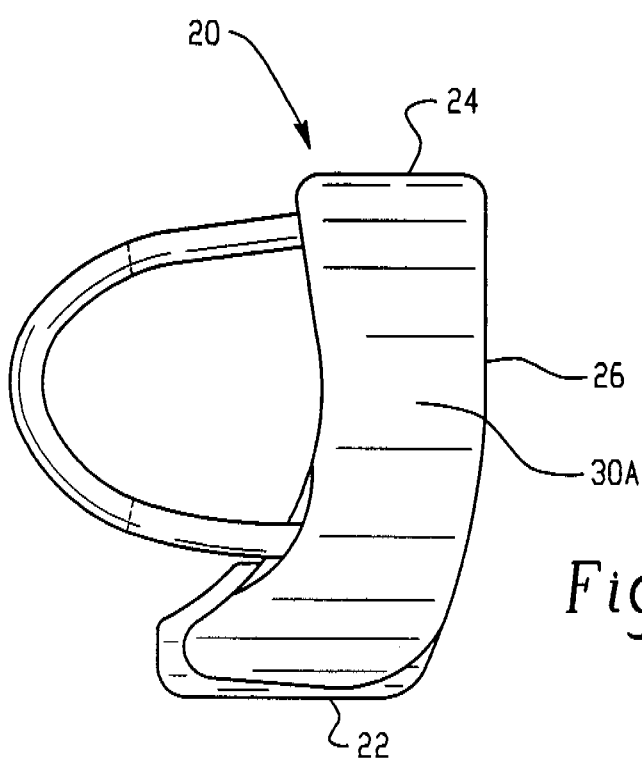


Fig. 19D

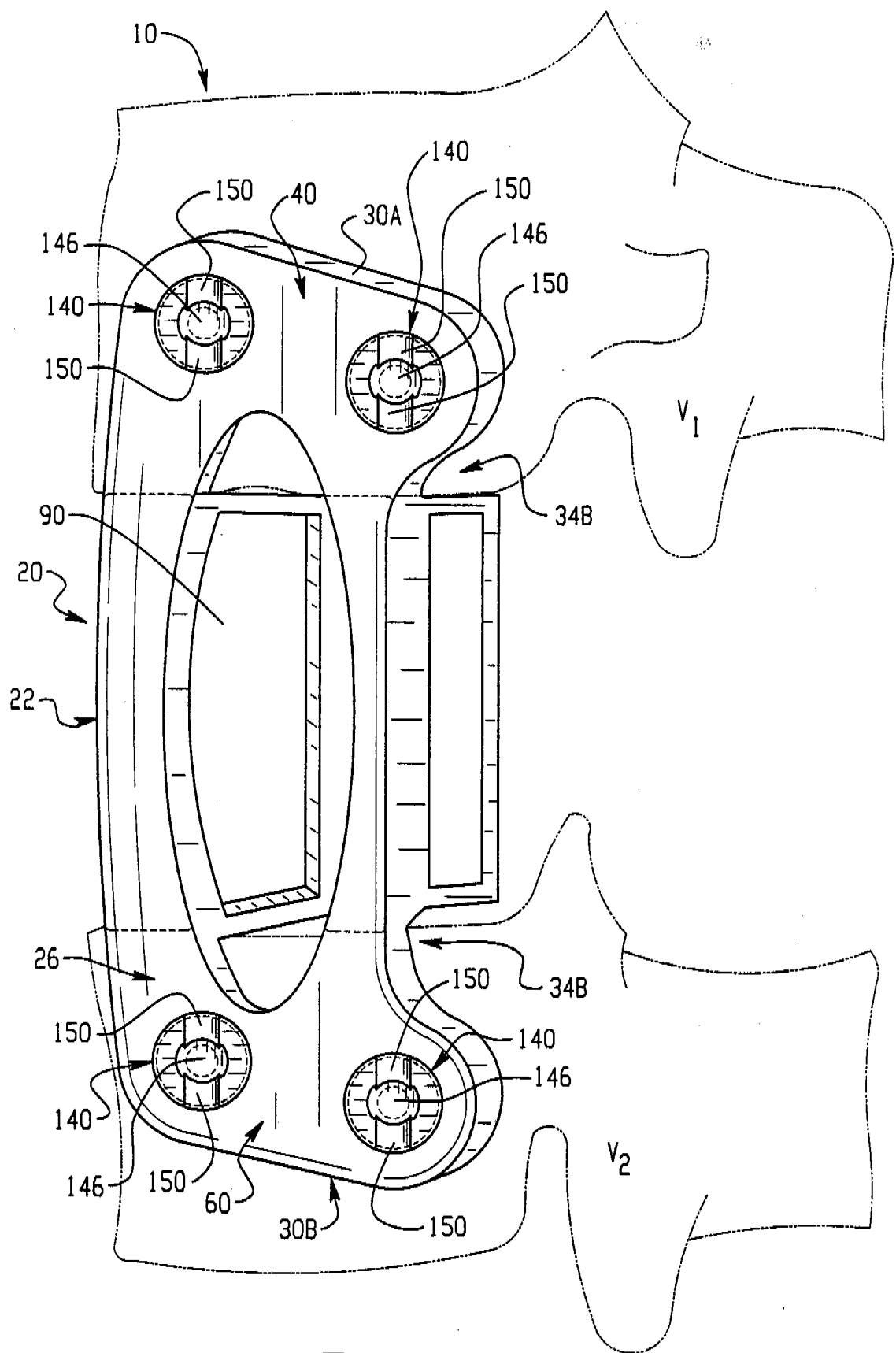


Fig. 19E

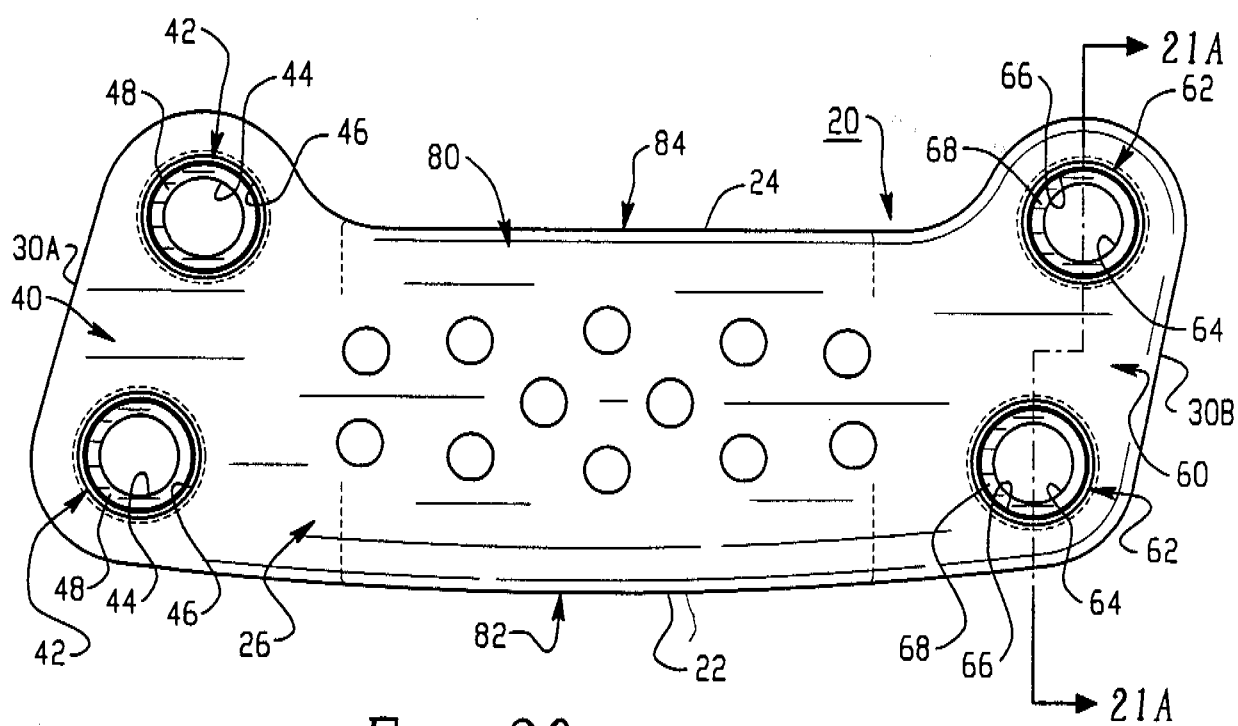


Fig. 20

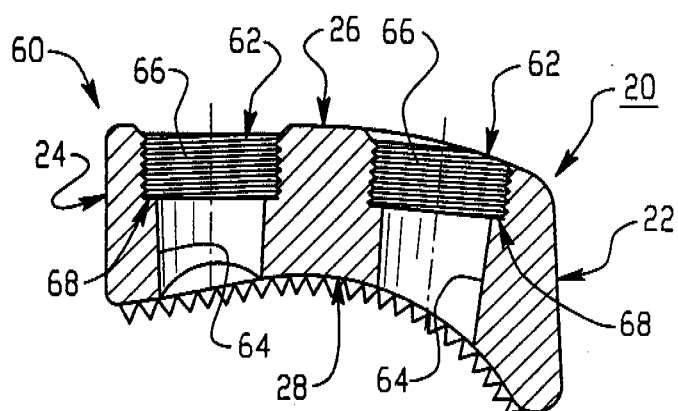


Fig. 21A

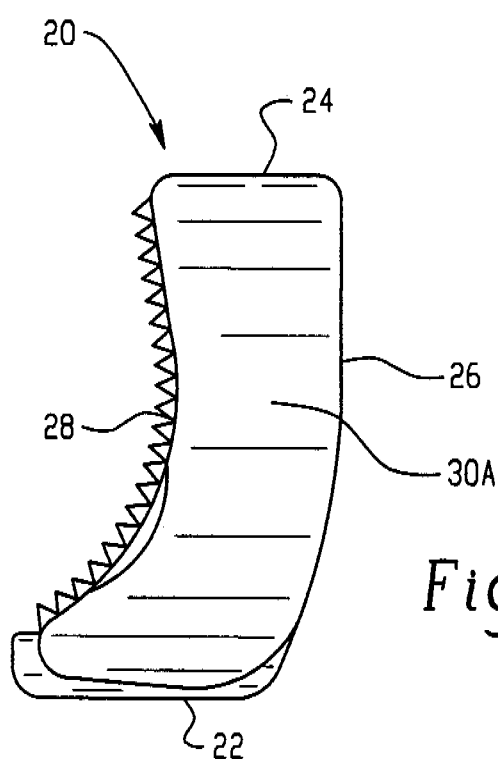


Fig. 21B

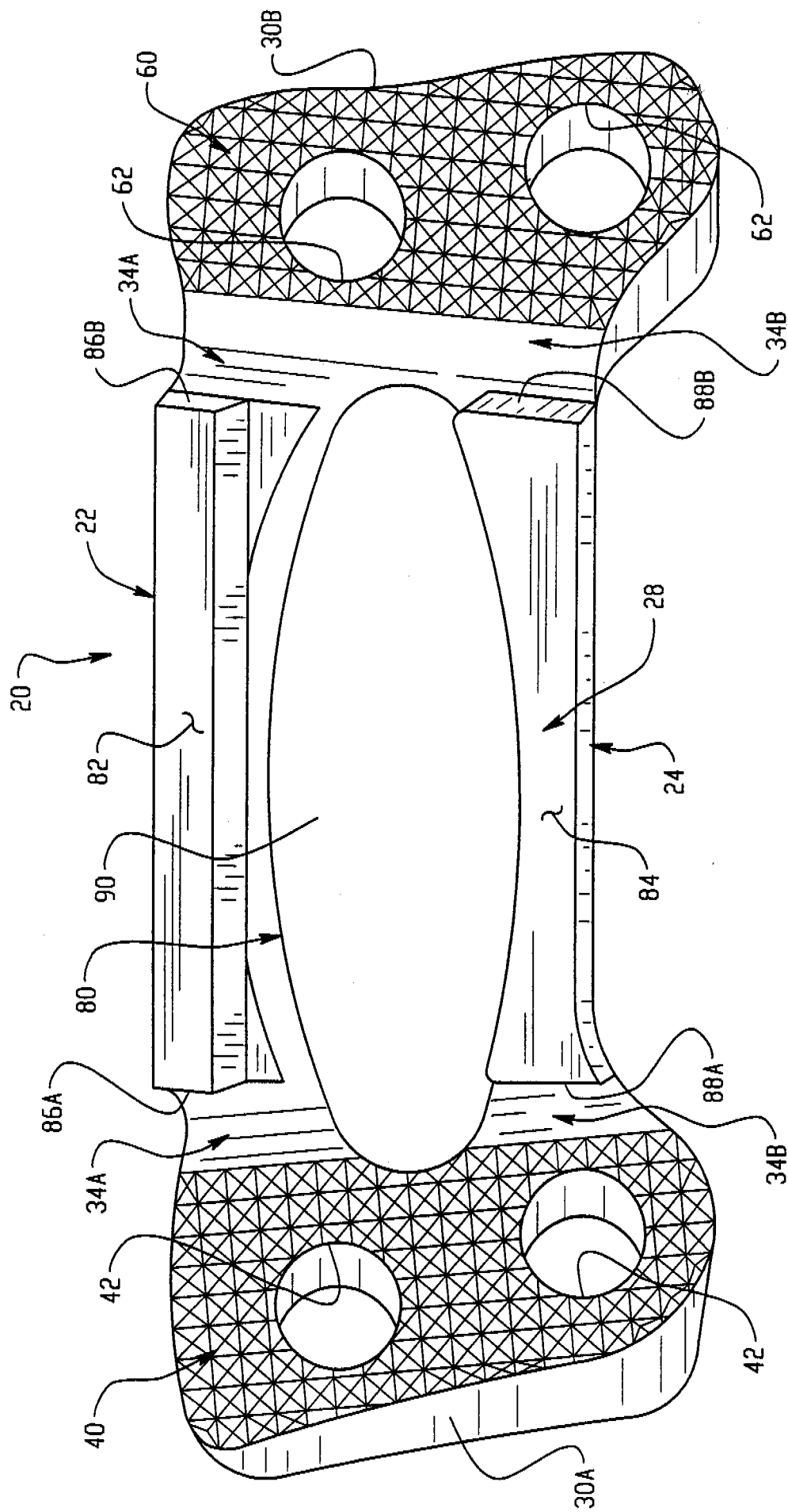


Fig. 21C

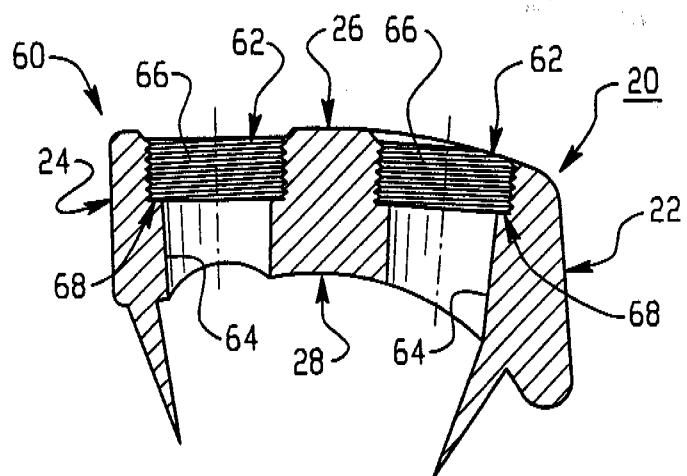


Fig. 21D

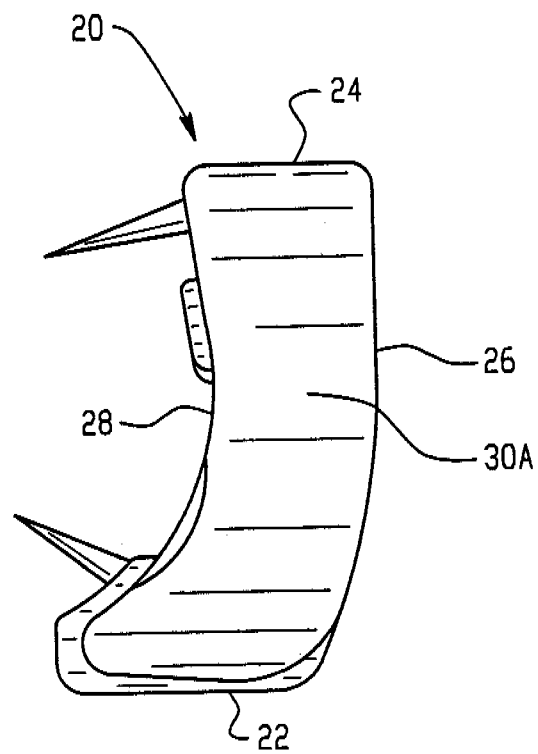


Fig. 21E

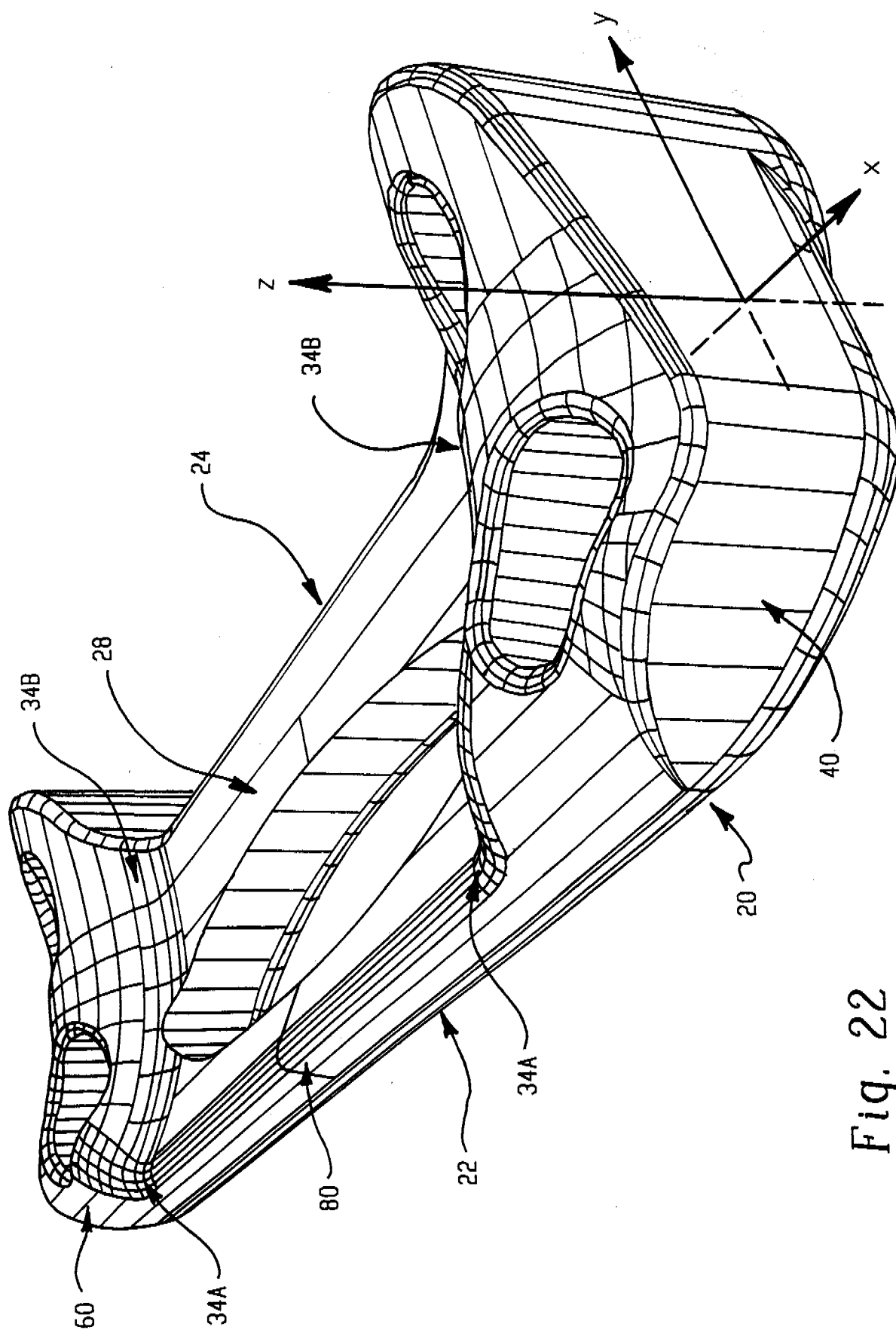


Fig. 22

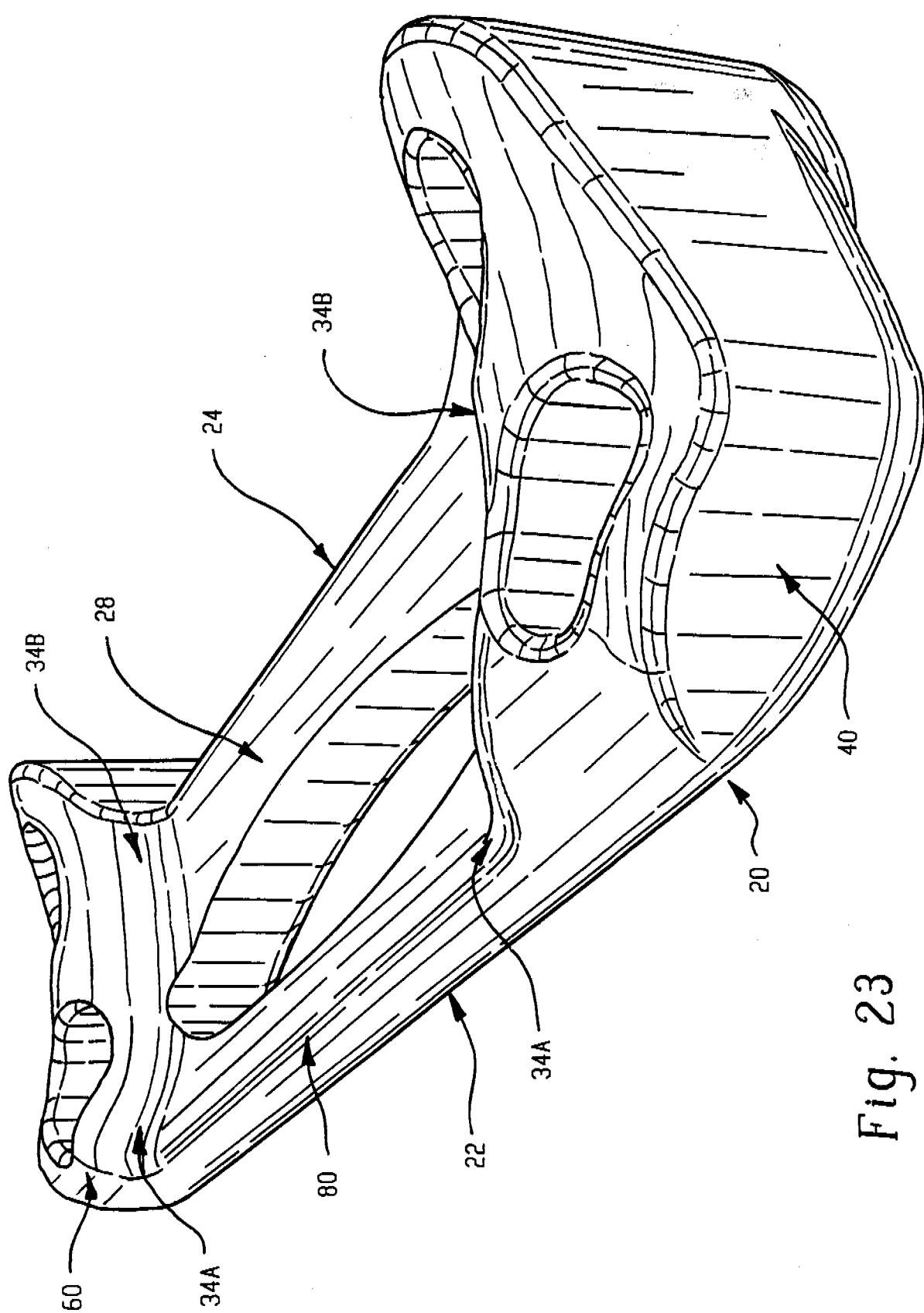


Fig. 23



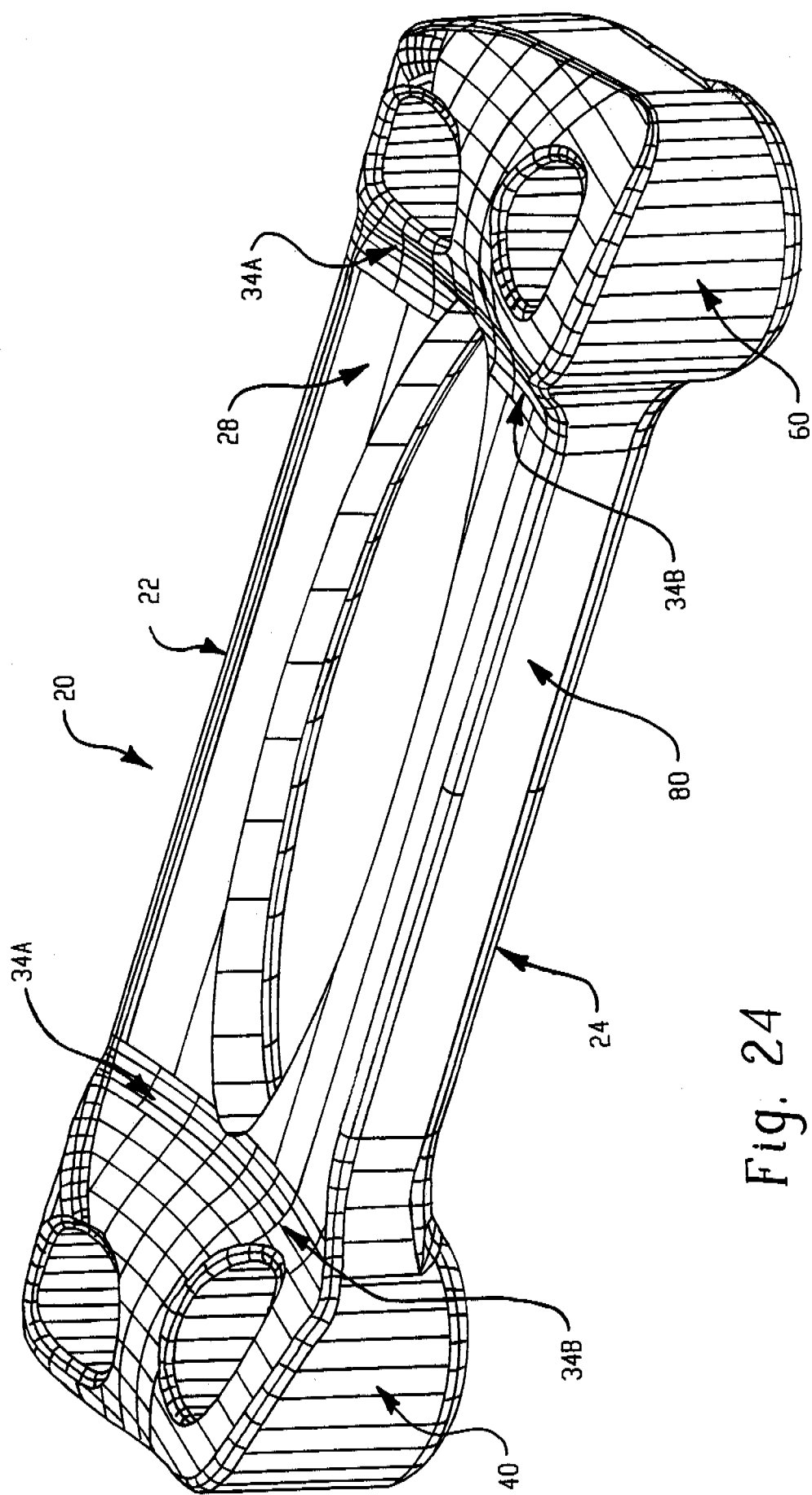


Fig. 24

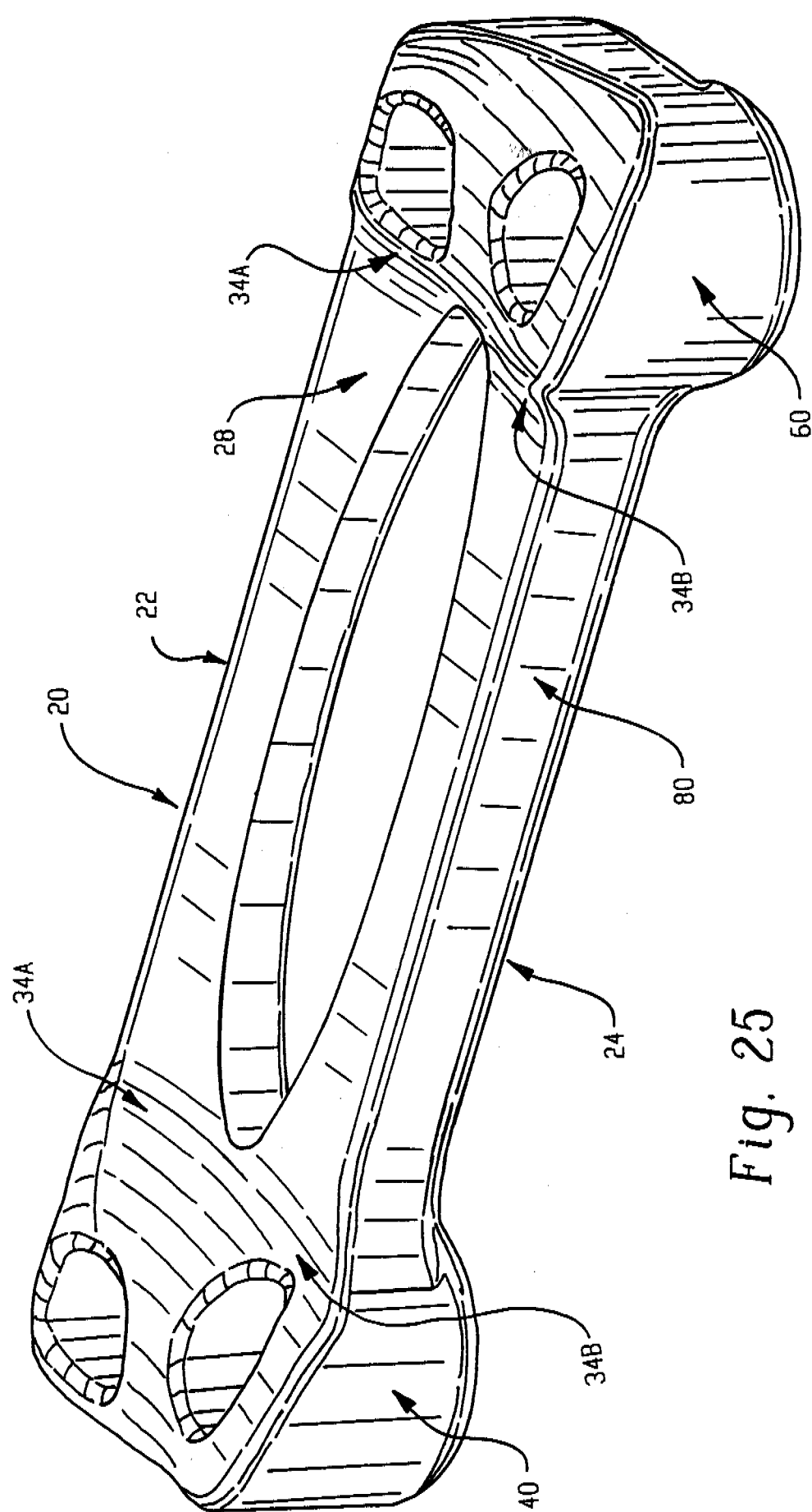


Fig. 25

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# B

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(Date)

APPLICATION NO.	FILING DATE	TOTAL CHARGE	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/114,996	07/14/98	033	ROBERT, E	3732 12/13/00
First Named Applicant	THEKEN, 35 USC 154(b) term ext. = 0 Days.			

**TITLE OF INVENTION** BONE FIXATION SYSTEM

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 23724-3	606-061.000	W31	UTILITY	YES	\$620.00	03/13/01

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the name of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Frost Brown Todd LLC

2 Robert H. Eichenberger

3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type). PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

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(B) RESIDENCE (CITY & STATE OR COUNTRY) Barborton, Ohio

Please check the appropriate assignee category indicated below (will not be printed on the patent)

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*Robert H. Eichenberger* 42,509 (Date) 03/13/01  
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Fax #703-872-9306

FROM: Robert Eichenberger, Reg. No. 42,509

DATE: November 24, 2004

PAGES: 4 in total (including cover sheet)

RE: U.S. Patent No. 6,228,085

Remarks: This facsimile is a request for Revocation of Power,  
New Appointment of Power of Attorney and Change of  
Correspondence.

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- (2) Forms: PTO/SB/82 and PTO/SB/96.

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Diane M. Miles, Paralegal  
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*Diane M. Miles*  
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11/24/04  
Date

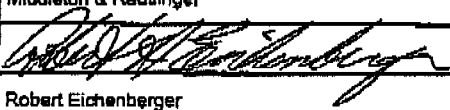
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/14,896 (6,228,085)	
	Filing Date	07/14/1999 (05/08/2001)	
	First Named Inventor	Eisemann	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	3	Attorney Docket Number	08337.114120

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input checked="" type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below): <b>Statement Under 37 CFR 3.73(b)</b>
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Middletton & Reutlinger		
Signature			
Printed name	Robert Eichenberger		
Date	November 24, 2004	Reg. No.	42,509

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Signature			
Typed or printed name	Diane M. Miles	Date	Nov. 24, 2004

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<b>REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS</b>	Application Number	09/114,996 (6,228,095)
	Filing Date	07/14/98 (05/08/2001)
	First Named Inventor	Eisemann
	Art Unit	
	Examiner Name	
	Attorney Docket Number	09337.114120

I hereby revoke all previous powers of attorney given in the above-identified application.

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OR

☒ I hereby appoint the practitioners associated with the Customer Number:

27868

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I am the:

☐ Applicant/Inventor.☒ Assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature			
Name	Randy The Ken		
Date	11/19/04	Telephone	330-753-9923

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ \*Total of \_\_\_\_\_ forms are submitted.

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**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Elsomann et al.Application No./Patent No.: 6,228,085 Filed/Issue Date: issued: 5/8/2001Entitled: Bone Fixation SystemTHEKEN SURGICAL LLC

(Name of Assignee)

a Limited Liability Company

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.  
The extent (by percentage) of its ownership interest is \_\_\_\_\_ %

in the patent application/patent identified above by virtue of either:

- A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

[Signature]

Signature

Randy Theken

Printed or Typed Name

Manager

Title

11/19/04

Date

330-753-9923

Telephone Number

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Fax #703-872-9306

FROM: Robert Eichenberger, Reg. No. 42,509

DATE: November 29, 2004

PAGES: 4 in total (including cover sheet)

RE: U.S. Patent No. 6,228,085 ✓

Remarks: This facsimile is a request for Revocation of Power,  
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- (2) Forms: PTO/SB/82 and PTO/SB/96.

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Diane M. Miles, Paralegal  
Person Signing

Diane M. Miles  
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002/004

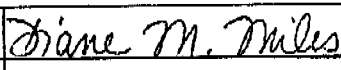
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/114,996 (6,228,085)
	Filing Date	07/14/1928 (05/09/2001)
	First Named Inventor	Eisemann
	Art Unit	
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	08337.114120

ENCLOSURES (Check all that apply)		
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Remarks		

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Firm Name	Middleton & Reutlinger		
Signature			
Printed name	Robert Eichenberger		
Date	November 29, 2004	Reg. No.	42,509

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Typed or printed name	Diane M. Miles	Date	November 29, 2004

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Application Number	09/114,996 (6,228,085)
Filing Date	07/14/98 (05/08/2001)
First Named Inventor	Eisermann
Art Unit	
Examiner Name	
Attorney Docket Number	09337.114120

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OR

☒ I hereby appoint the practitioners associated with the Customer Number:

27868

☒ Please change the correspondence address for the above-identified application to:

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OR

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Individual Name

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City

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Zip

Country

Telephone

Fax

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature

Name

Randy The Ken

Date

11/19/04

Telephone

330-753-9923

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

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**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Eisemann et al.Application No./Patent No.: 6,228,085 Filed/Issue Date: Issued: 5/8/2001Entitled: Bone Fixation SystemTHEKEN SURGICAL, LLC

(Name of Assignee)

a Limited Liability Company

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

[Signature]

Signature

Randy Theken

Printed or Typed Name

Manager

Title

11/19/04

Date

330-753-9923

Telephone Number

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Patent Number Information

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Patent Number Information

Application Number: **09/114996** [Order This](#) [File Assignments](#) Examiner Number: **74012 / ROBERT, EDUARDO**  
 Filing Date: **07/14/1998** Group Art Unit: **3732**  
 Effective Date: **07/14/1998** Class/Subclass: **606/061.000**  
 Application Received: **07/14/1998** Lost Case: **NO**  
 Patent Number: **6228085** Interference Number:  
 Issue Date: **05/08/2001** Unmatched Petition: **NO**  
 Date of Abandonment: **00/00/0000** L&R Code: **Secrecy**  
 Attorney Docket Number: **23724-3** Code: **1**  
 Status: **150 / PATENTED CASE** Third Level Review: **NO** Secrecy Order: **NO**  
 Confirmation Number: **9886** Status Date: **04/20/2001**  
 Title of Invention: **BONE FIXATION SYSTEM** Oral Hearing: **NO**

Bar Code	PALM Location	Location Date	Charge to Loc	Charge to Name	Employee Name	Location
09114996	9200	11/02/2001	No Charge to Location	No Charge to Name	LOE CONV DR1995U	

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/114,996	07/14/1998	RANDALL R. THEKEN	23724-3

27868  
 JOHN F. SALAZAR  
 MIDDLETON & REUTLINGER  
 2500 BROWN & WILLIAMSON TOWER  
 LOUISVILLE, KY 40202

CONFIRMATION NO. 9886



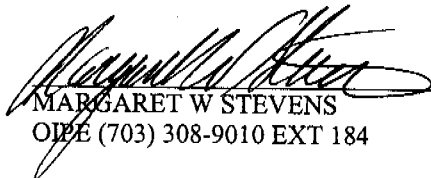
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Date Mailed: 10/02/2006

## NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/24/2004.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

  
 MARGARET W STEVENS  
 OPE (703) 308-9010 EXT 184

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/114,996	07/14/1998	RANDALL R. THEKEN	23724-3

ROBERT H. EICHENBERGER  
120 WEST SPRING STREET  
SUITE 400  
NEW ALBANY, IN 47150

CONFIRMATION NO. 9886



\*OC000000020654205\*

Date Mailed: 10/02/2006

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/24/2004.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

MARGARET W STEVENS  
OIPE (703) 308-9010 EXT 184

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# **PATENT APPLICATION FEE DETERMINATION RECORD**

Effective October 1, 1997

Application or Docket Number

09/114996

## **CLAIMS AS FILED - PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	36 minus 20 = *	16
INDEPENDENT CLAIMS	3 minus 3 = *	
MULTIPLE DEPENDENT CLAIM PRESENT		

\* If the difference in column 1 is less than zero, enter "0" in column 2

**SMALL ENTITY TYPE** ☐

OR

**OTHER THAN SMALL ENTITY**

RATE	FEE		RATE	FEE
	395.00	OR		790.00
x\$11=	176	OR	x\$22=	
x41=	/	OR	x82=	
+135=	/	OR	+270=	
TOTAL	571	OR	TOTAL	

## **CLAIMS AS AMENDED - PART II**

(Column 1)

(Column 2)

(Column 3)

**SMALL ENTITY**

OR

**OTHER THAN SMALL ENTITY**

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
x\$11=		OR	x\$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

**AMENDMENT A**

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

**AMENDMENT B**

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

**AMENDMENT C**

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."  
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.



**United States  
Patent and  
Trademark Office**

Patent Bibliographic Data				11/12/2008 11:16 AM	
Patent Number:	6228085		Application Number:	09114996	
Issue Date:	05/08/2001		Filing Date:	07/14/1998	
Title:	BONE FIXATION SYSTEM				
Status:	12th year fee window opens: 05/08/2012			Entity:	Large
Window Opens:	05/08/2012	Surcharge Date:	11/09/2012	Expiration:	N/A
Fee Amt Due:	Window not open	Surchg Amt Due:	Window not open	Total Amt Due:	Window not open
Fee Code:	1553	MAINTENANCE FEE DUE AT 11.5 YEARS			
Surcharge Fee Code:					
Most recent events (up to 7):	11/05/2008 11/04/2008 06/24/2004	Pat Hldr no Longer Claims Small Ent Stat Payment of Maintenance Fee, 8th Year, Large Entity. Payment of Maintenance Fee, 4th Yr, Small Entity. --- End of Maintenance History ---			
Address for fee purposes:	JOHN F. SALAZAR MIDDLETON & REUTLINGER 2500 BROWN & WILLIAMSON TOWER LOUISVILLE, KY 40202				



# Patent Assignment Abstract of Title

NOTE: Results display only for issued patents and published applications. For pending or abandoned applications please consult USPTO staff.

Total Assignments: 2

Patent #: [6228085](#) Issue Dt: 05/08/2001 Application #: 09114996 Filing Dt: 07/14/1998

Inventors: RANDALL R. THEKEN, LUKAS EISERMANN, BEN TAYLOR

Title: BONE FIXATION SYSTEM

Assignment: 1

Reel/Frame: [009331/0325](#) Recorded: 07/14/1998 Pages: 6

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: [THEKEN, RANDALL R.](#) Exec Dt: 06/30/1998

[EISERMANN, LUKAS](#) Exec Dt: 06/30/1998

[TAYLOR, BEN](#) Exec Dt: 07/09/1998

Assignee: [THEKEN SURGICAL L.L.P.](#)

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Assignment: 2

Reel/Frame: [019166/0475](#) Recorded: 04/16/2007 Pages: 8

Conveyance: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

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Assignee: [THEKEN SPINE, LLC](#)

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LOUISVILLE, KY 40202



US006228085B1

(12) **United States Patent**  
**Theken et al.**

(10) **Patent No.: US 6,228,085 B1**  
(45) **Date of Patent: May 8, 2001**

(54) **BONE FIXATION SYSTEM**

(75) Inventors: **Randall R. Theken**, Barberton; **Lukas Eisermann**, Cleveland, both of OH (US); **Ben Taylor**, Hertfordshire (GB)

(73) Assignee: **Theken Surgical LLC**, Barberton, OH (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/114,996**

(22) Filed: **Jul. 14, 1998**

(51) **Int. Cl.**<sup>7</sup> ..... **A61B 17/56**

(52) **U.S. Cl.** ..... **606/61**

(58) **Field of Search** ..... 606/61, 64, 69, 606/70, 71, 60; 623/17, 17.11, 17.16

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(List continued on next page.)

*Primary Examiner*—Gene Mancene

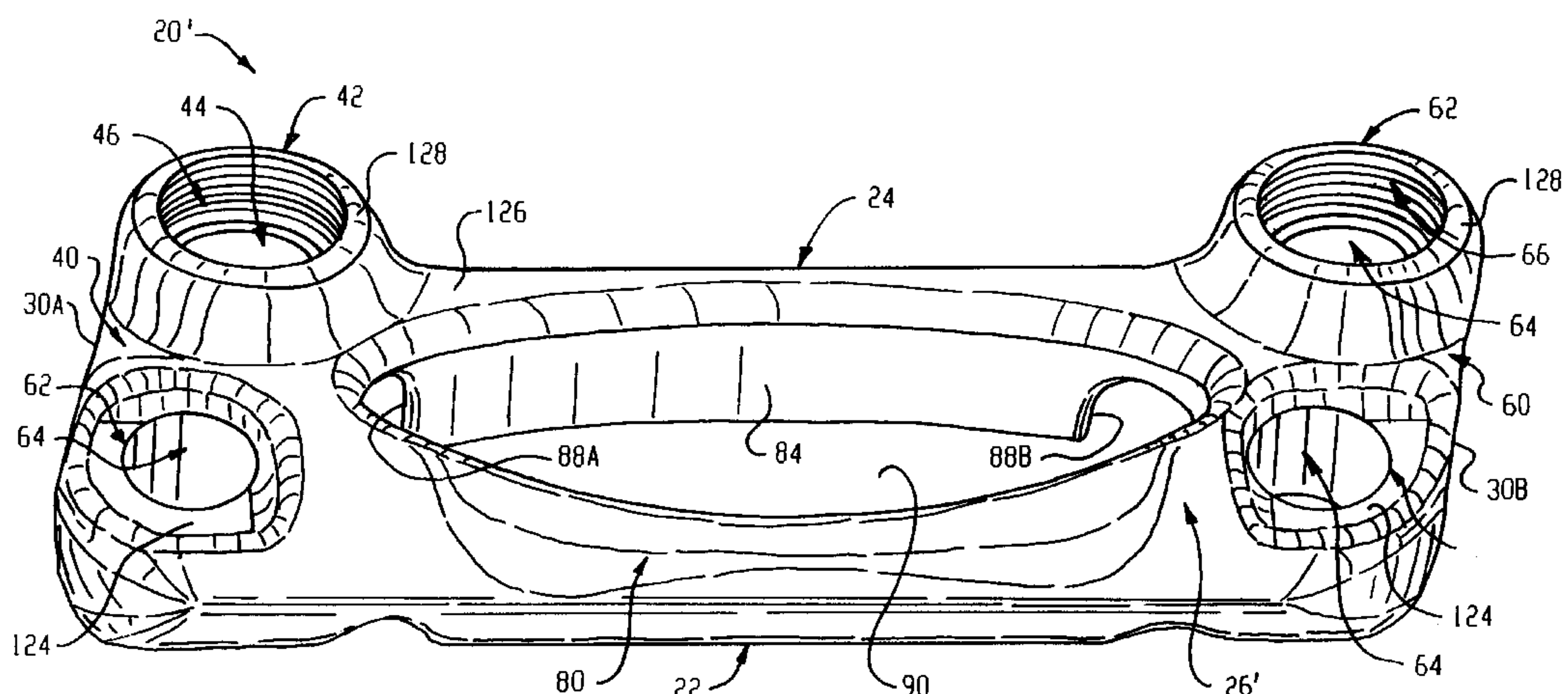
*Assistant Examiner*—Eduardo C. Robert

(74) *Attorney, Agent, or Firm*—Frost Brown Todd LLC; Robert H. Eichenberger

(57) **ABSTRACT**

An internal bone fixation system for the treatment of bone anomalies, such as thoraco-lumbar spinal instability. In accordance with a preferred embodiment, the fixation system includes a plate anatomically contoured to match the profile of lateral aspects common to thoracic and lumbar vertebrae, as well as the anterior profile. The contour of the plate allows for quicker implantation time, a lower profile, and a fit which allows for biomechanical load-sharing which increases the mechanical properties of the construct (i.e., stiffness, strength, and fatigue life). Moreover, the fixation system includes a fastener screw-plate interface which forces proper alignment between fastener screws and the plate, provides “pull-out” resistance and evenly distributes stresses on both the screw and the plate. Ledges are located on the medial surface at either end of the plate. The fixation system also includes set screws which effectively turn the screw construct into a bolt construct.

**33 Claims, 21 Drawing Sheets**



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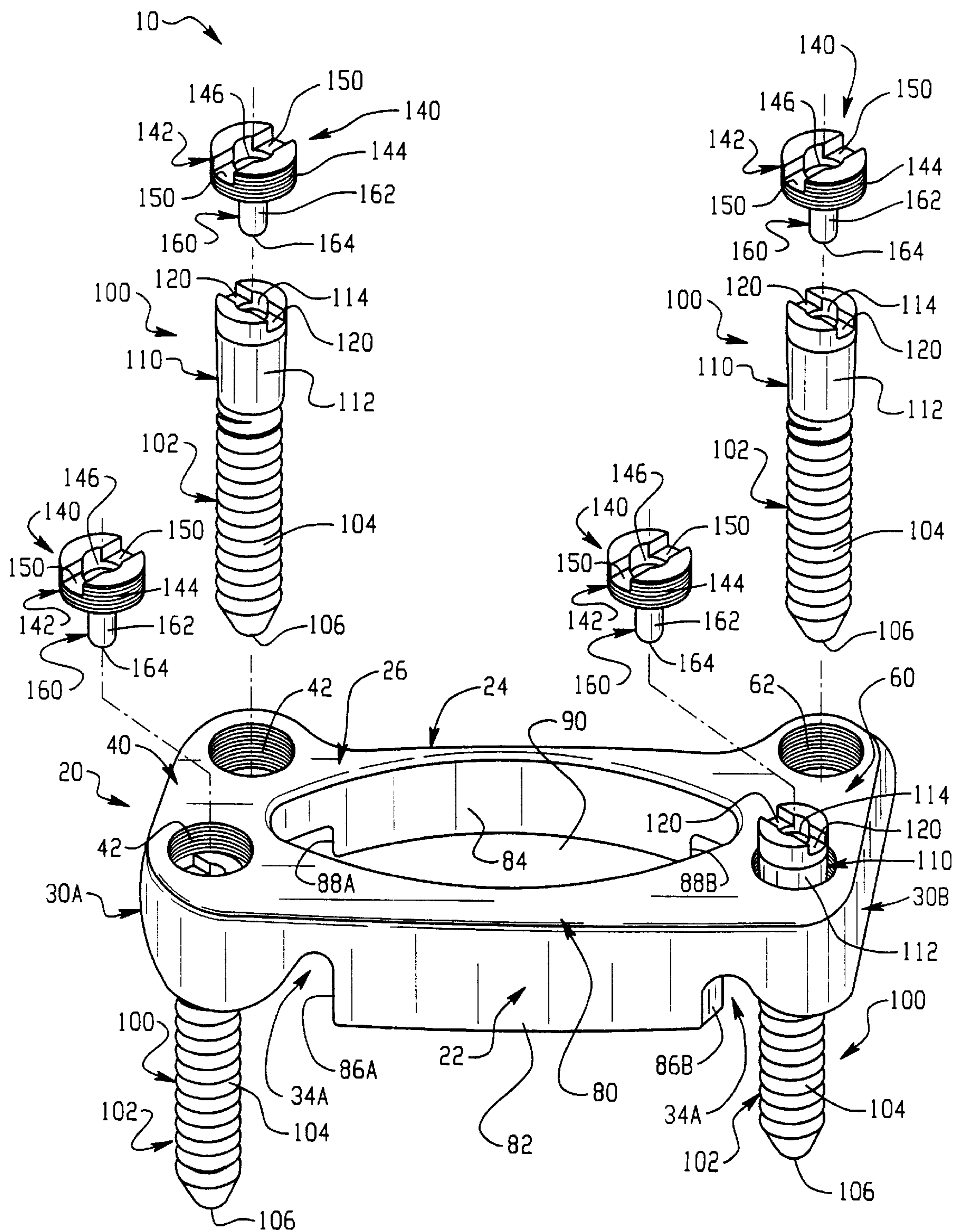
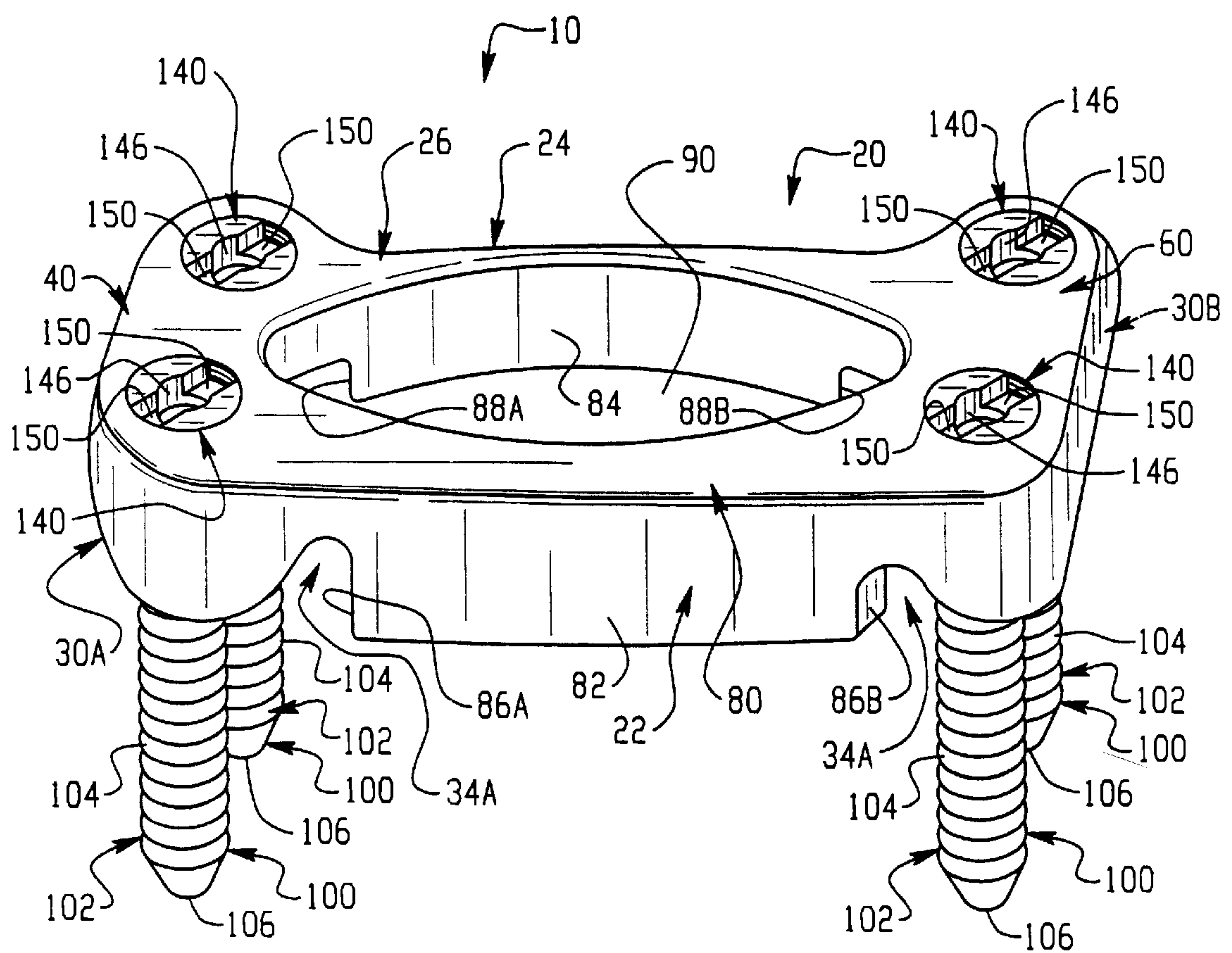


Fig. 1



*Fig. 2*

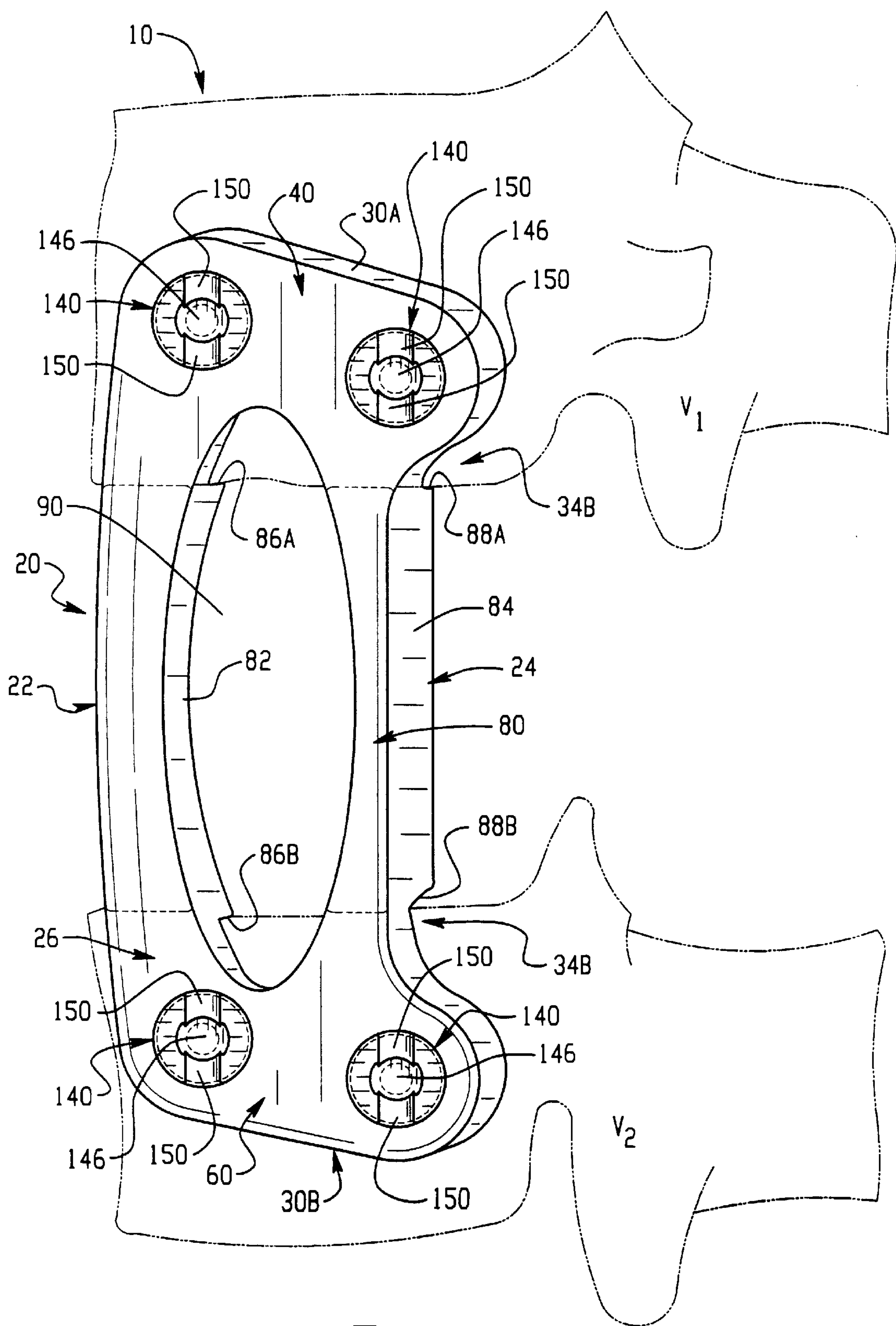


Fig. 3

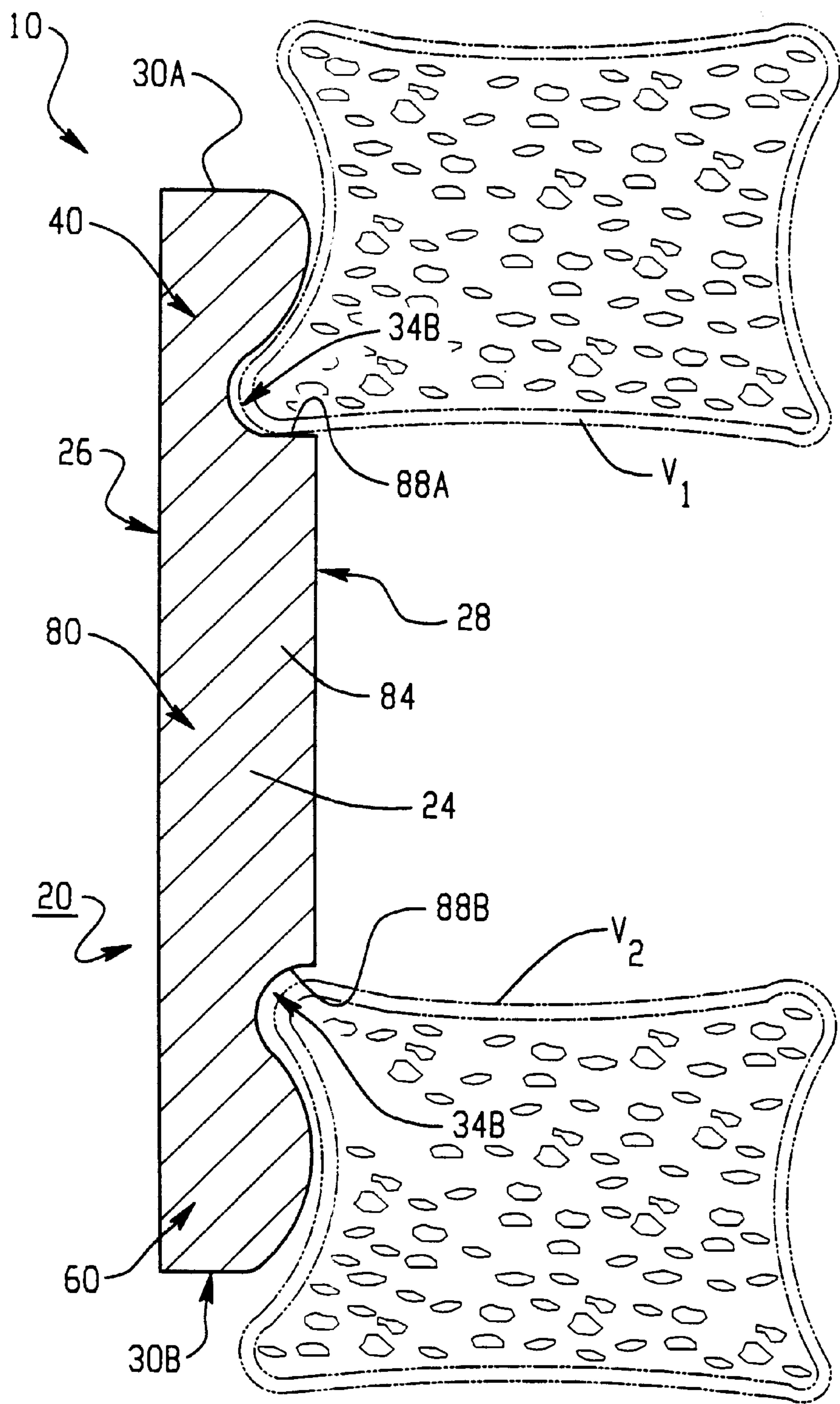


Fig. 4



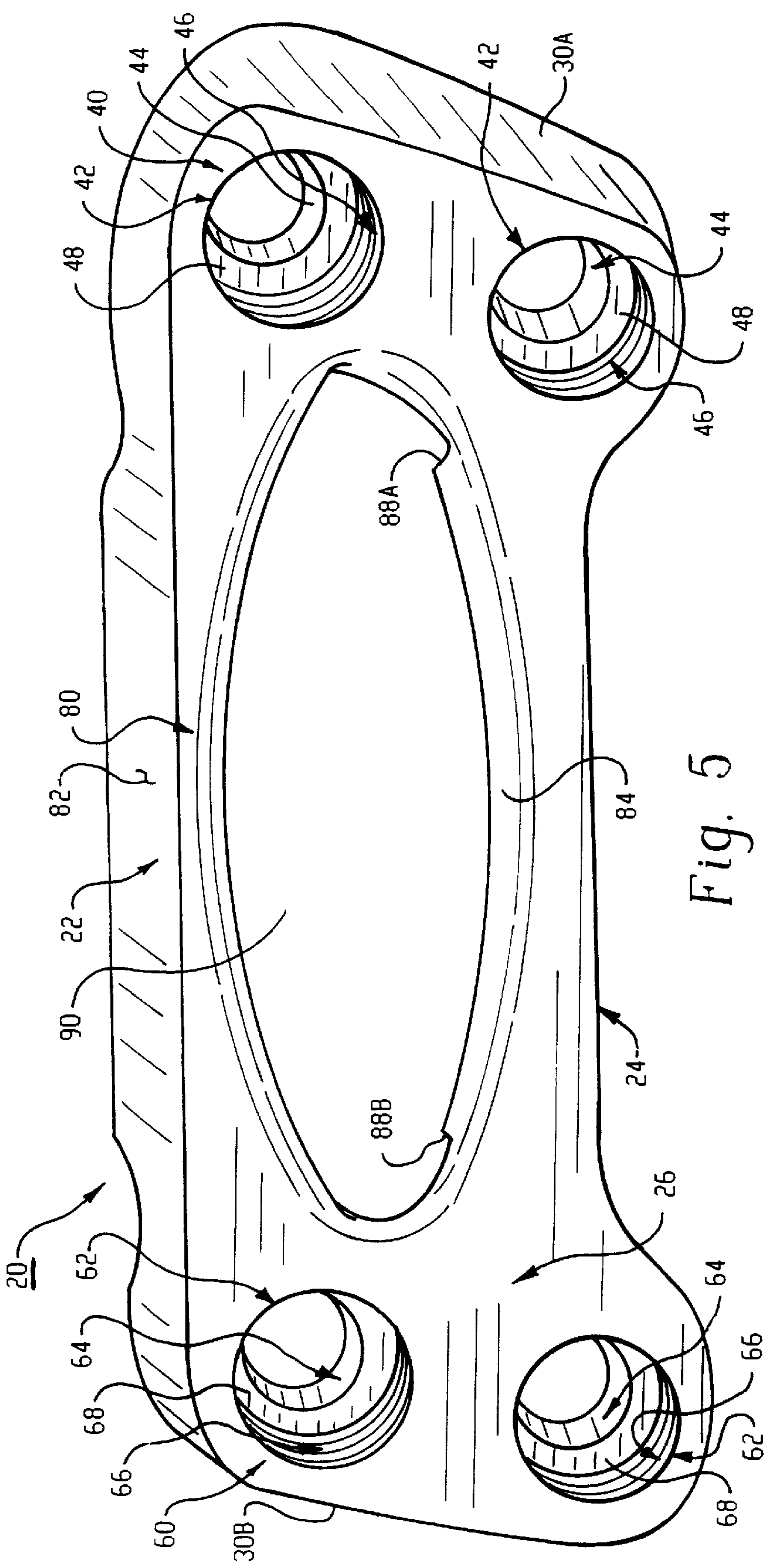


Fig. 5



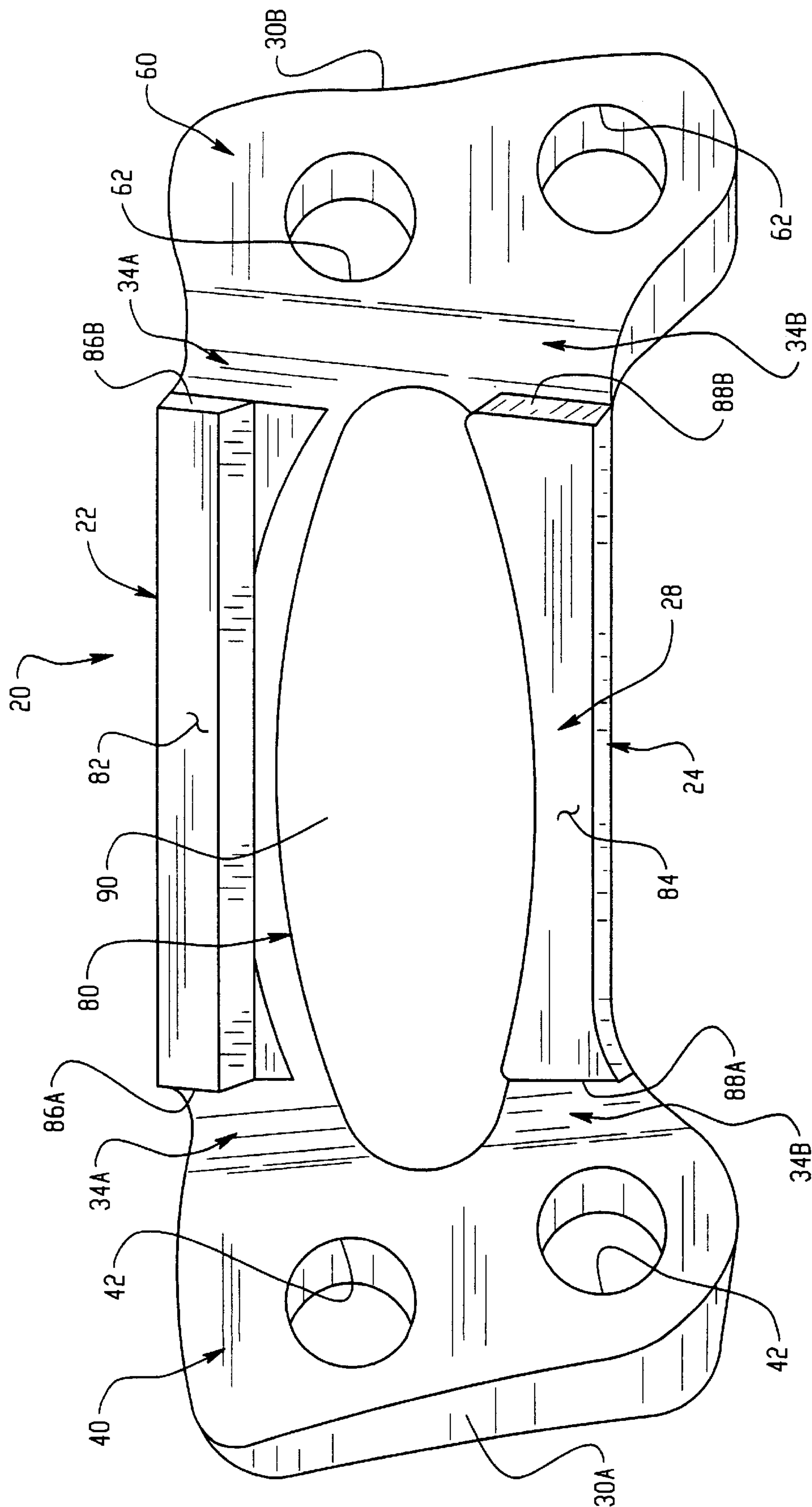


Fig. 6

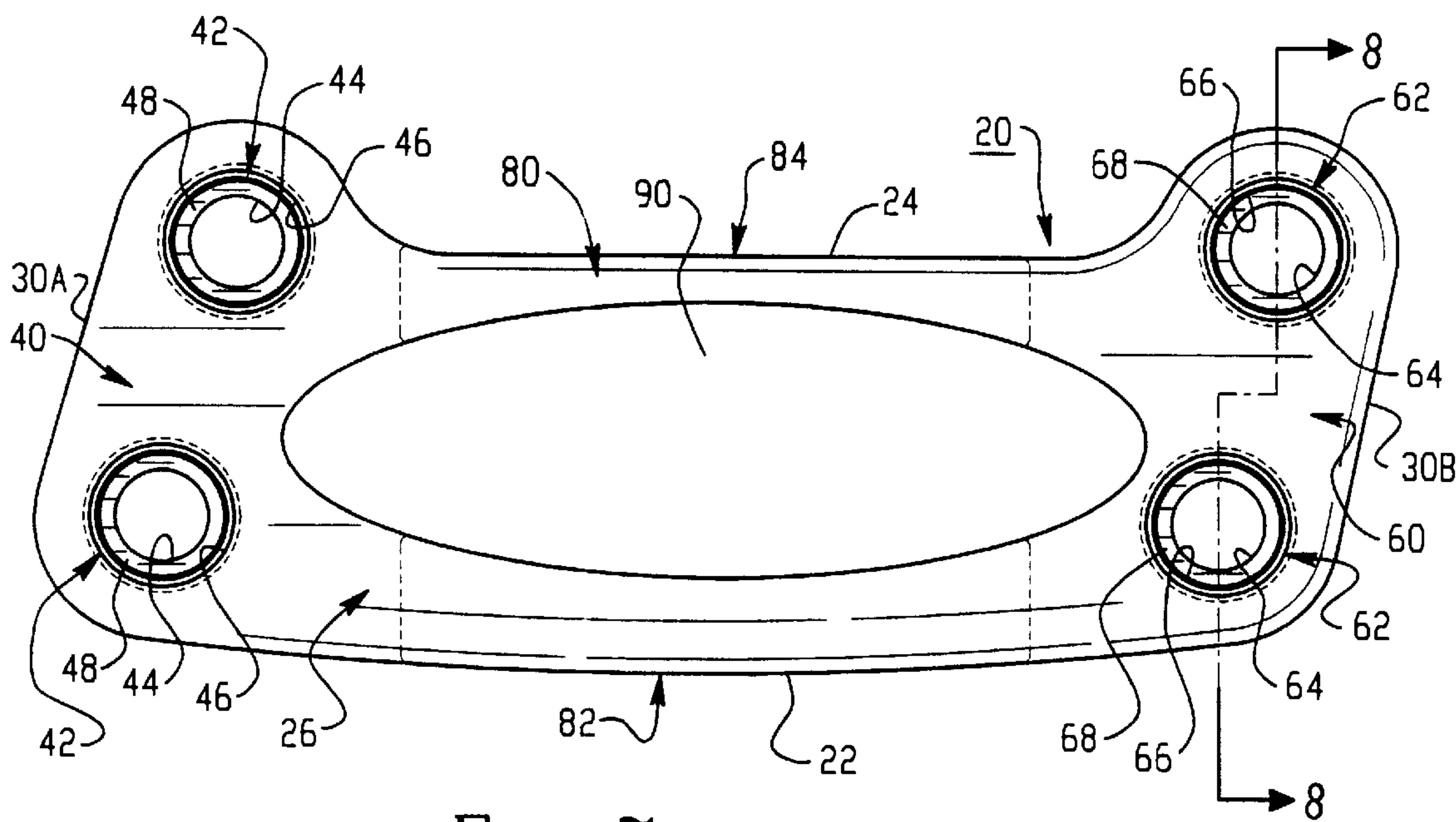


Fig. 7

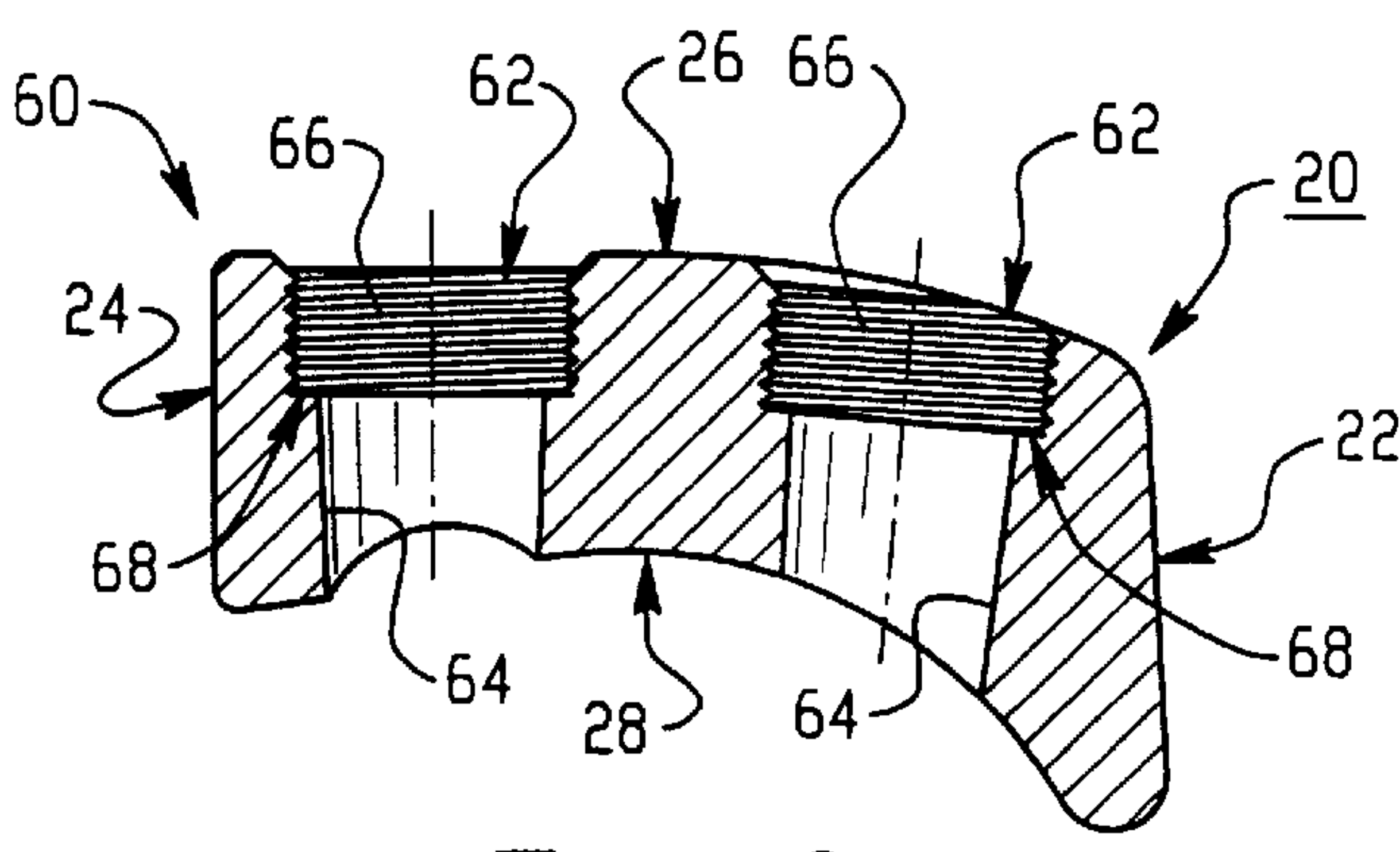


Fig. 8

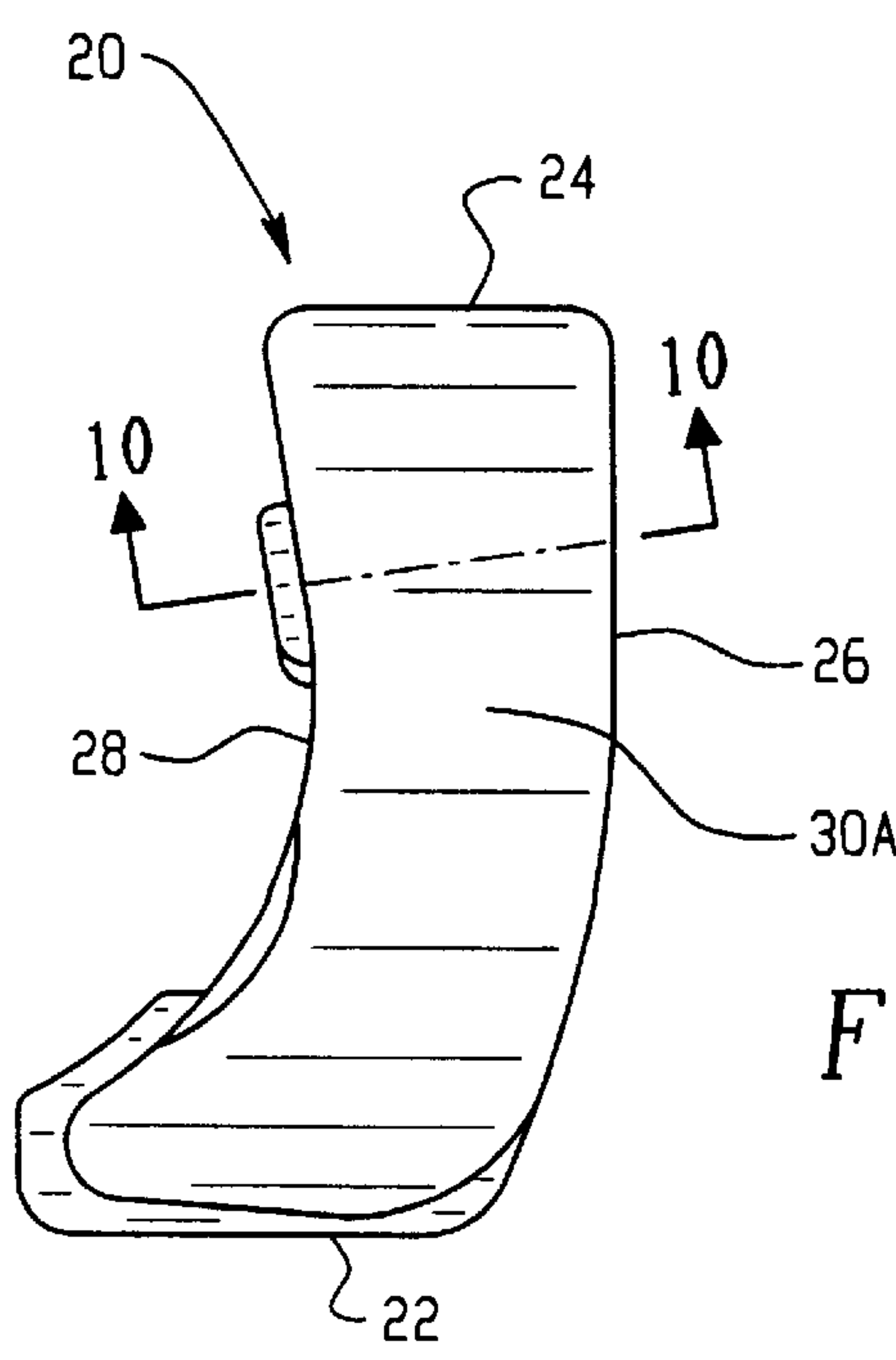
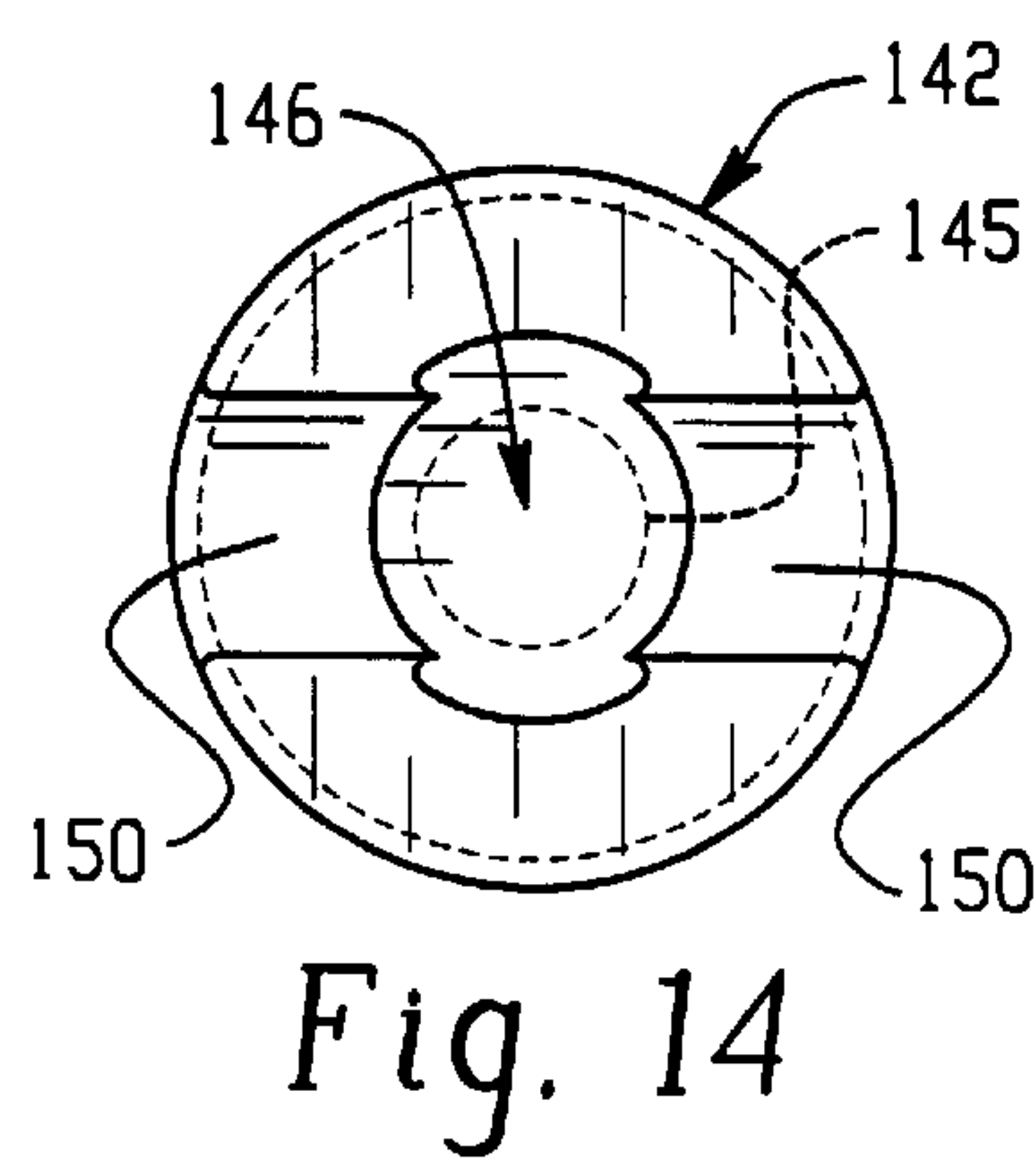
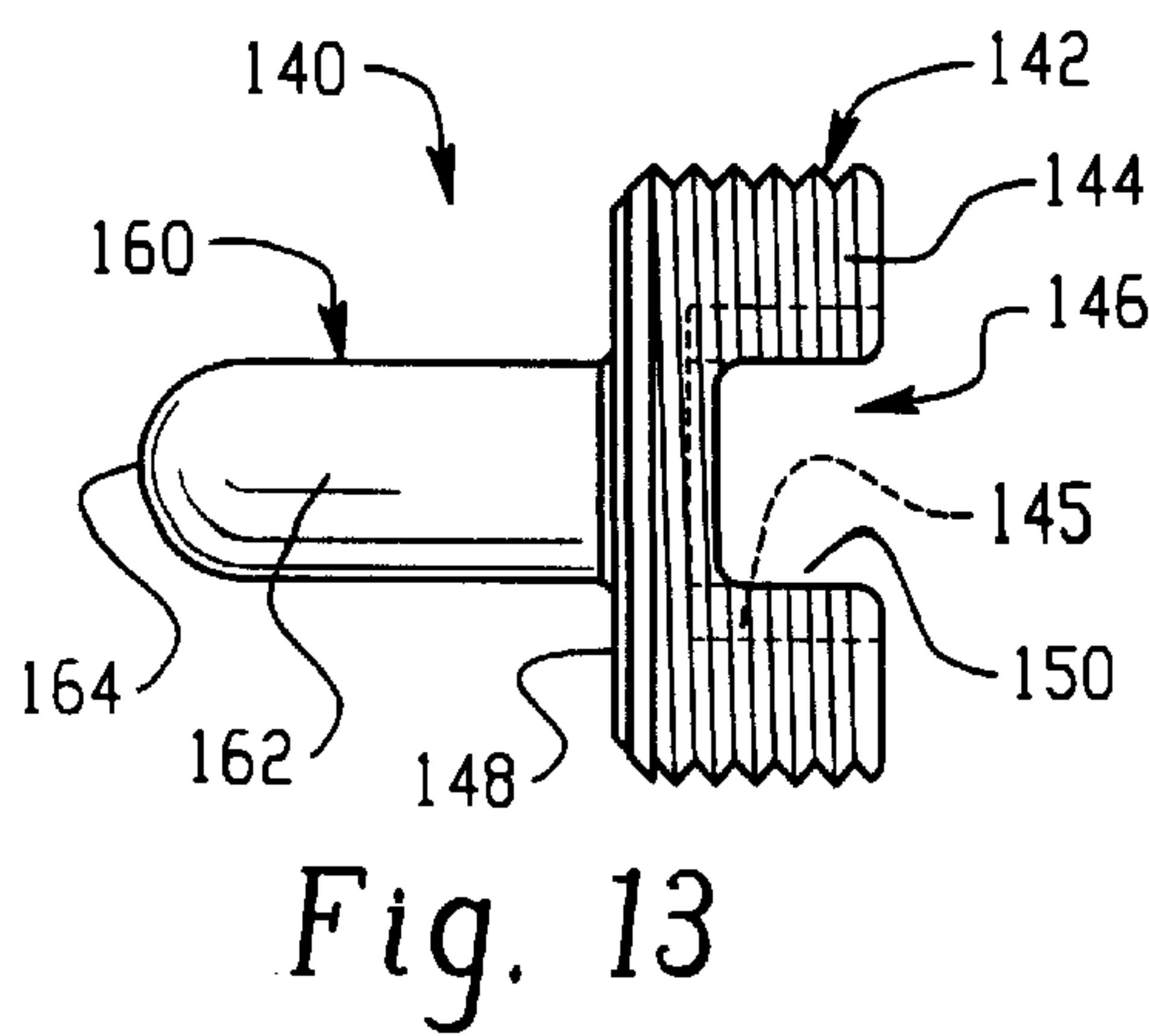
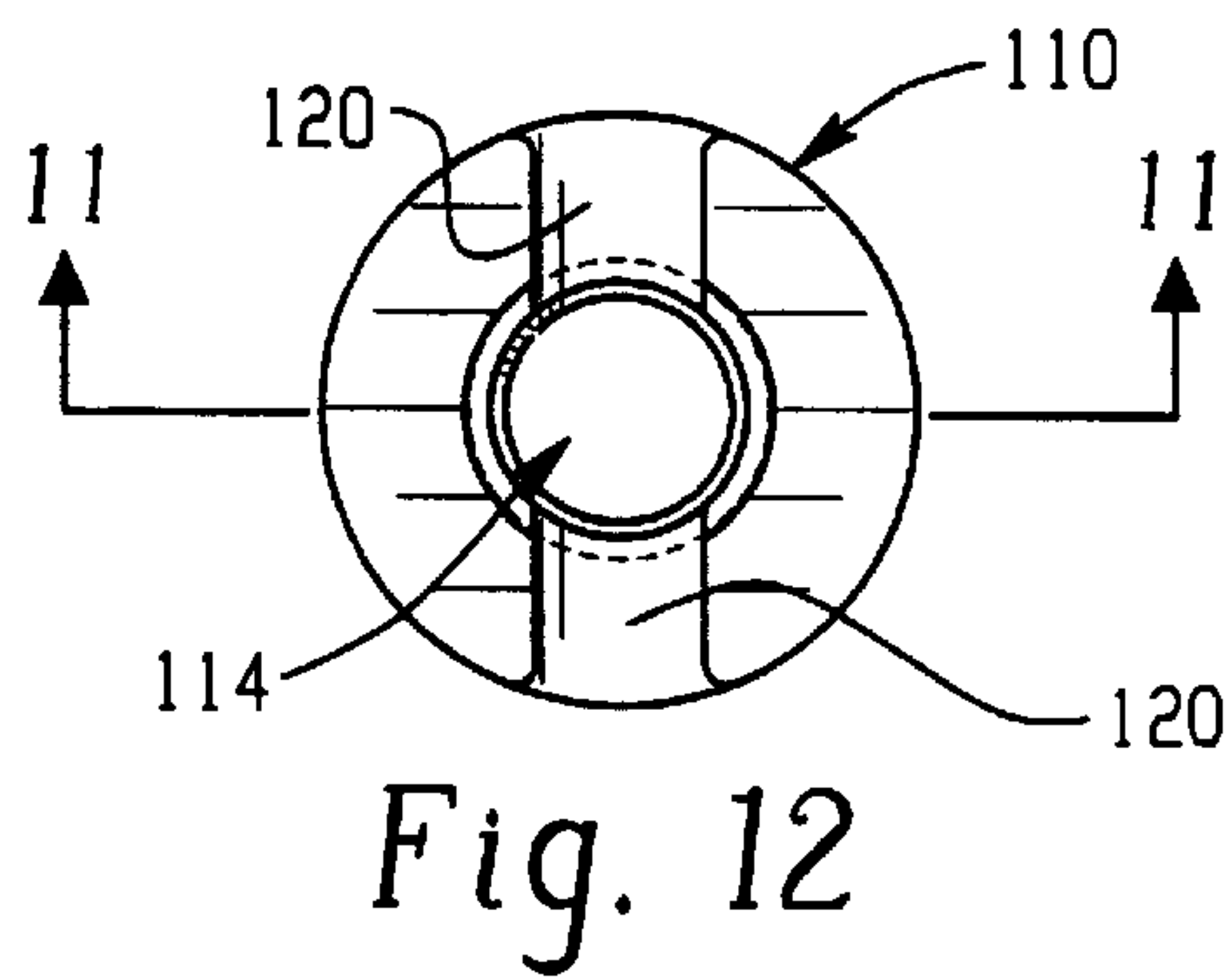
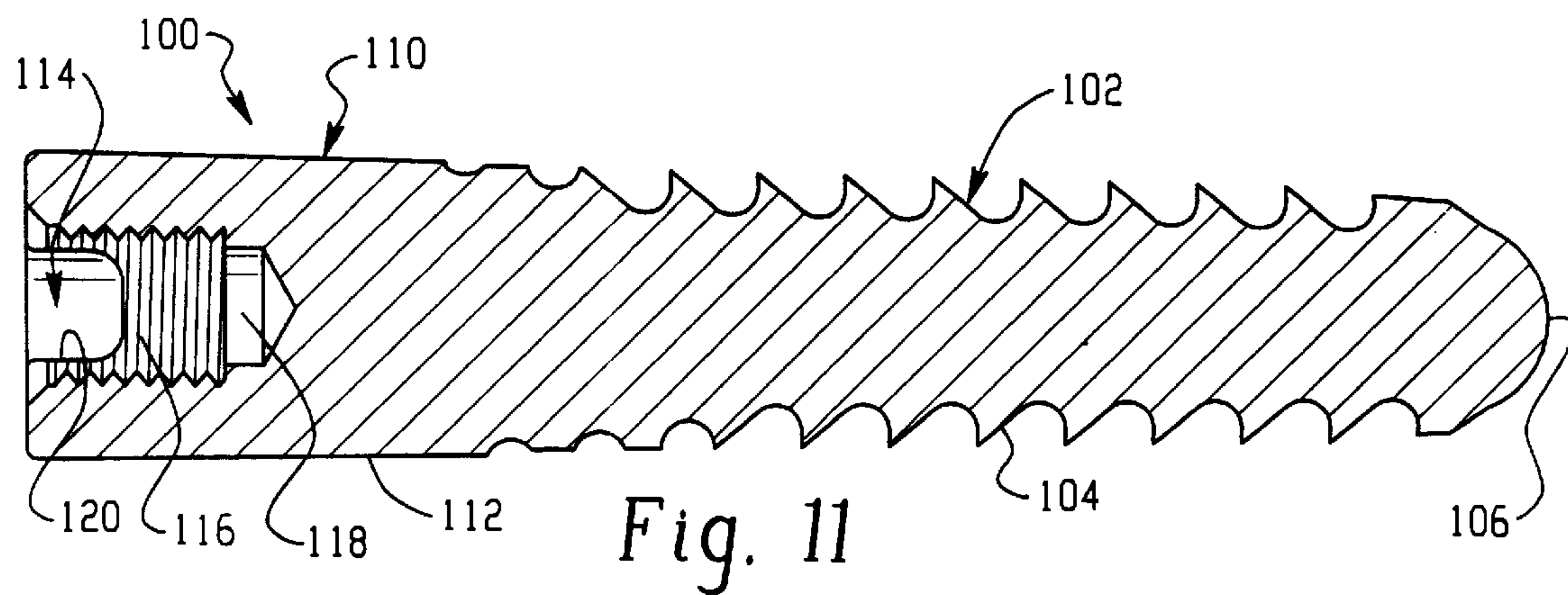
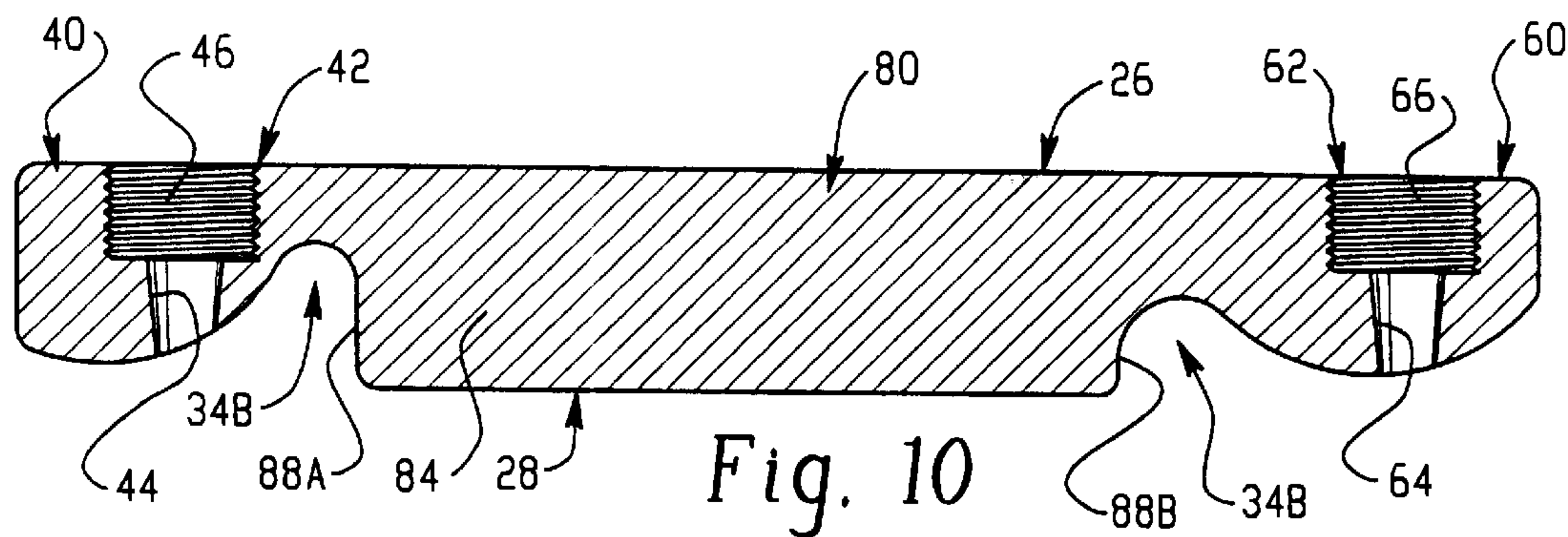


Fig. 9



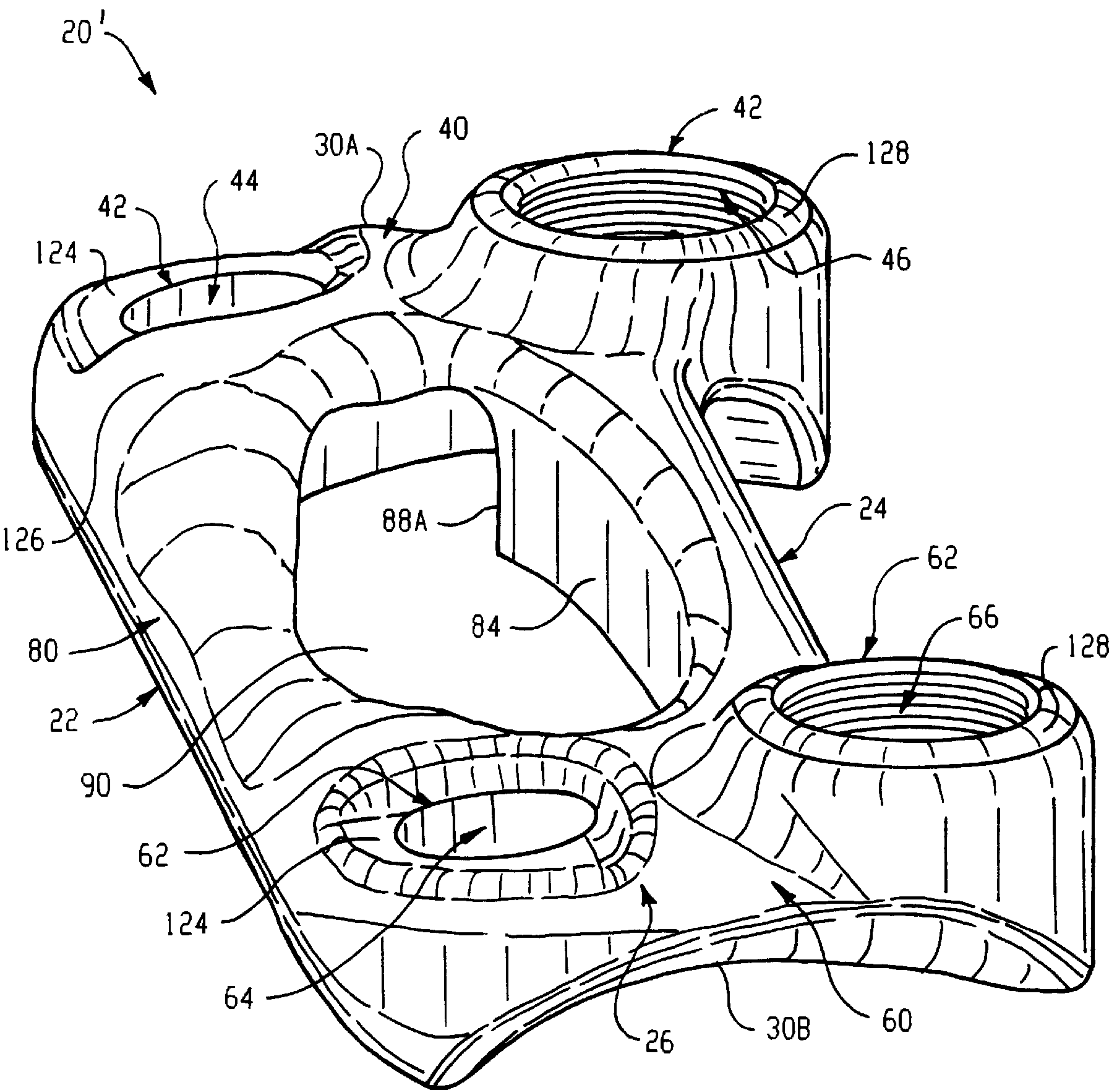


Fig. 15



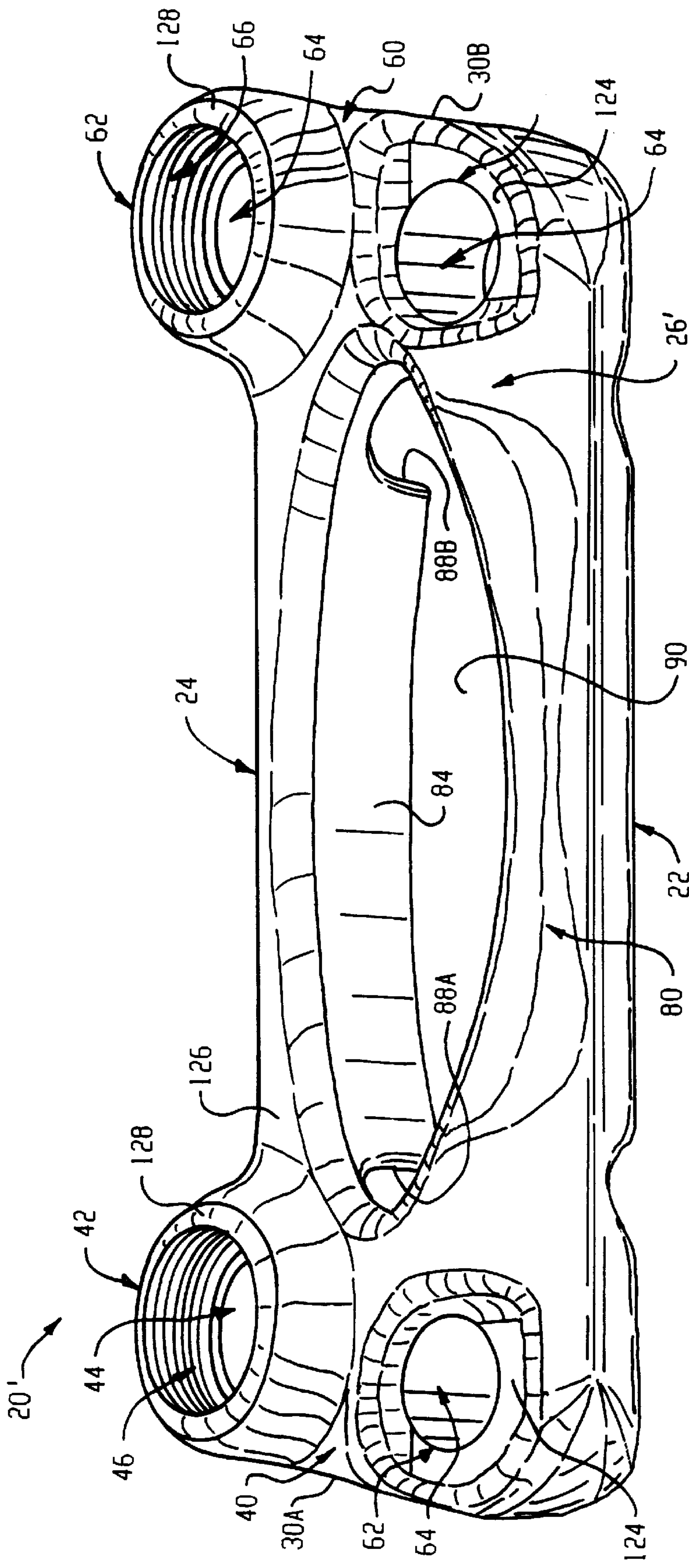
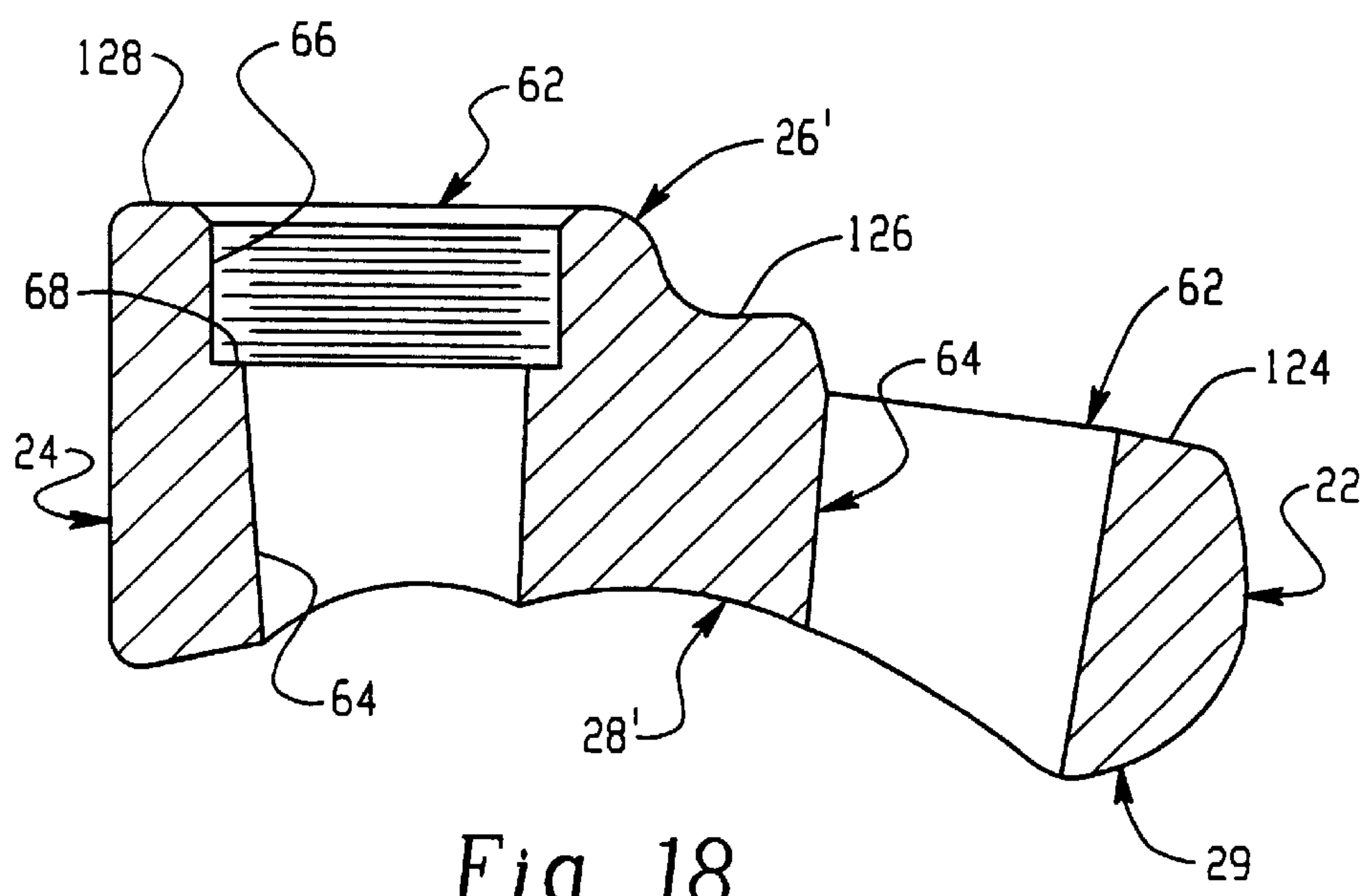
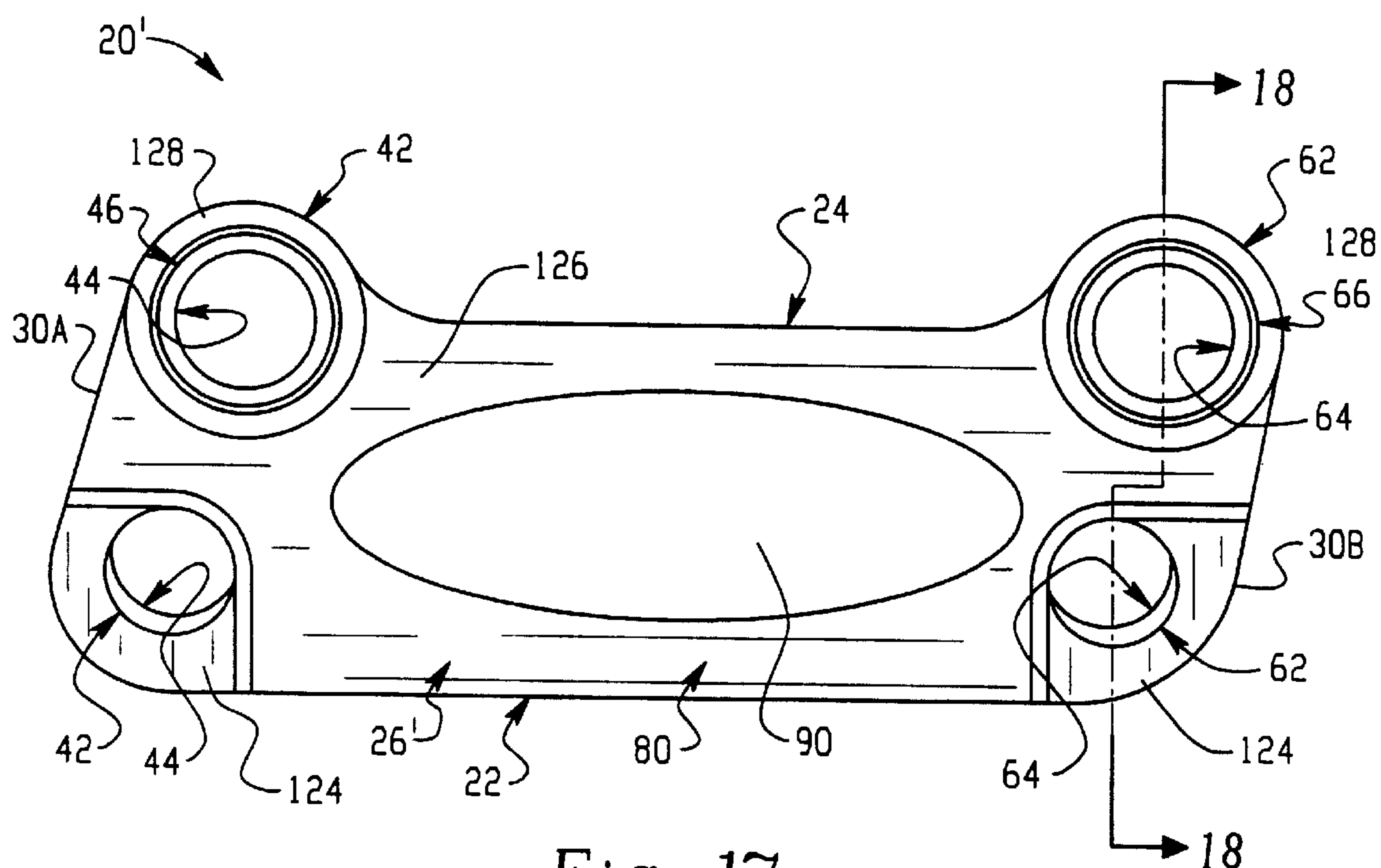


Fig. 16



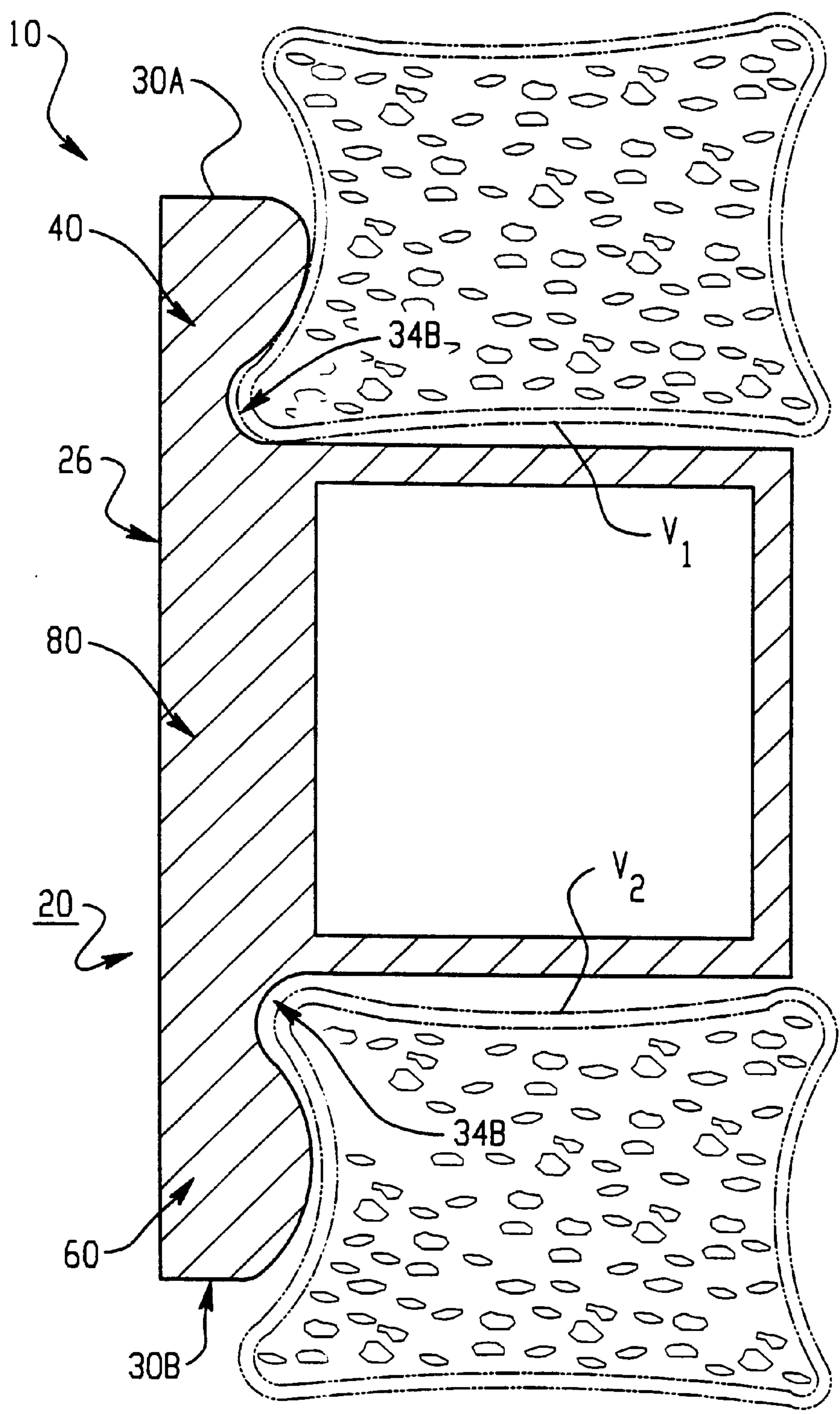
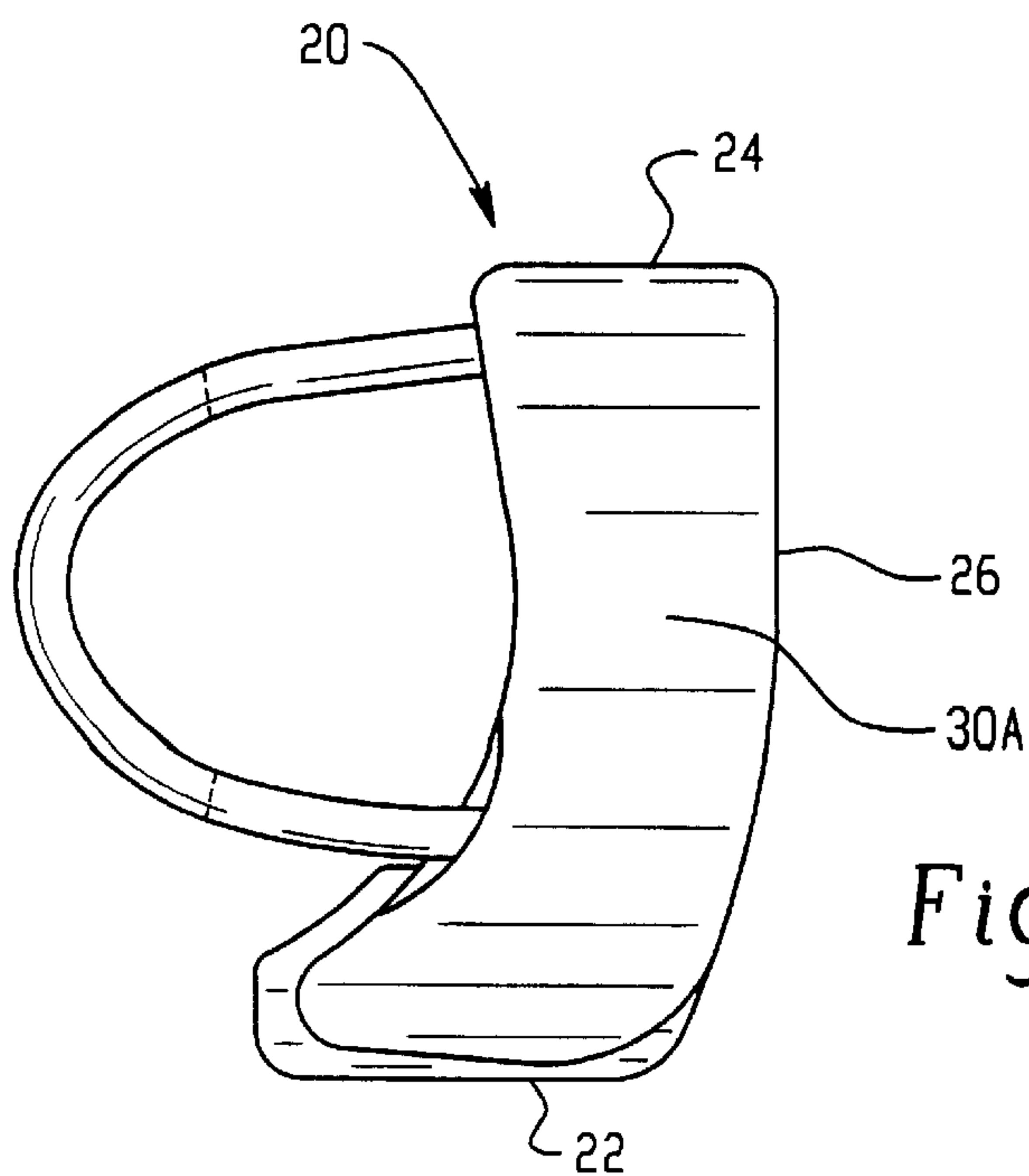
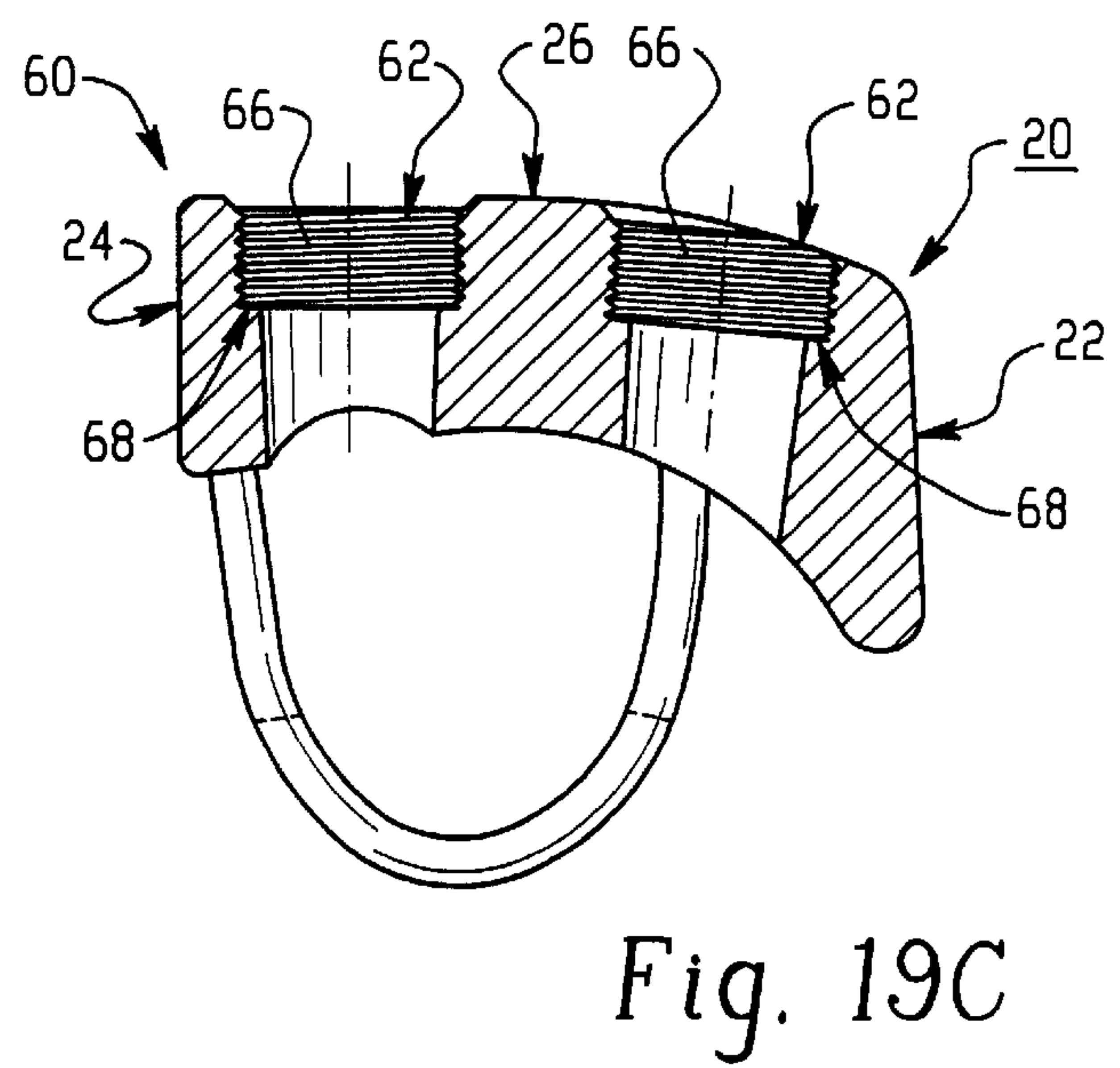
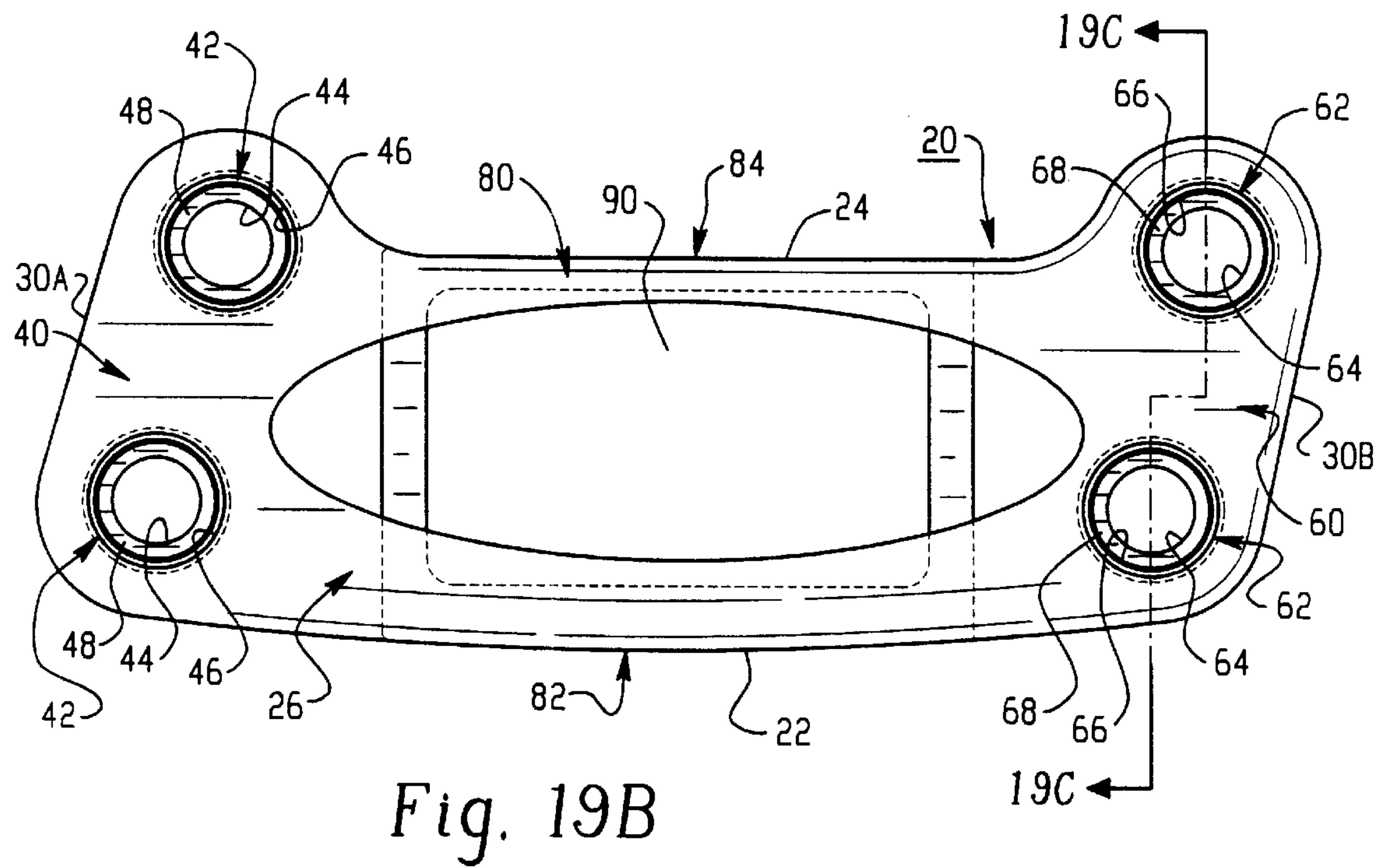


Fig. 19A





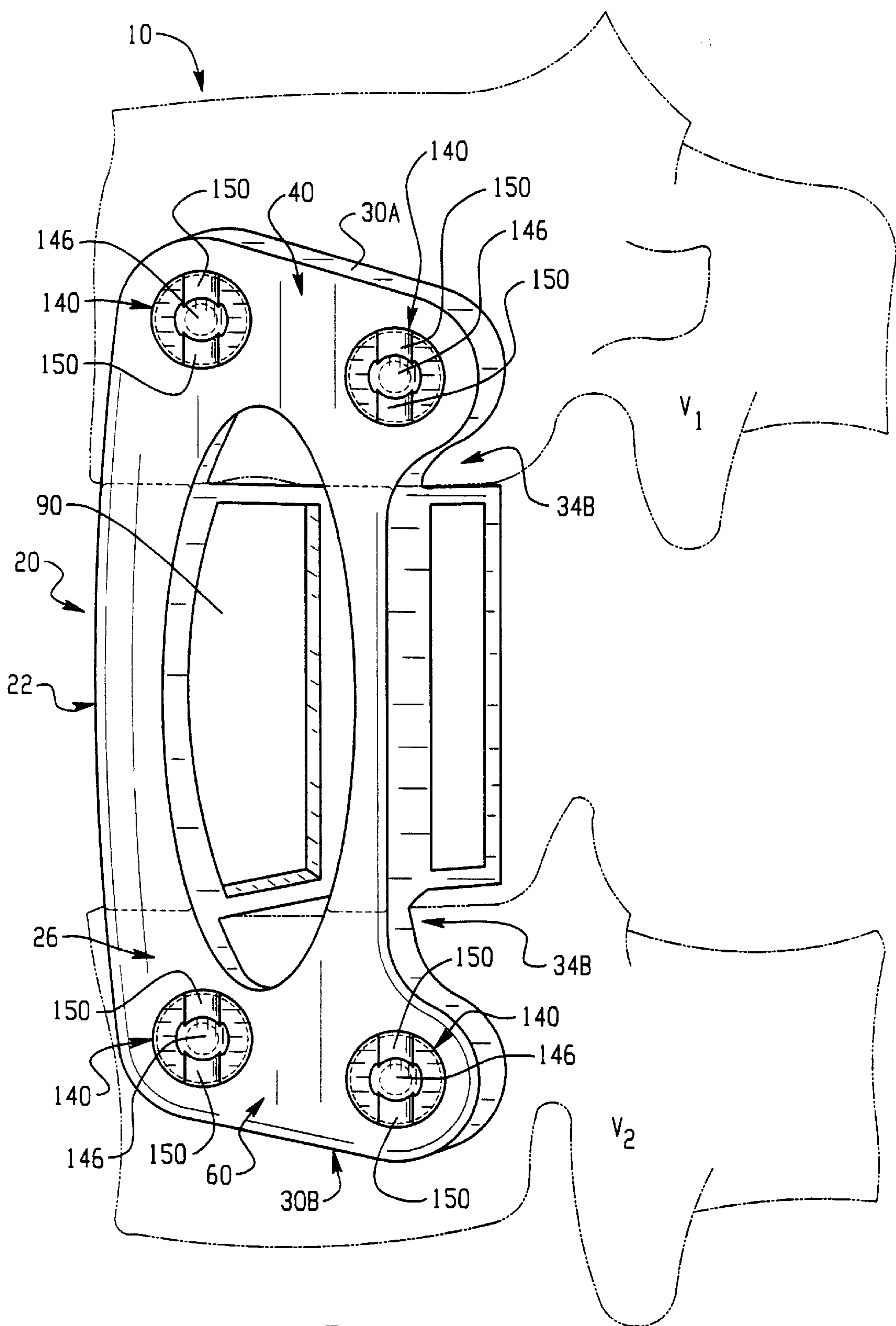


Fig. 19E

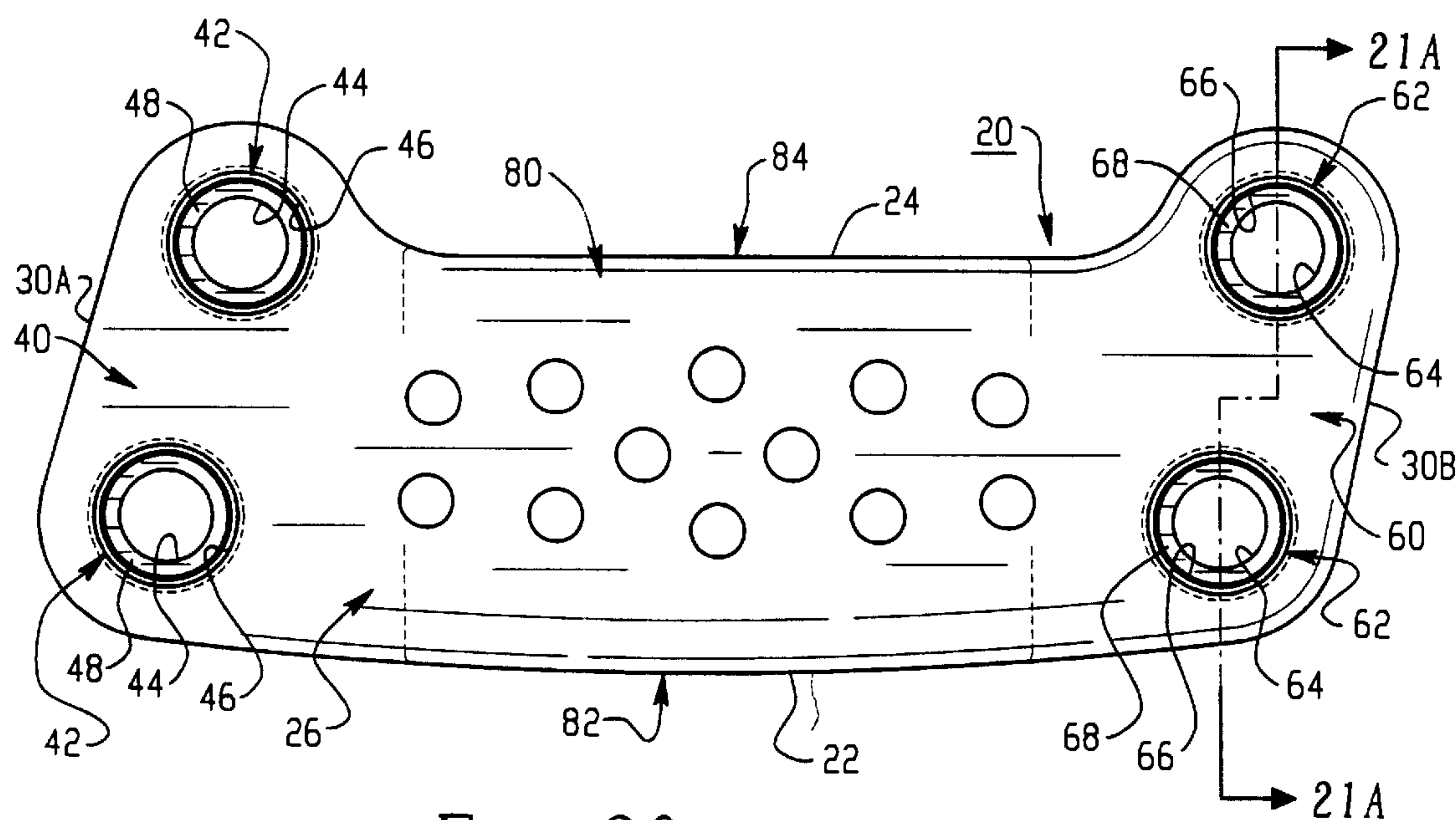


Fig. 20

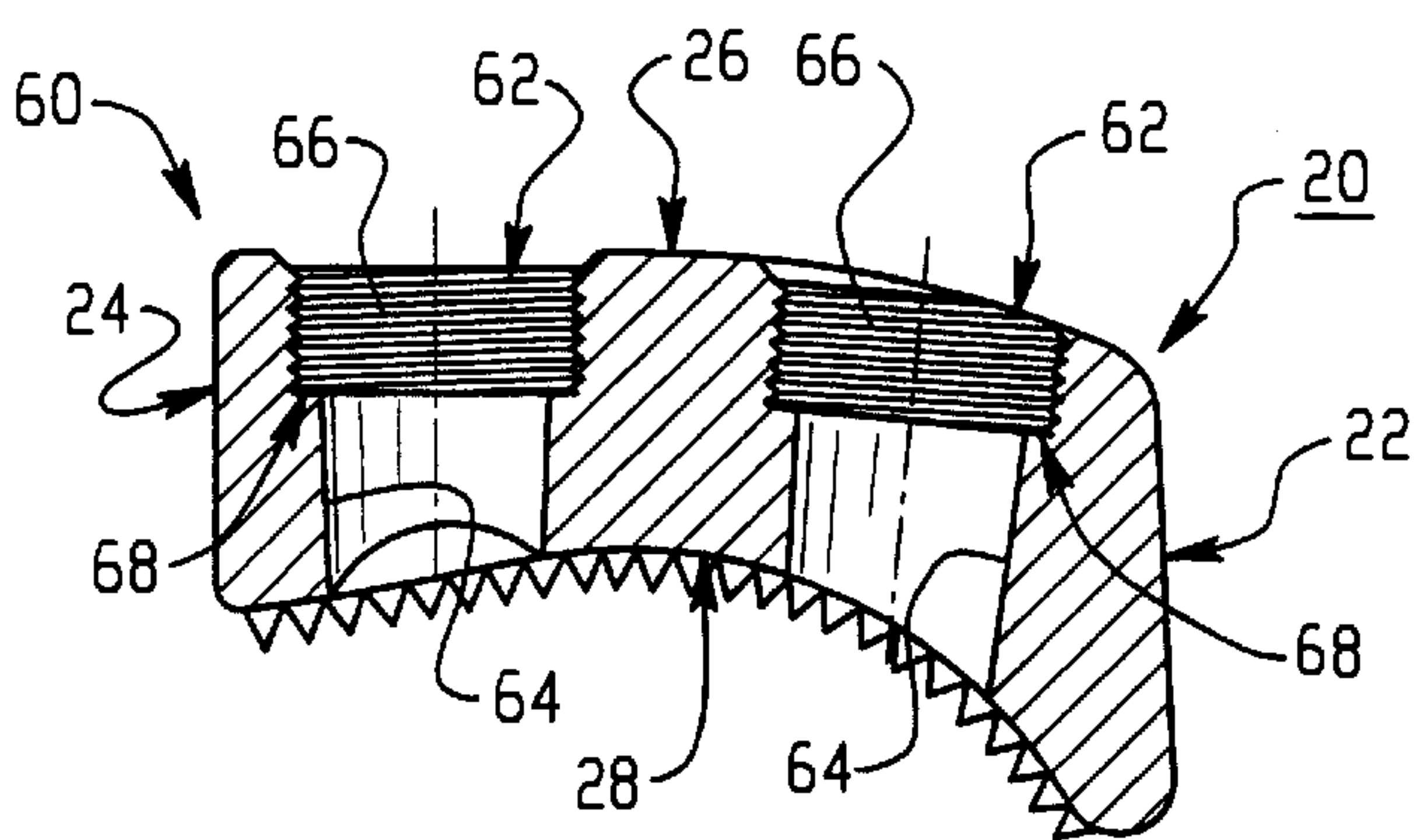


Fig. 21A

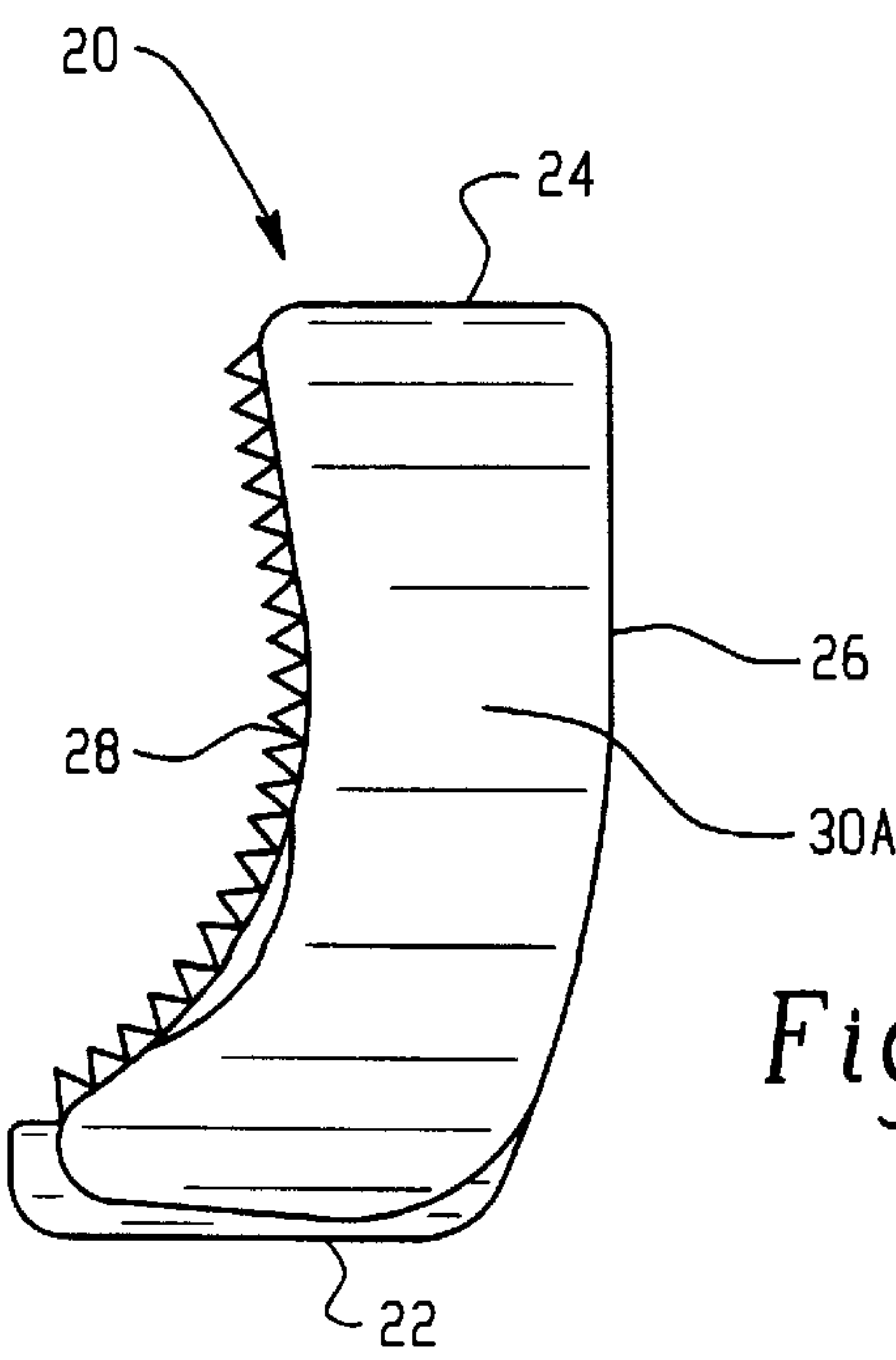


Fig. 21B

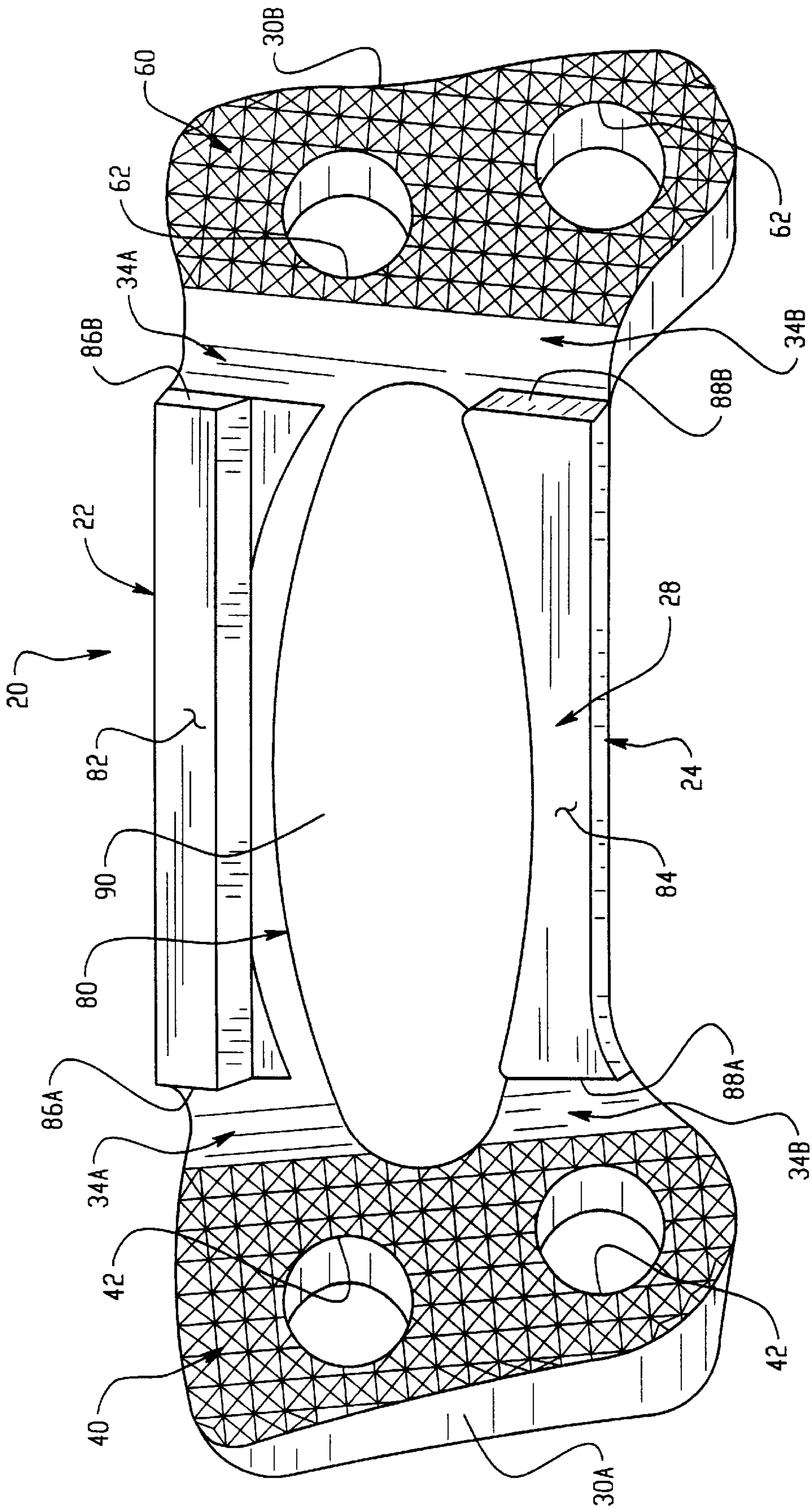


Fig. 21C

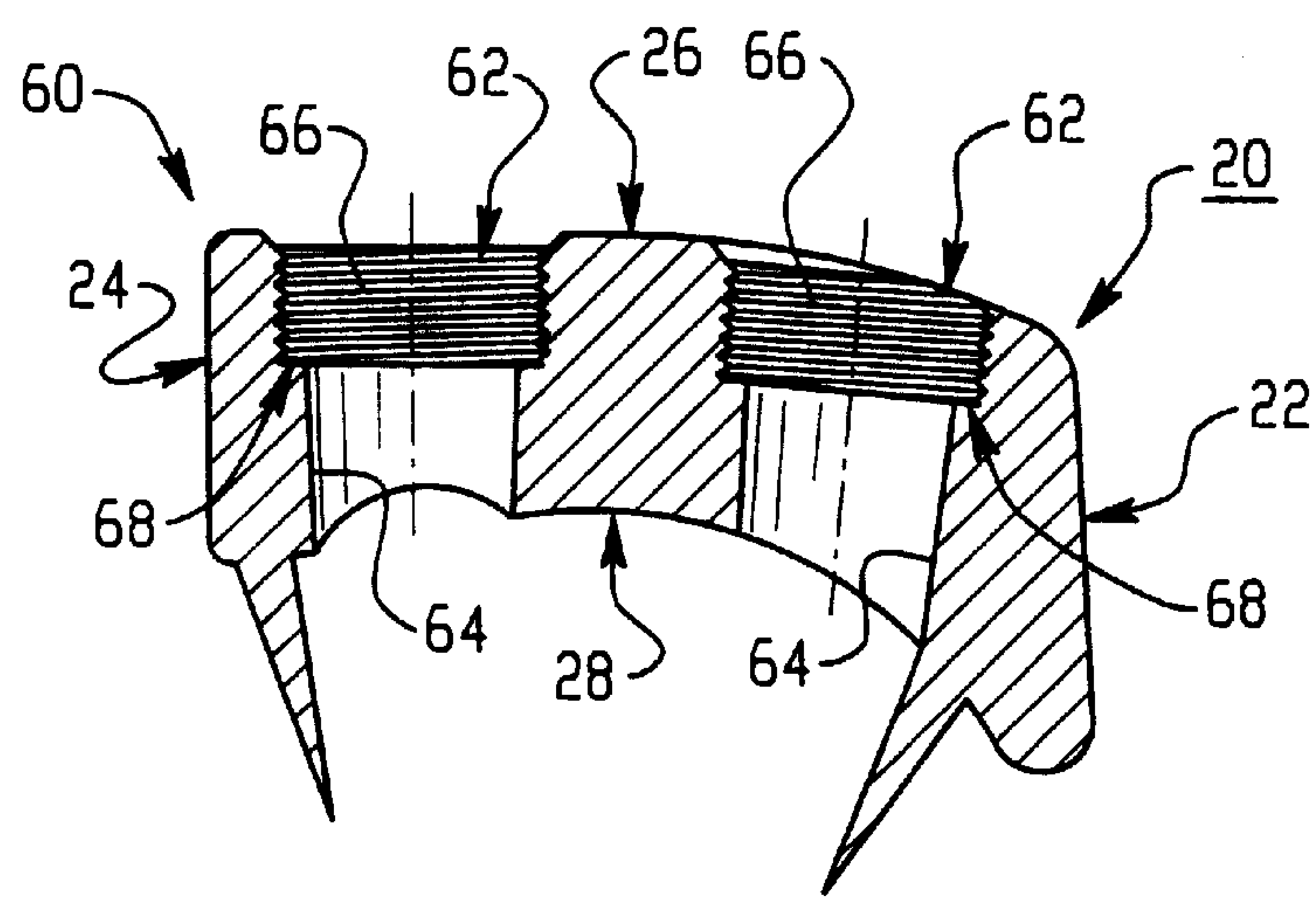


Fig. 21D

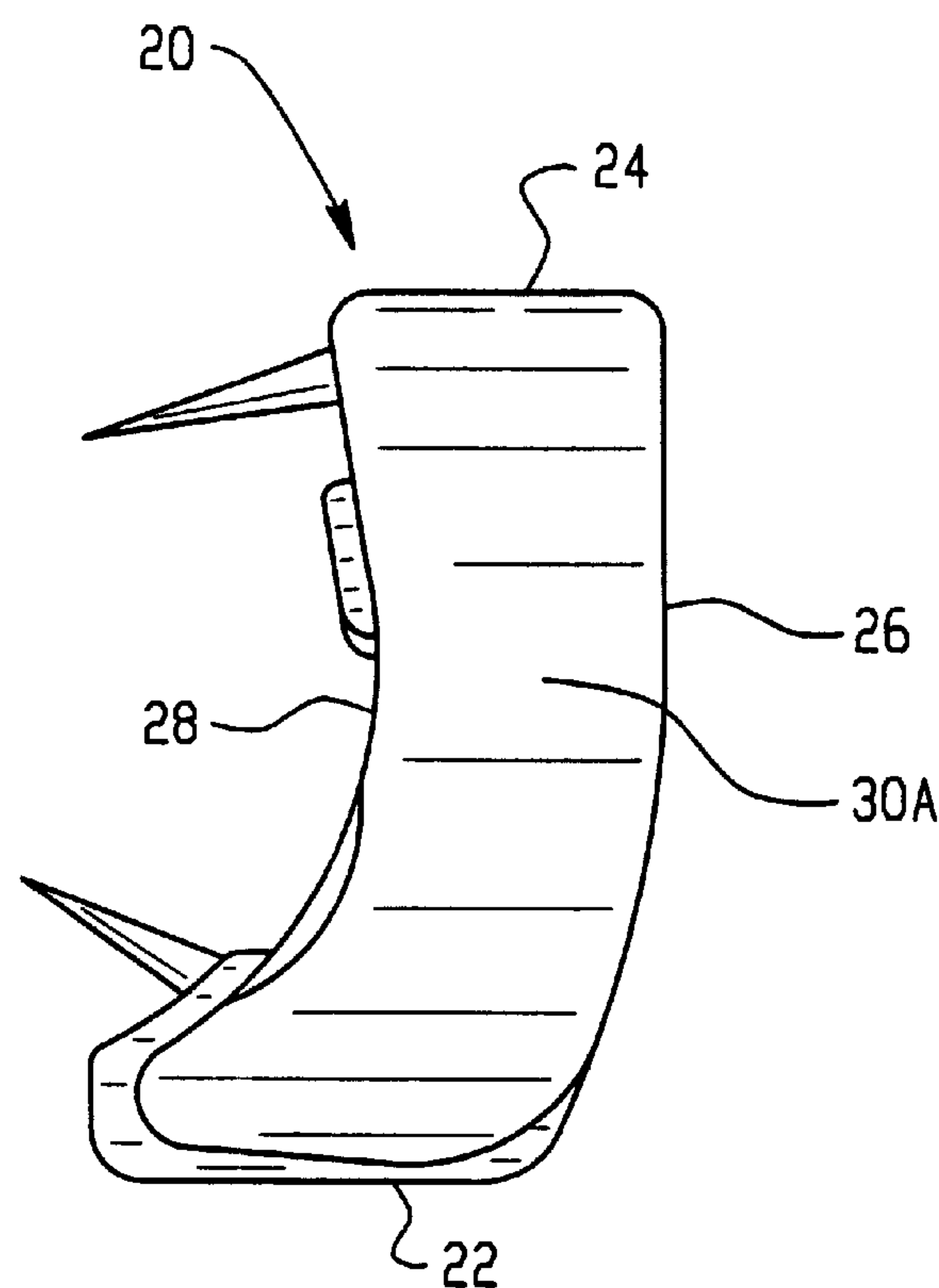


Fig. 21E



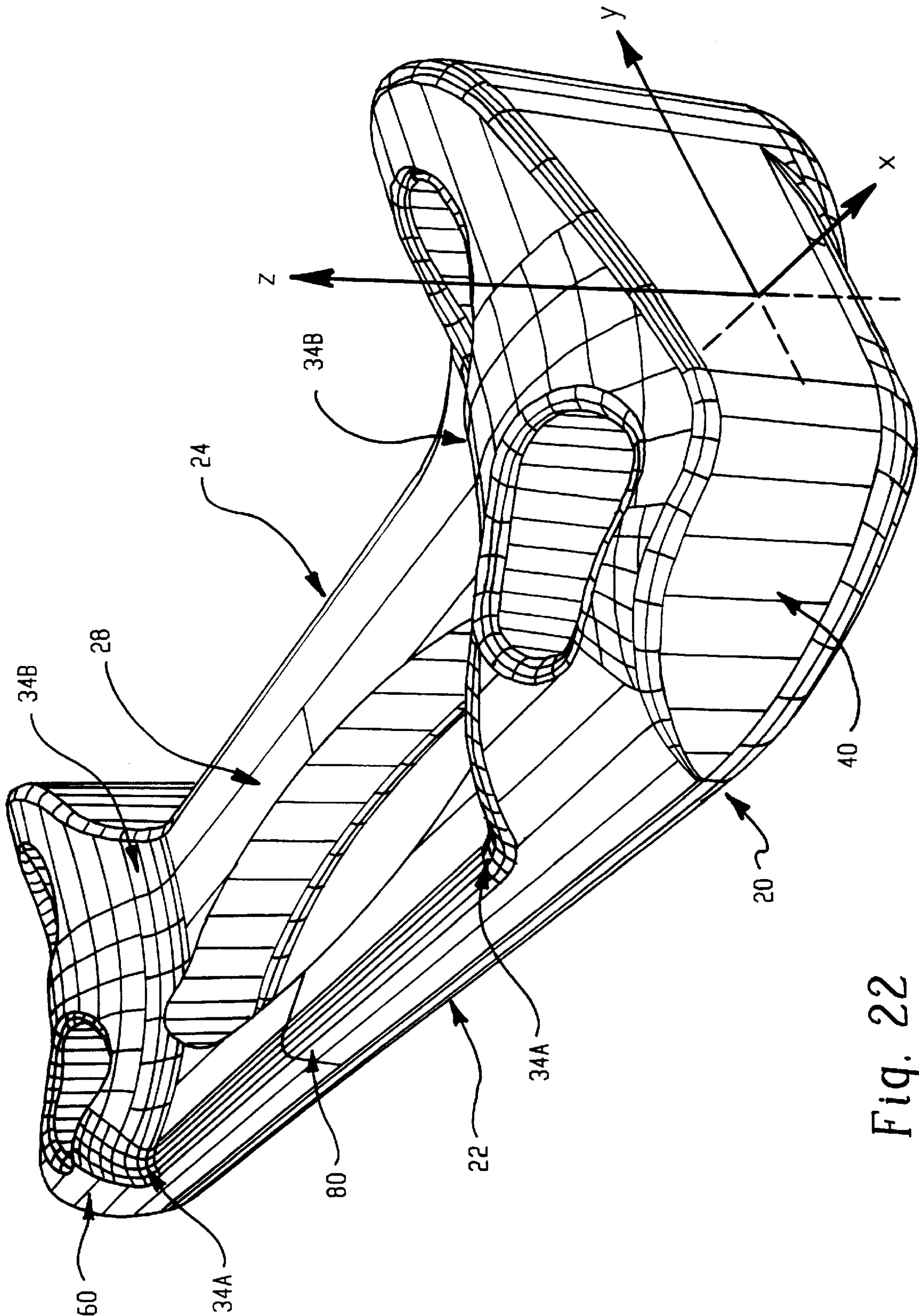


Fig. 22

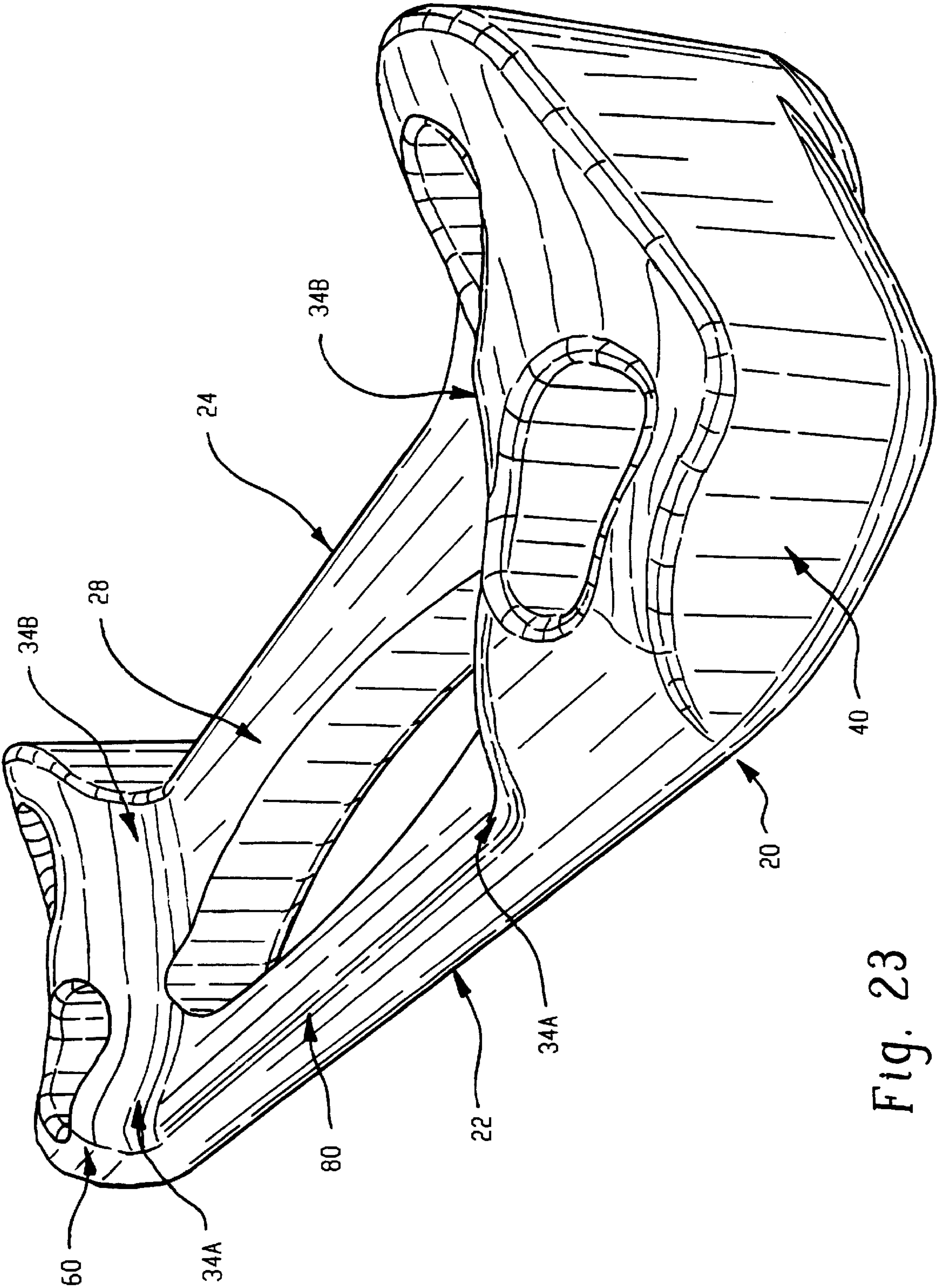


Fig. 23

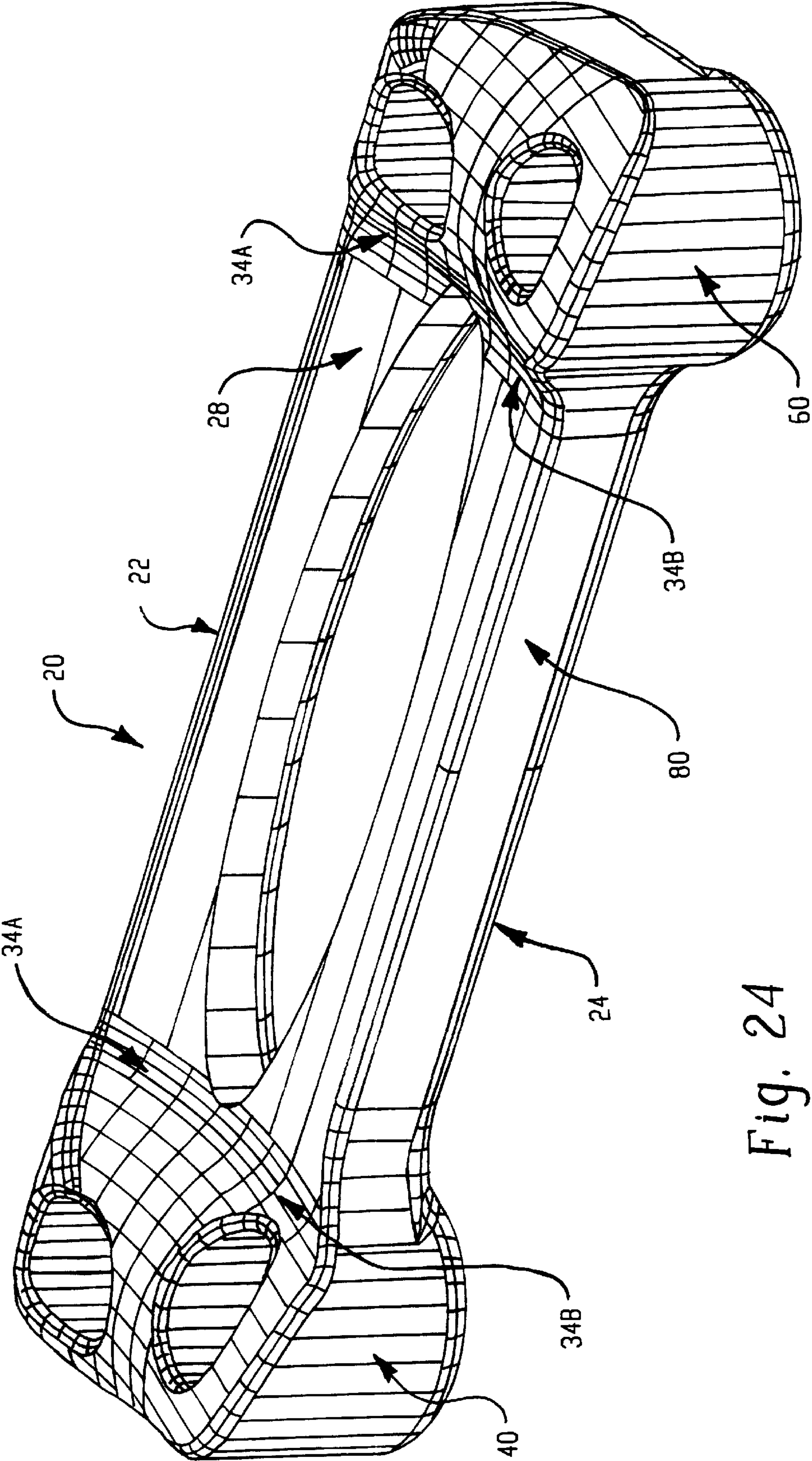


Fig. 24



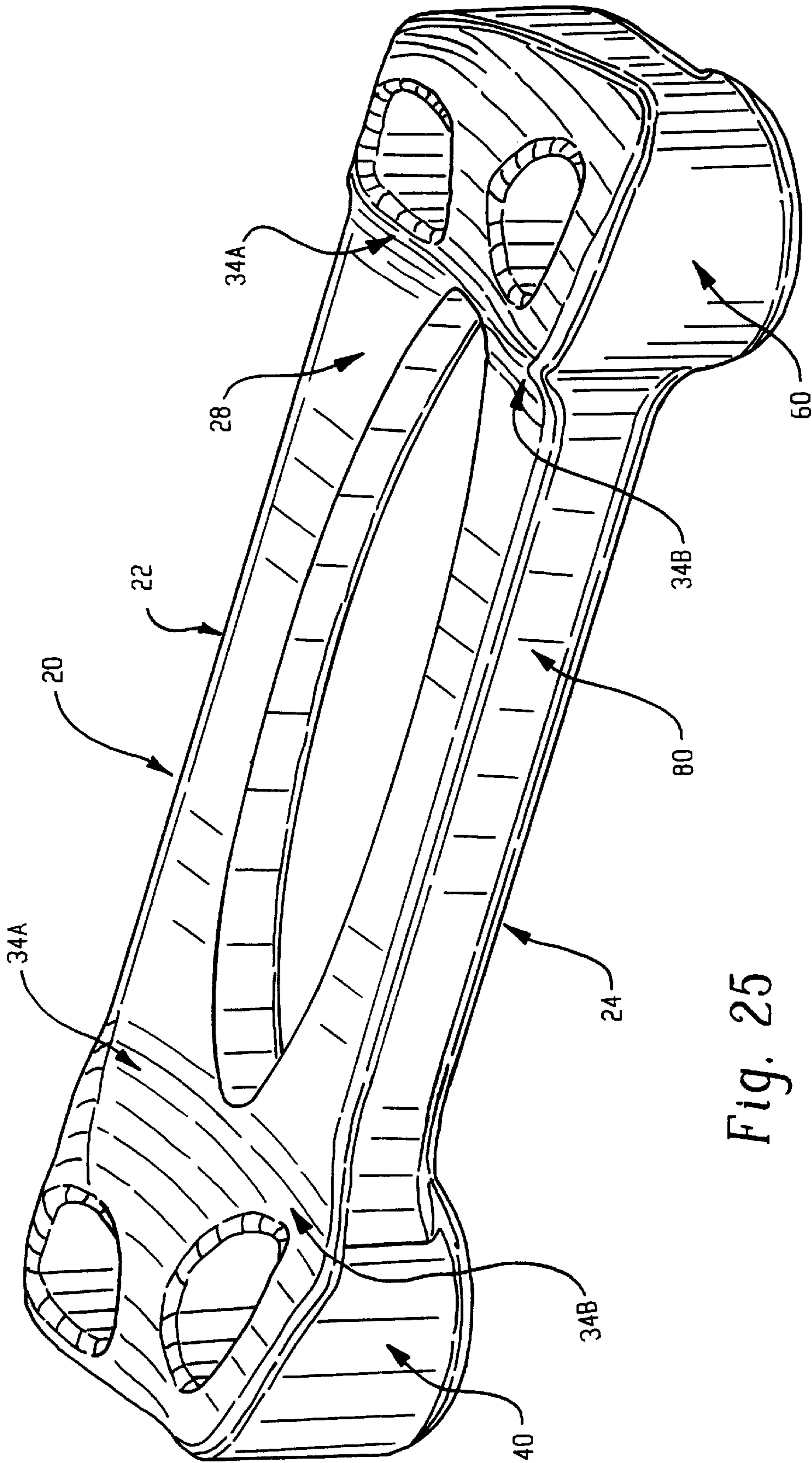


Fig. 25



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**BONE FIXATION SYSTEM****FIELD OF INVENTION**

The present invention relates generally to a bone fixation system, and more particularly to an internal bone fixation system for the treatment of bone anomalies, such as thoraco-lumbar spinal instability.

**BACKGROUND OF THE INVENTION**

Trauma, lumbar burst fractures, tumors, severe disc degeneration, and anterior fusion following multiple posterior operations, are just some of the causes of anterior thoraco-lumbar spinal instability. Anterior treatment of thoraco-lumbar spinal instability has included the use of a conventional fixation system comprised of a generally planar plate and fasteners. The plate is arranged between a pair of vertebrae, and has openings for receiving the fasteners. The fasteners engage the appropriate vertebra to affix the plate thereto.

Prior art fixation systems have several disadvantages. In this respect, the fixation systems have relatively flat plates that connect to the vertebrae by some combination of bolts or screws. Loading of such an implant system is primarily onto the smallest, weakest, and least stiff components of the fixation system. The entire load is taken by the screws at one end of the plate, and transferred through the plate to the screws at the other end of the plate. Furthermore, maximal stress on the plate occurs at the tensile (lateral) side of the plate. Accordingly, the stiffness, strength and fatigue properties of prior art fixation systems are deficient.

Moreover, prior art fixation systems have a profile that matches only the anterior profile of the vertebral bodies. As a result, surgeons are forced to cut a channel in the bone in order for the plate to fit properly. This leads to complex surgical procedures, long implantation times, and an anatomical fit which does not allow for biomechanical load-sharing which leads to improvements in mechanical properties such as stiffness, strength and fatigue life.

The present invention addresses these and other drawbacks of prior art bone fixation systems.

**SUMMARY OF THE INVENTION**

According to the present invention, there is provided a bone fixation system comprised of a plate and fasteners, wherein said plate is dimensioned to fit both the anterior and lateral profile of vertebral bodies.

An advantage of the present invention is the provision of a bone fixation system having greater stiffness than prior art systems.

Another advantage of the present invention is the provision of a bone fixation system having greater strength than prior art systems.

Still another advantage of the present invention is the provision of a bone fixation system having greater fatigue life than prior art systems.

Still another advantage of the present invention is the provision of a bone fixation system having an enhanced screw-plate interface for easier installation and improved security over prior art systems.

Still another advantage of the present invention is the provision of a bone fixation system having a plate contoured to fit the lateral profile of the vertebrae, thus providing added thickness for improved rigidity and forming a ledge for supporting the vertebrae in direct compression.

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Yet another advantage of the present invention is the provision of a bone fixation system having an improved anatomical fit over prior art systems.

Yet another advantage of the present invention is the provision of a bone fixation system that provides improved interoperative graft access and postoperative graft evaluation.

Yet another advantage of the present invention is the provision of a bone fixation system requiring less surgical complexity for installation.

Yet another advantage of the present invention is the provision of a fastener system for securely fastening a plate to a bone structure.

Still other advantages of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description, accompanying drawings and appended claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention may take physical form in certain parts and arrangements of parts, a preferred embodiment and method of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

FIG. 1 is an exploded perspective view of the bone fixation system according to a preferred embodiment of the present invention;

FIG. 2 is a perspective of the bone fixation system according to a preferred embodiment of the present invention;

FIG. 3 is a lateral side view of the bone fixation system according to a preferred embodiment of the present invention, as affixed to a pair of vertebral bodies;

FIG. 4 is a posterior sectional view of the bone fixation system, as affixed to a pair of vertebral bodies;

FIG. 5 is a lateral side view of the bone plate;

FIG. 6 is a medial side view of the bone plate shown in FIG. 5;

FIG. 7 is a top plan view of the lateral side of the bone plate;

FIG. 8 is a sectional view of the bone plate, taken along line 8—8 of FIG. 7;

FIG. 9 is an end view of the bone plate;

FIG. 10 is a sectional view of the bone plate, taken along line 10—10 of FIG. 9;

FIG. 11 is a sectional view of a screw, taken along line 11—11 of FIG. 12;

FIG. 12 is a top view of the screw shown in FIG. 1;

FIG. 13 is a side view of a set screw shown in FIG. 1;

FIG. 14 is a top view of the set screw shown in FIG. 1;

FIGS. 15 and 16 are perspective views of a bone plate according to an alternative embodiment of the present invention;

FIG. 17 is a top plan view of the bone plate shown in FIGS. 15 and 16;

FIG. 18 is a cross-sectional view of the bone plate, taken along line 18—18 of FIG. 17;

FIG. 19A is a posterior sectional view of the bone fixation system, as affixed to a pair of vertebral bodies, showing the ledge members connected together to form an intervertebral cage;

FIG. 19B is a top plan view of the lateral side of the bone plate, showing the ledge members connected together to form an intervertebral cage;



FIG. 19C is a sectional view of the bone plate, taken along line 8—8 of FIG. 19B, showing the ledge members connected together to form an intervertebral cage;

FIG. 19D is an end view of the bone plate, showing the ledge members connected together to form an intervertebral cage;

FIG. 19E is a lateral side view of the bone fixation system, as affixed to a pair of vertebral bodies, showing the ledge members connected together to form an intervertebral cage;

FIG. 20, is a top plan view of the lateral side of the bone plate, showing a window having a plurality of holes;

FIG. 21A is a sectional view of the bone plate, taken along line 8—8 of FIG. 20, showing an engagement structure comprising teeth;

FIG. 21B is an end view of the bone plate, showing an engagement structure comprising teeth;

FIG. 21C is a medial side view of the bone plate shown in FIG. 5, showing an engagement structure comprising teeth;

FIG. 21D is a sectional view of the bone plate, taken along line 8—8 of FIG. 20, showing an engagement structure comprising spikes;

FIG. 21E is an end view of the bone plate, showing an engagement structure comprising spikes.

FIG. 22 is a perspective view of a bone plate, taken from an anterior side perspective, showing the three-dimensional medial surface contours at top and bottom portions of the preferred embodiment and showing an alternative embodiment of support structure;

FIG. 23 is the perspective view of FIG. 22 shown as a three-dimensional surface model;

FIG. 24 is a perspective view of a bone plate, taken from a posterior side perspective, showing the three-dimensional medial surface contours at top and bottom portions of the preferred embodiment and showing an alternative embodiment of support structure; and

FIG. 25 is the perspective view of FIG. 24 shown as a three-dimensional surface model.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

It should be appreciated that while a preferred embodiment of the present invention will be described with particular reference to a bone fixation system for anterior treatment of thoraco-lumbar spinal instability, the present invention is also contemplated for use in connection with the treatment of other bone anomalies. In this regard, the present invention finds application in the treatment of bone structures in other regions of the spine, as well as bones located in regions outside the spine.

Referring now to the drawings wherein the showings are for the purposes of illustrating a preferred embodiment of the invention only and not for purposes of limiting same, FIG. 1 shows an exploded view of a bone fixation system 10, according to a preferred embodiment of the present invention. Fixation system 10 is generally comprised of a bone plate 20, a plurality of bone screws 100, and a plurality of set screws 140. As fully assembled, screws 100 are inserted through holes formed in plate 20 and driven into a bone structure (e.g., a vertebral body). Set screws 140 are also arranged inside the holes to further lock screws 100 in position (FIG. 2). FIGS. 3 and 4 illustrate fixation system 10 as attached to vertebral bodies V<sub>1</sub> and V<sub>2</sub>. A complete description of the assembly and installation of fixation

system 10 is provided in detail below. In the preferred embodiment illustrated herein, fixation system 10 is configured for treatment of vertebrae T11 to L3.

Turning now to FIGS. 3 thru 10, plate 20 will be described in detail. Plate 20 is generally comprised of a top (cephalad) portion 40, a bottom (caudal) portion 60, and a bridge portion 80. Moreover, plate 20 has an anterior side 22, a posterior side 24, a lateral side 26, a medial side 28, and upper and lower sides 30A, 30B. Plate 20 has a length which is at least sufficient to enable plate 20 to connect at least two vertebrae. However, it will be appreciated that the length of the plate in any particular installation will depend upon the condition to be corrected and the number of vertebrae to be held in a desired spatial relationship relative to each other by plate 20.

Top portion 40 includes a pair of generally circular openings 42, which are dimensioned to receive fastener means, namely, bone screw 100 and set screw 140. Each circular opening 42 has a tapered section 44 and a threaded section 46, as best seen in FIG. 10. Tapered section 44 is generally concentric with threaded section 46. Tapered section 44 has a taper (e.g., Morse taper) extending from a first end adjacent to threaded section 46 to a second end terminating at medial side 28. The taper formed in circular opening 42 matches a mating taper formed on screw 100, as will be explained in detail below in connection with FIG. 11. Threaded section 46 includes threads that mate with threads formed on set screw 140, as will also be explained below.

Tapered section 44 has a diameter which is smaller than the diameter of the adjacent threaded section 46. As a result, an annular shoulder 48 is formed at the interface between tapered section 44 and threaded section 46. Set screw 140 is driven against the top of screw 100, thus forcing screw 100 into tapered section 44.

Bottom portion 60 is similar to top portion 40. Bottom portion 60 includes a pair of generally circular openings 62, which are dimensioned to receive fastener means, namely, screw 100 and set screw 140. Each circular opening 62 has a tapered section 64 and a threaded section 66. Tapered section 64 is generally concentric with threaded section 66. Tapered section 64 tapers from a first end adjacent to threaded section 66 to a second end terminating at medial side 28 (FIGS. 8 and 10). The taper formed in circular opening 62 matches a mating (Morse) taper formed on screw 100, as will be explained below in connection with FIG. 11. Threaded section 66 includes threads that mate with the threads formed on set screw 140, as will also be described below.

Tapered section 64 has a diameter which is smaller than the diameter of the adjacent threaded section 66. As a result, an annular shoulder 68 is formed at the interface between threaded section 66 and tapered section 64. Set screw 140 is driven against the top of screw 100, thus forcing screw 100 into tapered section 64.

It should be appreciated that generally circular openings 42, 62 could be replaced with a plurality of elongated slots.

Bridge portion 80 interconnects top portion 40 and bottom portion 60, and is dimensioned to span an intervertebral space. It is understood that bridge portion 80 can be lengthened or shortened depending upon the total length of plate 20 required for the particular vertebral anatomy. Bridge portion 80 is generally comprised of an anterior wall 82 and posterior wall 84. Anterior wall 82 and posterior wall 84 extend downward from lateral side 26 and act as "struts." It should be appreciated that the length and width of walls 82, 84 may vary. A recess 90 is defined by anterior wall 82,



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posterior wall **84**, and top and bottom portions **40**, **60**. Recess **90** provides an observation window in plate **20**. The observation window allows interoperative graft access and postoperative graft evaluation (i.e., visualization of the healing process in the bone graft) from a lateral X-ray. Graft is not obscured radiographically from any standard view. As illustrated in FIGS. 1–3 and 5–7, recess **90** has a generally elliptical or oval shape. However, it will be appreciated that recess **90** may have varying geometries, including a rectangle, a square, an oval, a parallelogram, or an irregular shape. Moreover, recess **90** could be comprised of a plurality of smaller recesses or holes. Recess **90** could also narrow inward toward the center region to allow visualization of the edges of a graft.

Furthermore, other types of observation windows may be formed in plate **20**. In this regard, one or more suitable openings may be formed in walls **82** and **84** to provide improved anterior-posterior plane visualization. Other embodiments include an observation window formed of solid material, wherein the material is radiolucent, such as a carbon-fiber reinforced polyaryletherketone polymer, and an observation window which has a cap or lid that may be attached to the plate to retain and/or compress graft.

Gaps or notches **34A** are formed between anterior wall **82** and top and bottom portions **40**, **60**. Likewise, gaps or notches **34B** are formed between posterior wall **84** and top and bottom portions **40**, **60**. The gaps or notches **34A** bounding anterior wall **82** define a ledge **86A** at the upper end of anterior wall **82**, and a ledge **86B** at the lower end of anterior wall **82**. Likewise, the gaps or notches **34B** bounding posterior wall **84** define a ledge **88A** at the upper end of posterior wall **84**, and a ledge **88B** at the lower end of posterior wall **84**.

Referring now with particular reference to FIGS. 3 and 4, the gaps or notches **34A**, **34B** are dimensioned to receive a portion of a vertebral body. Ledges **86A**, **86B**, **88A** and **88B** provide support surfaces that protrude into the corpectomy space, so that the endplates of the adjacent vertebral bodies rest on at least one ledge at either end of plate **20** (FIG. 4). It should be noted that suitable graft material will fill the gap between vertebral bodies  $V_1$  and  $V_2$ . The graft material has been omitted from FIGS. 3 and 4 so as to more clearly illustrate the present invention.

It should be understood that ledges **86A**, **88A**, and ledges **86B**, **88B** may be respectively spaced apart from each other by various dimensions. This may allow plate **20** to be used after a corpectomy procedure or after a discectomy procedure. The ledges may extend the full width of the vertebral body. In such case, a pair of “struts” may be connected to each other, effectively forming an intervertebral cage device as an integral unit to the plate. According to alternative embodiments of the present invention, plate **20** could have ledges which are composed of bioresorbable compound (e.g., poly-lactic acid), a bone graft, or a bone graft substitute material. In yet another embodiment of the present invention all of the ledges could be omitted to form a plate which has a flatter, generally planar profile.

It should be appreciated that medial side **28** has an outer surface that is anatomically contoured to match the profile of aspects common to vertebral bodies (e.g., thoracic and lumbar vertebrae). The surface of medial side **28** is contoured to fit the vertebrae. Accordingly, the anterior portion of the medial side surface is relatively curved. The posterior portion of the medial side surface is generally flat in cross-section. Furthermore, as indicated above, plate **20** has gaps or notches **34A**, **34B** which are dimensioned to receive a

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portion of the vertebral bodies. The above-mentioned properties allow: (1) plate **20** to have a low profile (i.e., plate **20** sits “down into,” rather than “on top of” the bone), (2) bio-mechanical load-sharing, which increases the mechanical properties of fixation system **10** (i.e., stiffness, strength and fatigue life), and (3) faster implantation times, as will be explained in detail below.

It will be appreciated that the surface of medial side **28** may have a varied geometry (e.g., engagement members) to allow fitting into the waist(s) of the vertebral bodies, such as steps, spines or teeth. Moreover, the surface of medial side **28** may be formed so as to bite into a bone at the waist of the vertebral bodies, such as with a spike or sharp tooth. Furthermore, the surface of medial side **28** may have a surface treatment which allows bone ingrowth, such as plasma spray, bead-sintering, knurling, hydroxyapatite, bio-active material, a plurality of small holes, roughened or otherwise irregular surfaces.

Screws **100** will now be described in detail with reference to FIGS. 1–2 and 11–12. Each screw **100** is generally comprised of threaded portion **102** and a head portion **110**. Threaded portion **102** extends from the lower end of head portion **110** to rounded tip **106**. Threads **104** are formed along the length of threaded portion **102**. Threaded portion **102** is screwed into a vertebral body  $V_1$ ,  $V_2$ , as will be explained below.

Head portion **110** includes a tapered outer surface **112** and a recess **114**, as best seen in FIG. 11. Tapered outer surface **112** tapers from the top of head portion **110** to the adjacent threaded portion **102**. The taper of outer surface **112** matches the taper formed in tapered sections **44** and **64** of plate **20**. The mating tapers align screw **20** with circular openings **42**, **62**, minimize local stress concentration, and provide pull-out resistance.

Recess **114** has a threaded section **116** and an inner recess section **118**. Threaded section **116** has a radius greater than the radius of inner section **118**. Notches **120** are formed in head portion **110**. Recess **114**, threads **116** and notches **120** are dimensioned to interface with a conventional instrument (e.g., a screw driver with a draw rod) for rotating screw **100**. It should be understood that head portion **110** may take other forms suitable for interfacing with other types of instruments for rotating screw **100**. Moreover, it should be appreciated that other types of suitable fastening devices may be substituted for screws **100**.

In a preferred embodiment of the present invention, screws **100** have a diameter of approximately 7.0 mm, and have a length in the range of approximately 30 mm to 60 mm.

It will be appreciated that screw **100** may have other suitable geometries. For instance, the tapered head could be replaced by a spherical head. The spherical head would allow variable screw angulation. Other suitable alternative geometries include a screw with a flat or oval head which could be captured by a set screw. Moreover, the head of the screw could have a diameter greater than the opening in the bone plate, such that the head of the screw sits on top of the bone plate.

Set screw **140** will now be described with reference to FIGS. 1–2 and 13–14. Set screws **140** are generally comprised of a head portion **142** and a “dog point” or alignment member **160** integral therewith. Head portion **142** includes a threaded outer surface **144**, a recess **146** and a front face **148**. Threaded outer surface **144** has threads that mate with the threads of threaded sections **46** and **66** of plate **20**. In a preferred embodiment of the present invention, head portion



**142** has an outer diameter of approximately 9.5 mm. Recess **146** has internal threads. Moreover, notches **150** are formed at the upper end of head portion **142**. Similar to the head portion **110** of screw **100**, recess **146**, threads **145** and notches **150** are dimensioned to interface with a conventional instrument (e.g., a screw driver with a draw rod) for rotating set screw **140**. It should be understood that head portion **142** may take other forms suitable for interfacing with other types of instruments for rotating set screw **142**.

Alignment member **160** is integrally attached to head portion **142** at front face **148**. According to a preferred embodiment, alignment member **160** includes a generally cylindrical elongated portion **162** and a full spherical radius tip **164** at the distal end thereof. It will be appreciated elongated portion **162** may have other suitable geometries (e.g., hex, square, etc.). Moreover, tip **164** may be flat or have other suitable geometries.

It will be appreciated that set screw **140** may have alternative configurations. In this regard, the alignment member could have a non-circular shape or a sharp tip. In another embodiment alignment member **160** may be omitted from set screw **140**, thus providing a set screw with a generally planar front face. Moreover, the alignment member **160** could be omitted and replaced with a hole extending through the entire set screw. In this case, the alignment member (e.g., dog point) could be located on the driving instrument. In yet another embodiment, a cannulated (i.e., tubular) bone screw could be used with a set screw that is aligned by driving it along a wire inserted through the bone screw (and also through the set screw).

In a preferred embodiment of the present invention, set screw **140** has a diameter of approximately 9.5 mm.

It will be appreciated that in an alternative embodiment of the present invention, set screws **140** could be replaced by other suitable locking mechanisms.

Both screws **100** and set screws **140** are preferably made of implant grade titanium alloy (Ti-6Al-4V (ELI) per ASTM F-136), or other biocompatible material, such as stainless steel, carbon fiber reinforced polyaryletherketone composites and the like.

It should be appreciated that screws **100**, set screws **140**, and the respective screw and set screw interfaces formed in plate **20** (i.e., screw-plate interface) are suitable for use with other similar connecting devices, including hooks, rod connectors, ligament anchors, and the like.

Moreover, it should be appreciated that the screws, set screws, and screw and set screw interface formed in plate **20** may take various alternative forms. For instance, a slightly offset set screw could be used to provide the locking force. In yet another embodiment, the plate could be arranged with only a taper interface for receiving only tapered-head screws, without the use of any set screws. Other alternatives, include the use of a press fit mechanism in which a screw is driven into an undersized hole formed in the plate. As a result, locking is provided by material deformation. In yet another embodiment, an alternative locking screw geometry, such as a spherical-head screw with a set screw driven directly down onto them could be employed. Such an arrangement could provide a variable-screw angle system. Another option is to provide a screw with slots or holes arranged to correspond to similar geometries formed on the plate. The holes could be filled with bone cement or similar material to prevent screw movement, in lieu of a set screw. Other alternatives include a set screw which compresses more than one screw to provide locking, and a plate which has a plurality of slots for variable screw placement.

As indicated above, fixation system **10** is particularly well suited for the treatment of thoraco-lumbar spinal instability caused by such conditions as trauma, tumor, severe disc degeneration, and anterior fusion following multiple posterior operations including pseudoarthrosis. A brief summary of the preferred surgical technique will now be described.

Prior to installation, medial-lateral and anterior-posterior X-rays, CT scans, and MRI images may be useful in determining angular deformity, degree of canal compromise, and potential instability. Moreover, such images may also be useful to approximate the correct size of plate **20** and length of screw **100**.

The patient undergoing treatment is positioned in a lateral decubitus position. Preferably, a retroperitoneal or combined thoraco-lumbar surgical approach is used. Next, the spine is exposed one level above and one level below the damaged segment. The site is then prepared by removing the disc material adjacent to the damaged vertebrae. A vertebral body distractor is placed inside the site, against the caudal endplate of the cephalad body and the cephalad endplate of the caudal body. A distraction sufficient to assist in the corpectomy procedure is then applied. Following distraction a corpectomy procedure is performed.

Graft placement is carried out by: (1) measuring the medial-lateral width of the vertebral bodies to determine the screw length required, (2) measuring the graft site, (3) harvesting and shaping an autologous tri-cortical iliac crest graft to fit within the site created, (4) determining the appropriate plate size by comparison to the graft site measurement, (5) placing the graft, (6) removing the vertebral body distractor, and (7) placing additional morselized graft anterior to the strut graft, if needed.

Installation of fixation system **10** will now be described with particular reference to FIGS. 1-4. After the graft has been properly sized and an appropriate sized plate **20** has been selected, plate **20** will fit into the narrow waist of the adjacent vertebral bodies. At least one ledge of **86A** and **88A**, and one ledge of **86B** and **88B**, should contact each adjacent vertebral body. This allows the load to be transferred through the "struts" (i.e., walls **82** and **84**) of plate **20**, rather than through screws **100**. It should be noted that unusual anatomy may require some bone material to be removed to allow plate **20** to seat properly on the vertebral body.

Next, a first hole is created at the posterior caudal location. An awl cannula is inserted into the appropriate circular opening **42**, **62** in plate **20**. The awl shaft is then inserted through the awl cannula. The lateral cortex is punctured by firmly pushing down on the awl shaft. As an alternative procedure, the awl shaft may be screwed onto the awl cannula, and the awl is then used as a one-piece instrument. However, this may cause difficulty in creating a properly aligned hole, which in turn may cause difficulty in placing screws **100**.

A first screw **100** is then driven into the bone. In this regard, a screw **100** is loaded onto the driver using a flat-ended draw rod. Turning the draw rod clockwise will pull screw **100** firmly against the driver. Screw **100** is then driven into the bone. However, screw **100** is not fully tightened. This prevents the opposite end of plate **20** from lifting off the bone slightly, making it difficult to place subsequent screws. Proper screw length should be verified, either radiographically or by direct palpation. At least one full thread should engage the contralateral cortex. It should be appreciated that the driving tapered head **112** of screw **100** into mating tapered section **44**, **64** of plate **20**, forces



proper alignment between screw 100 and plate 20, provides “pull-out” resistance, and evenly distributes stresses on both screw 100 and plate 20. The latter may significantly affect the fatigue life of screws 100.

The above steps are repeated for the remaining screws 100. The second screw inserted should be the other posterior side location. The third and fourth screws should be the remaining anterior side locations. None of the screws should be completely tightened until all of the screws have been inserted.

Next, set screws 140 are loaded onto the driver. Alignment member 160 of set screw 140 is inserted into recess 114 of screw 100 to aid in locating set screw 140 and prevent cross-threading. Alignment member 160 forces an orthogonal alignment of threaded outer surface 144 and mating threaded section 46, 66 of plate 20. It should be appreciated that the radius of threaded section 116 is larger than the radius of alignment member 160. Set screws 140 are preferably tightened to approximately 60 inch-pounds. It should be noted that set screws 140 may be inserted into circular openings 42, 62 in any sequence desired.

It should be appreciated that driving set screws 140 on top of screws 100 forces screws 100 deeper into tapered section 44, 64, and prevents screws 100 from moving. As a result, the set screws have effectively turned an all-screw construct into an all-bolt construct.

Following installation, the wound is closed, and post-operative procedures are implemented.

As indicated above, plate 20 itself is contoured to fit the lateral profile of the thoraco-lumbar vertebrae. Since the primary use of the present invention is some form of a corpectomy or discectomy procedure, plate 20 takes advantage of the removed bone medial to the implant. The added thickness provides for better rigidity for plate 20, and allows for ledges 86A, 86B, 88A, 88B that are able to support the vertebrae in direct compression. Since the material is added into the corpectomy space, the profile of the construct is lower, as compared to prior art plate designs.

The present invention also provides significant improvements in stiffness and stress. Computer simulations show plate 20 to be approximately 7X to 10X stiffer than prior art plates. Moreover, the maximal stress concentrations of plate 20 were found to be approximately ¼ to ¾ the maximal stress concentrations of prior art plates.

As indicated above, plate 20 is anatomically fitted to the vertebral bodies. Consequently, a significant portion of the stress will be transferred directly to plate 20, rather than through screws 100. Plate 20 supports vertebral bodies in a manner similar to a corpectomy cage. Such loading condition shields screws 100, thus extending their fatigue life.

The present invention provides an enhanced screw-plate interface. As indicated above, the head portion of screws 100 have a taper, which matches a taper on plate 20. The mating tapers prevent screws 100 from backing out once tightening force is applied. In addition, set screws 140 are driven into plate 20 directly on top of screws 100, thus preventing any noticeable movement.

It should be appreciated that plate 20 may take other suitable forms. For instance, plate 20 could have a generally flat profile, thus virtually eliminating the downward extending walls 82 and 84 and corresponding ledges 86 and 88. Moreover, plate 20 could be modified to receive only a screw, rather than a screw and a set screw.

Turning now to FIGS. 15–18, an alternative embodiment of the bone plate will be described. Bone plate 20' is similar

in many respects to bone plate 20 described above. However, bone plate 20' reduces the amount of material needed to form the bone plate. Moreover, bone plate 20' has a reduced profile, which in turn is less intrusive to body tissue. In order to provide these features, the lateral side of the bone plate has been modified as shown in the figures. In particular, lateral side 26' has three primary surface levels. Lower surface 124 is located adjacent to the anterior side circular openings 42, 62. Upper surface 128 is located adjacent to the posterior side circular openings 42, 62. A middle surface 126 is located between lower surface 124 and upper surface 128. Middle surface 126 comprises the majority of lateral side 26', as best seen in FIG. 17. Generally sloping surfaces provide a transition between the lower, middle and upper surfaces, as best seen in FIGS. 15–16 and 18.

It should be appreciated that upper surface 128 is at the same general level as the surface of lateral side 26 of bone plate 20 (FIG. 8). Middle surface 126 and lower surface 124 are reduced from this level. The level of lower surface 124 is reduced to a level wherein the threaded sections of anterior side circular openings 42, 62 are removed. In this regard, anterior side circular openings 42, 62 include only a respective tapered section 44, 64. Consequently, no set screw 140 is used in connection with the anterior side circular openings 42, 62 of bone plate 20'. The top surface of head portion 110 of screw 100 is generally flush with lower surface 124, when bone plate 20' is appropriately installed. Posterior side circular openings 42, 62 are configured the same as those described in connection with bone plate 20.

It should also be noted that bone plate 20' has slightly modified medial side 28'. In this regard, a rounded corner portion 29 is formed at the anterior end of medial side 28' (FIG. 18). This differs from the protruding corner formed at the anterior end of medial side 28 of bone plate 20 described above (FIG. 8). Rounded corner portion 29 allows for yet more reductions in material.

The invention has been described with reference to a preferred embodiment. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. It is intended that all such modifications and alterations be included insofar as they come within the scope of the appended claims or the equivalents thereof.

Having thus described the invention, it is now claimed:

1. A bone fixation system comprising:
  - a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between said top portion and said bottom portion, said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion, and said bottom portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion, said medial side of said top and bottom portions being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;
  - at least one support structure having medial surface contours extending substantially from an anterior surface of said three-dimensionally contoured elongated



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- plate to a posterior surface of said three-dimensionally contoured elongated plate, said medial surface contours capable of engaging external surfaces of bone structures; and
- a fastener for fastening said plate to said bone structures. 5
2. A bone fixation system according to claim 1, wherein said at least one support structure includes contoured gaps located adjacent to said top and bottom portions.
3. A bone fixation system according to claim 2, wherein said contoured gaps have support surfaces that are connected together to form an intervertebral cage device. 10
4. A bone fixation system according to claim 2, wherein said contoured gaps include at least one of: bioresorbable compound, bone graft, or bone graft substitute material. 15
5. A bone fixation system according to claim 1, wherein said bridge portion includes at least one window extending from a lateral side through a medial side of said bridge portion for observation of a graft area.
6. A bone fixation system according to claim 5, wherein said at least one window includes an opening having a general shape of: an ellipse, rectangle, square, oval or parallelogram. 20
7. A bone fixation system according to claim 5, wherein said at least one window includes a plurality of holes. 25
8. A bone fixation system according to claim 5, wherein said at least one window has an irregular shape.
9. A bone fixation system according to claim 1, wherein said top and bottom portions each include at least one opening dimensioned to receive said fastener. 30
10. A bone fixation system according to claim 9, wherein said at least one fastener opening includes a first fastener receiving section having a tapered surface, said fastener including a mating tapered surface, wherein said mating tapered surface generally matches the tapered surface of said first fastener receiving section. 35
11. A bone fixation system according to claim 10, wherein said fastener includes a set screw member having a threaded surface.
12. A bone fixation system according to claim 9, wherein said at least one opening includes a section dimensioned to receive a press fit fastener. 40
13. A bone fixation system according to claim 9, wherein said at least one opening is an elongated slot.
14. A bone fixation system according to claim 9, wherein said fastener includes a head portion, said at least one opening dimensioned to receive at least a portion of said head portion. 45
15. A bone fixation system according to claim 14, wherein said head portion is generally spherical, oval, hex or flat. 50
16. A bone fixation system according to claim 9, wherein said fastener includes a head portion, said head portion having a diameter greater than said at least one opening.
17. A bone fixation system according to claim 1, wherein said plate has a medial side having engagement structure for engaging with at least one of said bone structure. 55
18. A bone fixation system according to claim 17, wherein said engagement structure includes at least one of: spikes and teeth.
19. A bone fixation system according to claim 1, wherein said plate has a medial side having a surface treatment allowing bone ingrowth. 60
20. A bone fixation system according to claim 19, wherein said surface treatment includes at least one of: plasma spray, bead sintering, knurling, hydroxyapatite, bioactive material, a plurality of holes, and roughened or otherwise irregular surfaces. 65

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21. A bone fixation system comprising:  
an elongated plate means having a top portion, a bottom portion, and a bridge portion integrally spanning between the top portion and bottom portion, said bridge portion for connecting at least two bone structures; and  
a fastener means for fastening the plate means to said at least two bone structures; and  
wherein said top and bottom portions each include at least one opening dimensioned to receive said fastener means; and  
wherein said at least one opening includes a first fastener receiving section having a tapered surface, said fastener means including a mating tapered surface, wherein said mating tapered surface generally matching the tapered surface of said first fastener receiving section; and  
wherein said fastener means includes a set screw member having a threaded surface; and  
wherein said at least one opening includes a second fastener receiving section having a mating threaded surface, said mating threaded surface generally matching the threaded surface of said set screw member.
22. A bone fixation system according to claim 21, wherein said set screw member includes an means for aligning said set screw with said at least one opening.
23. A bone fixation system according to claim 21, wherein said fastener means includes a head portion and wherein said at least one opening is dimensioned to receive at least a portion of said head portion.
24. A bone fixation system according to claim 23, wherein said head portion is generally spherical, oval, hex, or flat.
25. A bone fixation system according to claim 21, wherein said fastener means includes a head portion, said head portion having a diameter greater than said at least one opening.
26. A bone fixation system according to claim 21, wherein said at least one opening is an elongated slot.
27. A bone fixation system according to claim 21, wherein said at least one opening includes a section dimensioned to receive a press fit fastener.
28. A bone fixation system comprising:  
a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between said top portion and said bottom portion, said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion, and said bottom portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion, said medial side of said top and bottom portions being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;  
at least one support structure capable of engaging external surfaces of bone structures at terminal ends of said bone structures; and  
a fastener for fastening said plate to said bone structures.
29. A bone fixation system according to claim 28, wherein said bridge portion includes at least one window extending from a lateral side through a medial side of said bridge portion for observation of a graft area.
30. A bone fixation stem according to claim 28, wherein said at least one support structure includes ledge members located adjacent to said top and bottom portions.



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31. A bone fixation system according to claim 30, wherein said ledge members are connected together to form an intervertebral cage device.

32. A bone fixation system according to claim 30, wherein said ledge members include at least one of: bioresorbable compound, bone graft, or bone graft substitute material. 5

33. A bone fixation system comprising:  
a three-dimensionally contoured elongated plate having a top portion, a bottom portion, and a bridge portion integrally spanning between said top portion and said bottom portion along the longitudinal axis of said three-dimensionally contoured elongated plate, said three-dimensionally contoured elongated plate further having a lateral-medial axis and an anterior-posterior axis, said top portion having a medial side comprising three dimensional surface contours extending substantially from an upper end of said top portion to said bridge portion and extending substantially from an anterior side of said top portion to a posterior side of said top portion wherein said three dimensional surface contours further comprise contours about said longitudinal and said anterior-posterior axes, and said bottom

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portion having a medial side comprising three dimensional surface contours extending substantially from a lower end of said bottom portion to said bridge portion and extending substantially from an anterior side of said bottom portion to a posterior side of said bottom portion wherein said three dimensional surface contours further comprise contours about said longitudinal and said anterior-posterior axes, said three-dimensional surface contours of said top portion and bottom portion being contoured to anatomically fit both an anterior and a lateral profile of a bone structure;

at least one support structure having medial surface contours extending substantially from an anterior surface of said three-dimensionally contoured elongated plate to a posterior surface of said three-dimensionally contoured elongated plate, said medial surface contours capable of engaging external surfaces of bone structures; and

a fastener for fastening said plate to said bone structures.

\* \* \* \* \*

## Fatigue Characterization of Hook/Rod Assemblies Loaded in Compression

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- <sup>^</sup> Rolando Puno, MD, Medical Director, Orthopaedic Biomechanics Research Lab and Assistant Professor, University of Louisville, Louisville, Kentucky.
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First presented at "The 2nd International Meeting on Advanced Spine Techniques" April 26-29, 1995.

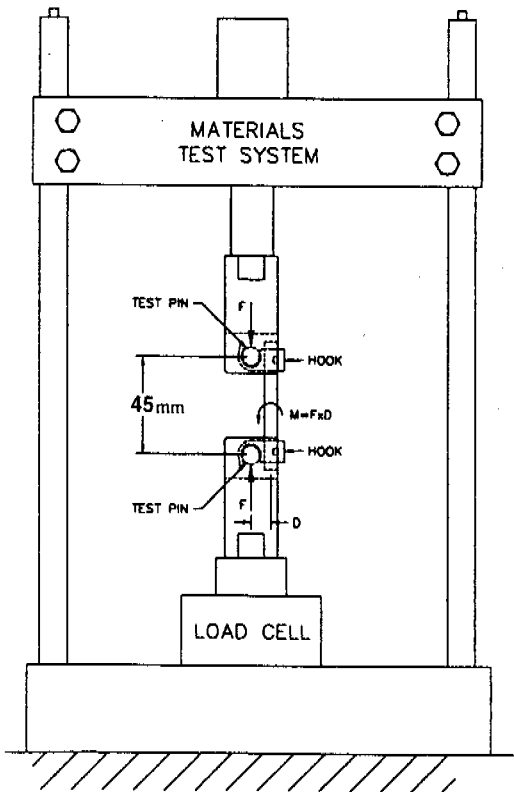


INTRODUCTION:

The Harrington hook/rod system was the most widely used posterior spinal instrumentation for nearly three decades. Improving on Harrington's concepts, the Cotrel-Dubousset (CD) system, developed in France in the early 1980's, utilized additional hook fixation sites to facilitate manipulation and correction of the spine while improving construct stiffness. Recently, other systems such as Texas Scottish Rite Hospital (TSRH), Isola and Synergy have evolved, attempting to minimize the possibility of fatigue failure and/or loss of correction. The purpose of this study is to compare fatigue endurance limits (FEL) and dynamic stiffness of Harrington, CD, TSRH, Isola and Synergy hook/rod assemblies loaded in compression.

MATERIALS AND METHODS:

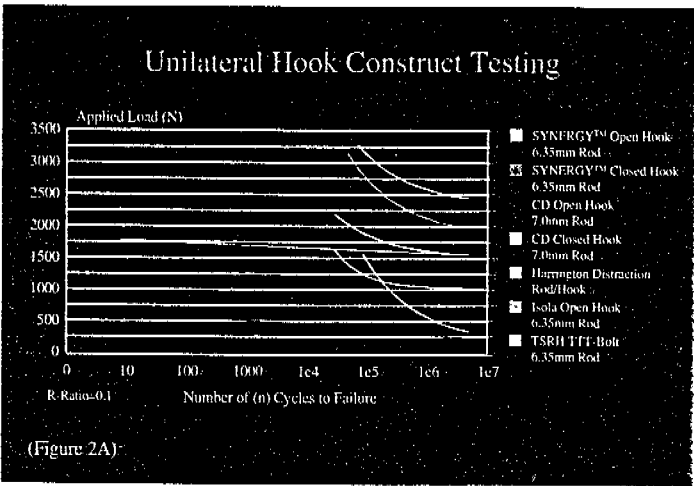
All constructs were assembled according to manufacturer specifications and conducted under ambient conditions. A minimum of four constructs from each design were tested in dynamic compression. Each construct consisted of two hooks and one rod, with the hooks loaded through test pins placed in the hook throat and spaced 45mm apart along the rod (Figure 1). The constructs were tested under cyclic fatigue to develop load/moment vs. number of cycles curves, and dynamic stiffness was determined within the first 1000 cycles of each test by capturing peak and valley points from both force and displacement sine waves. Differences were evaluated for statistical significance for dynamic stiffness in the standard manner ( $p=0.05$ ), and for FEL by determining if the 95% confidence limits fitted to each curve overlapped. The designs tested were Harrington closed hooks on distraction rod, CD open hooks on knurled 7mm rod, CD closed hooks with two set screws on knurled 7mm rod, TSRH single post hooks with top tightening t-bolt on 6.35mm rod, Isola open hooks on 6.35mm rod, Synergy open hooks on 6.35mm rod, and Synergy closed hooks on 6.35mm rod.



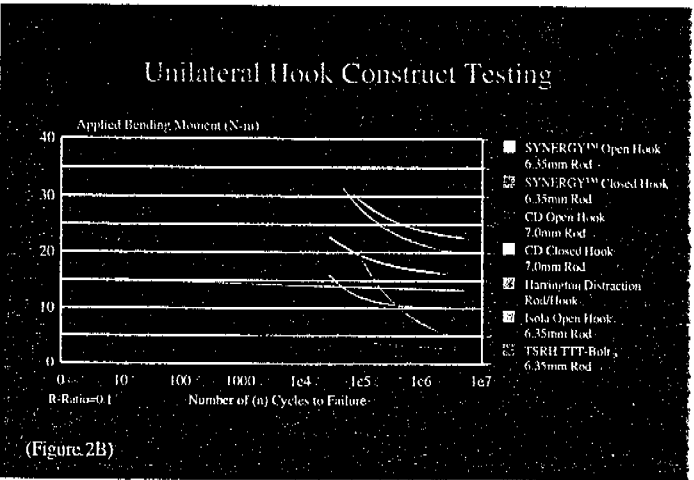
(Figure 1)

RESULTS:

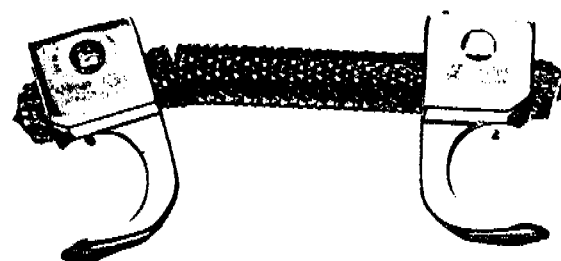
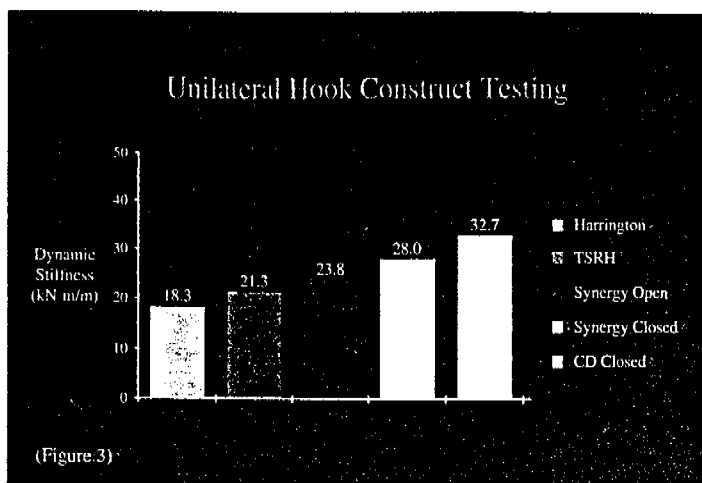
The load vs. number of cycles curves (Figure 2A) show significant differences in FEL between all constructs except Isola Open vs. Harrington and CD Open vs. TSRH. The moment vs. number of cycles curves (Figure 2B) show differences between all constructs except CD Open vs. TSRH. The CD Open and Isola Open constructs were not able to generate a fatigue curve as any load above the FEL caused collapse of the construct in 20 cycles or less. The dynamic stiffness values (Figure 3) show differences between all constructs except the Harrington vs. TSRH and the TSRH vs. Synergy Open. The CD Open and Isola Open constructs were not able to generate a stiffness average with only one value for each. Typical failure modes for the different designs are shown in Figure 4A-F.



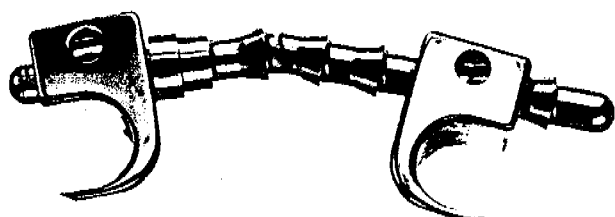
(Figure 2A)



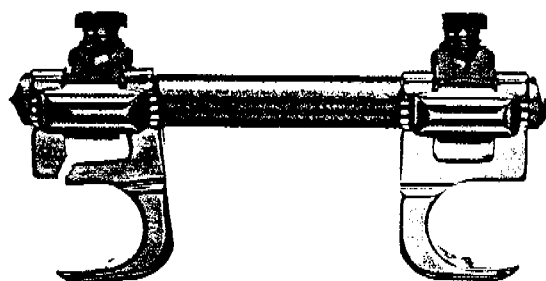
(Figure 2B)



(Figure 4D)



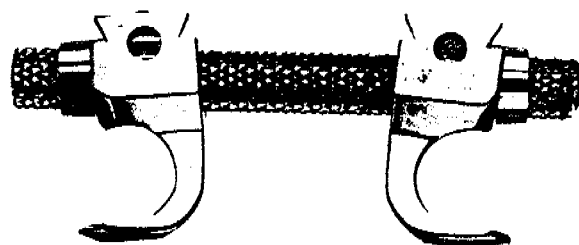
(Figure 4A)



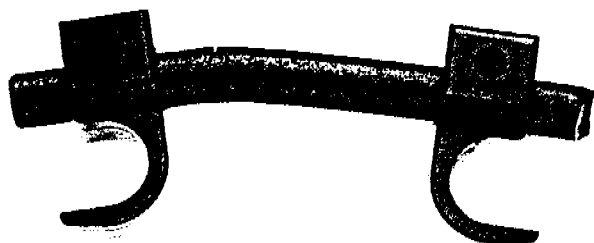
(Figure 4E)



(Figure 4B)



(Figure 4F)



(Figure 4C)

### CONCLUSIONS:

For the construct tested, stiffness and FEL's have generally improved as posterior hook instrumentation has evolved from the Harrington design. The increases in stiffness appear to be primarily due to increased rod stiffness and improved hook to rod clamping mechanisms. The increases in FEL appear to be primarily due to enhanced rod geometry and improved hook to rod clamping mechanisms, while the decreases can be traced to failure of the hook to rod clamping mechanism and/or the hook itself. Of clinical relevance, assuming all instrumentation is used with the same number of hook fixation sites, these increases should lead to reduced occurrences of instrumentation failure and loss of correction, and may contribute to higher rates of fusion.



PINNACLE

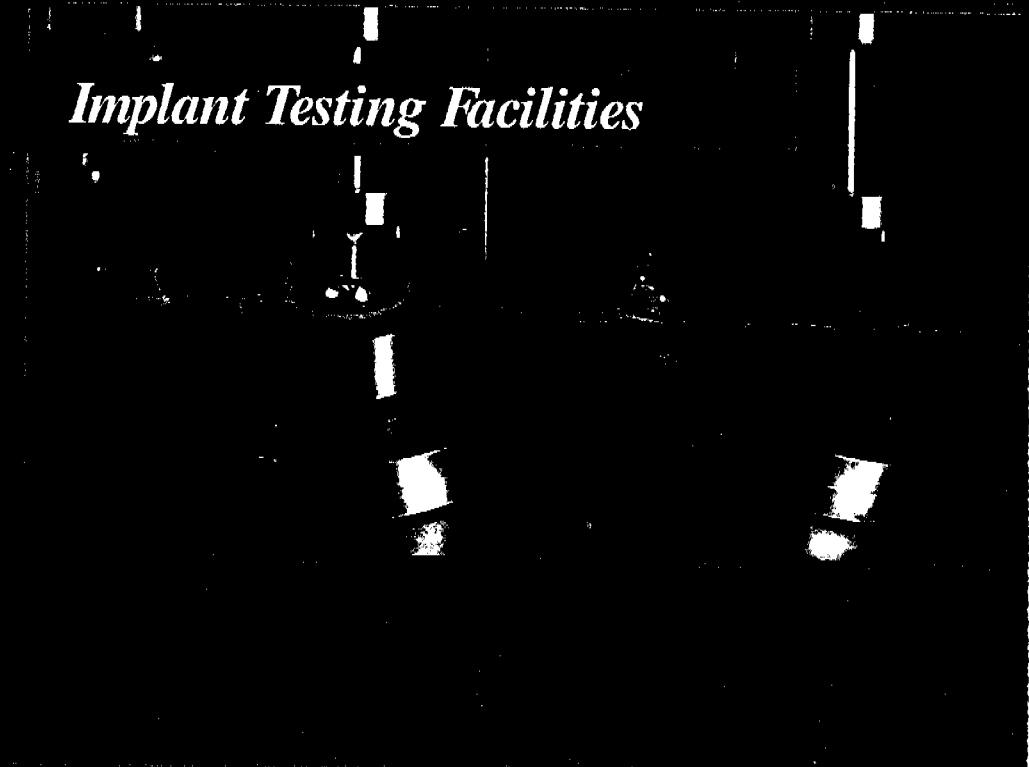
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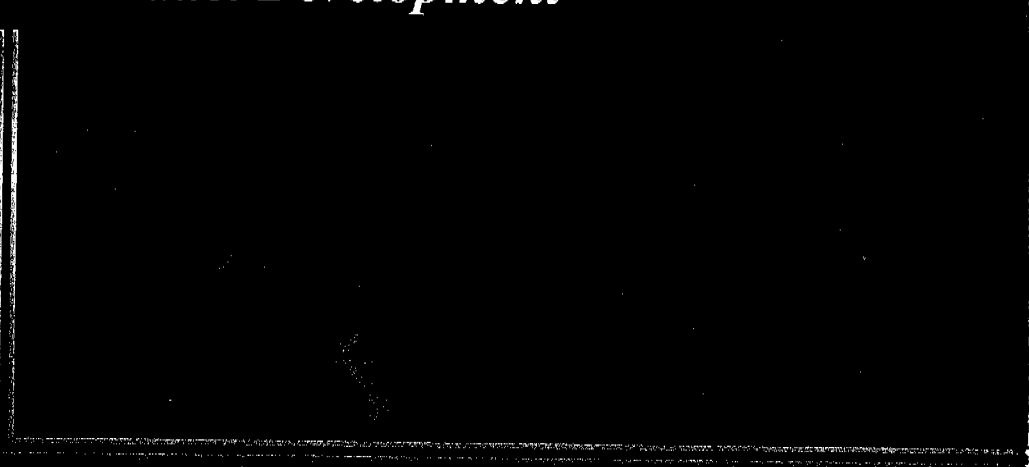
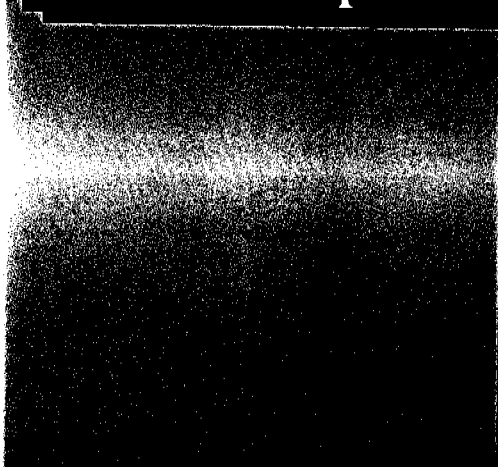
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A tremendous growth in the use of orthopaedic implants has occurred over the past twenty years; though age old problems of prosthesis wear, fixation, and biocompatibility have yet to be solved. Competition in the market place is fierce, and the demand for product safety and reliability is continually increasing. Success in the global marketplace is dependent upon medical manufacturers being increasingly more innovative in improving the performance of devices, utilizing technology to rapidly get product to market, and delivering the product at the right price to healthcare purchasers. The design, development, and testing of orthopaedic implants demands multi-disciplinary personnel, but maintaining a comprehensive in-house technical base can be prohibitively expensive. This is where Theken Orthopaedic with its reputation in design, development, and testing can help.

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At Theken Orthopaedic the most essential attribute of our organization is the dovetail collaboration of our associates. This reinforces a guiding principle of ours, that a dedicated group working in harmony can accomplish far more than an equal number of individuals. Theken Orthopaedic is a company with strong values that are reflected in the quality of our work, in our management philosophies, and in the progressive and imaginative ideas we develop to support our customers needs.

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Randy Theken  
President

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Our Orthopaedic Testing Facility is a state-of-the-art facility designed to simulate the in vivo environment of the human body. We offer a wide range of testing services, including mechanical, biological, and clinical testing, to meet the needs of our clients. Our facilities are equipped with the latest technology and staffed by experienced professionals, ensuring that every test is conducted with precision and accuracy. We are committed to providing our clients with the most reliable and comprehensive testing services available in the industry. Our facilities are designed to simulate the in vivo environment of the human body, ensuring the highest quality and performance of our implants. We offer a wide range of testing services, including mechanical, biological, and clinical testing, to meet the needs of our clients. Our facilities are equipped with the latest technology and staffed by experienced professionals, ensuring that every test is conducted with precision and accuracy. We are committed to providing our clients with the most reliable and comprehensive testing services available in the industry.

Theken Orthopaedic provides a wide range of testing services, including mechanical, biological, and clinical testing, to meet the needs of our clients. Our facilities are equipped with the latest technology and staffed by experienced professionals, ensuring that every test is conducted with precision and accuracy. We are committed to providing our clients with the most reliable and comprehensive testing services available in the industry. Our facilities are designed to simulate the in vivo environment of the human body, ensuring the highest quality and performance of our implants. We offer a wide range of testing services, including mechanical, biological, and clinical testing, to meet the needs of our clients. Our facilities are equipped with the latest technology and staffed by experienced professionals, ensuring that every test is conducted with precision and accuracy. We are committed to providing our clients with the most reliable and comprehensive testing services available in the industry.

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**S**uccess in product development is a complex process. It requires a combination of technical expertise, creative thinking, and efficient communication. Theken Orthopaedic's Product Development team is dedicated to creating innovative solutions that meet the needs of our customers. We work closely with our clients to understand their requirements and develop a customised product that meets their needs. Our team is experienced in all aspects of product development, from initial concept to final production. We use the latest technology and materials to create products that are both functional and aesthetically pleasing. Our commitment to quality and customer service is what sets us apart from the competition. We are proud to be a leader in the orthopaedic industry and look forward to continuing our growth and innovation.

Computer-aided design (CAD) is a key technology in product development. It allows us to create detailed 3D models of our products, which can be used to simulate their performance and identify potential issues before production. This helps us to optimise our designs and ensure that our products are of the highest quality. CAD also allows us to create customised products for our clients, which is a key competitive advantage. We use CAD to create products that are both functional and aesthetically pleasing. Our commitment to quality and customer service is what sets us apart from the competition. We are proud to be a leader in the orthopaedic industry and look forward to continuing our growth and innovation.

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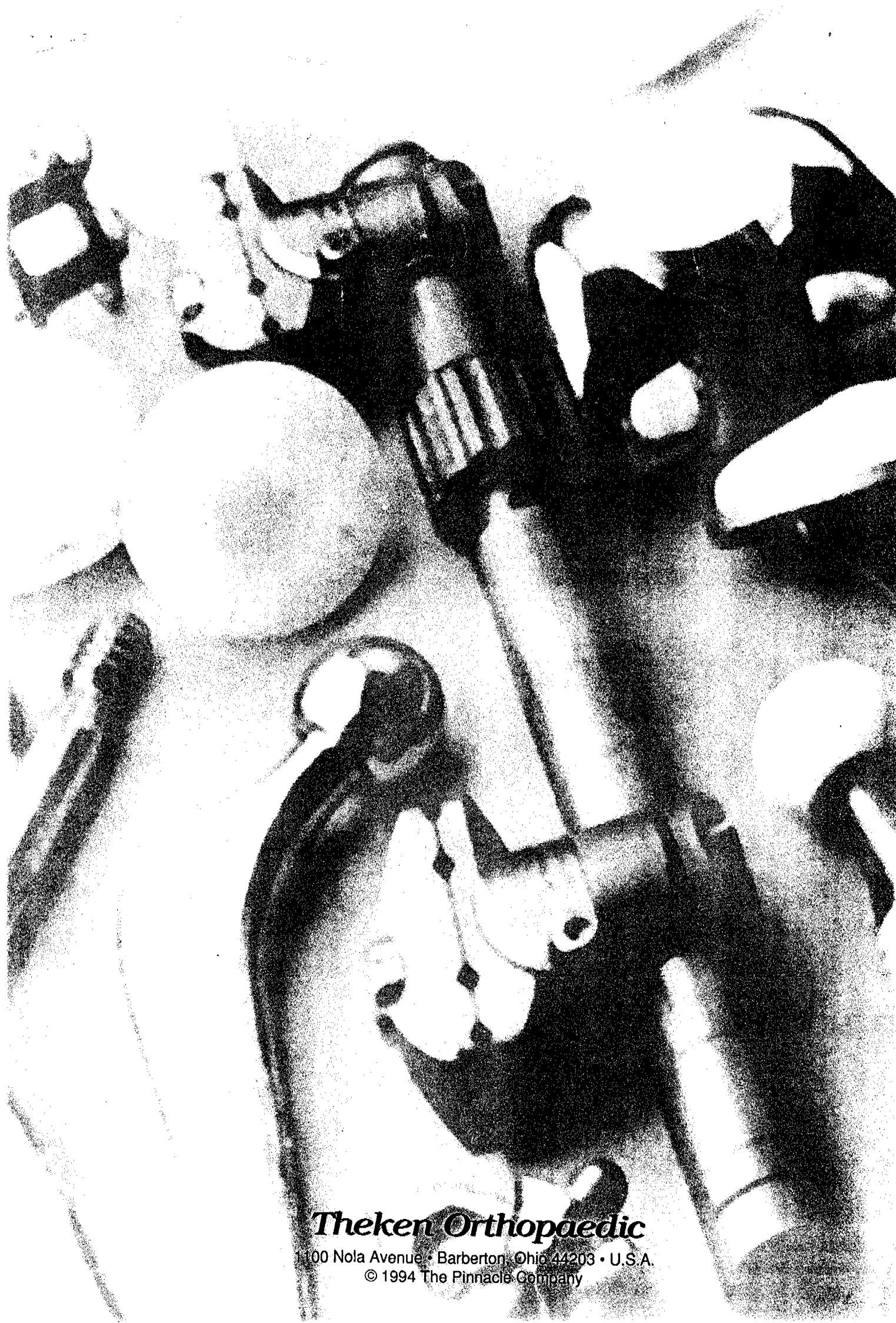
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## **Fatigue Characterization of Anterior Screw/Rod Constructs in Axial Compression**

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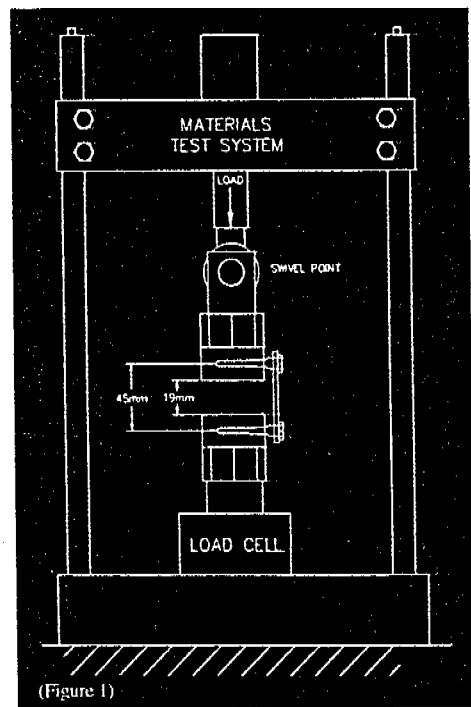
First presented at "The 2nd International Meeting on Advanced Spine Techniques" April 26-29, 1995.

INTRODUCTION:

Zielke anterior spinal instrumentation revolutionized scoliosis surgery in the 1970's, allowing powerful correction and stabilization of the anterior column of the spine. However, recent studies have shown significant instances of rod breakage and/or loss of correction with this instrumentation. Harms modified the Zielke system with polyaxial screws to give the instrumentation more degrees of freedom, but used a similar threaded rod. The Texas Scottish Rite Hospital (TSRH) anterior system elected to use a solid 4.75mm diameter rod and larger diameter screws (6.5mm) instead of the 6mm screws and 3.2mm or 4mm threaded rods of the Zielke system, believing that this would minimize instrumentation failure and loss of correction while providing a stiffer construct. The Synergy anterior system also uses a solid 4.75mm rod and has a variety of screw options including 6mm and 6.5mm diameter screws in open and closed designs. The purpose of this study is to compare fatigue endurance limits (FEL) and dynamic stiffness of Zielke, Harms, TSRH and Synergy screw/rod constructs.

MATERIALS AND METHODS:

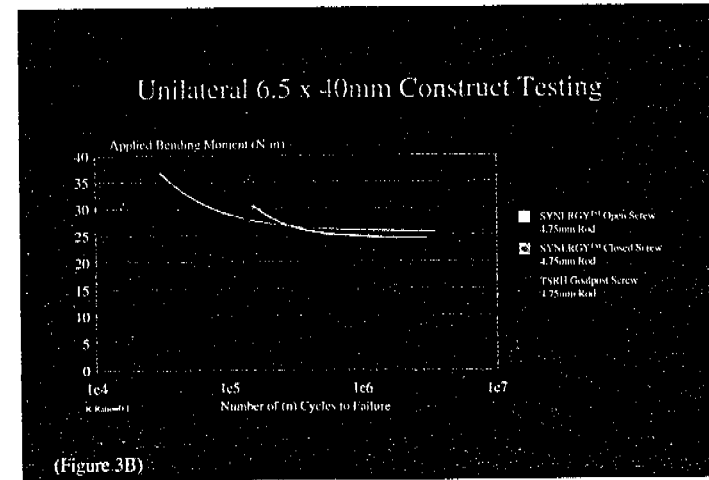
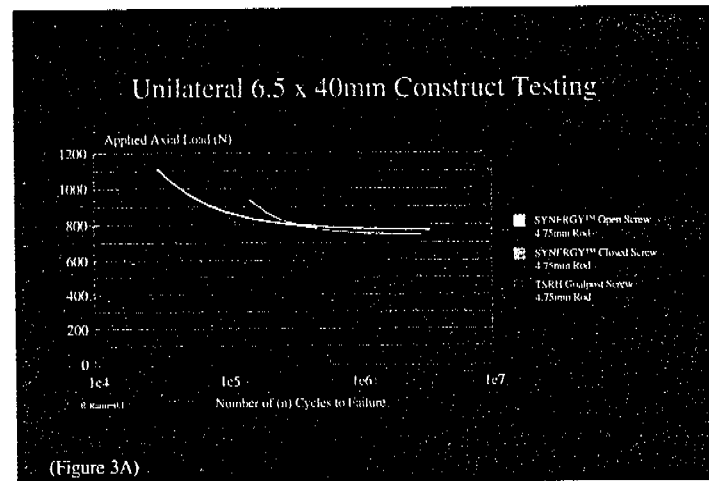
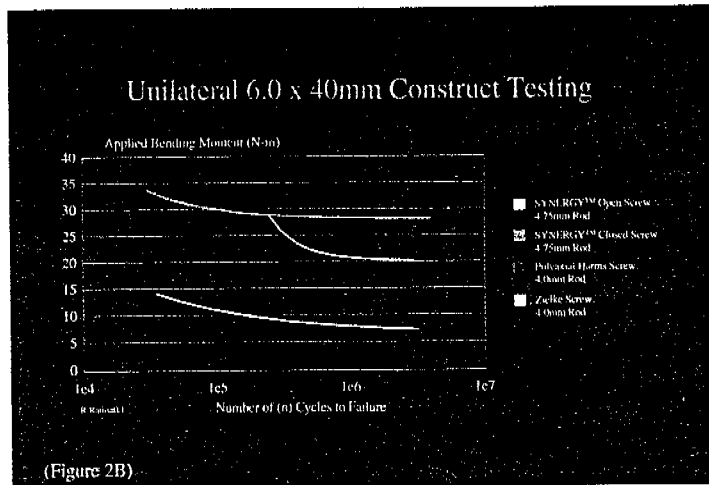
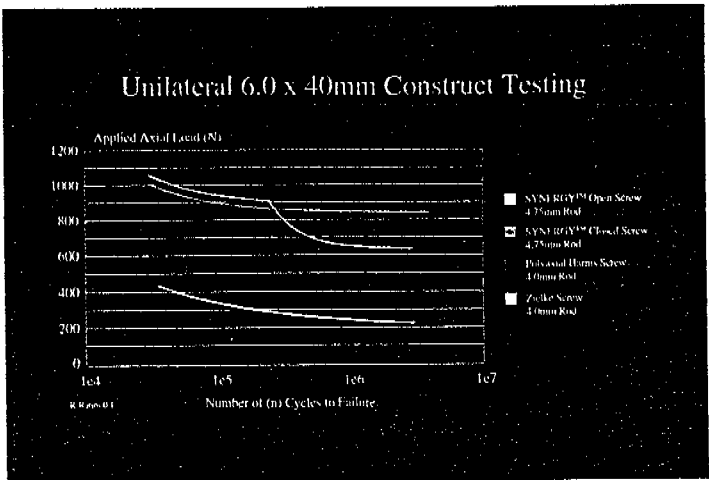
All constructs were assembled according to manufacturer specifications and conducted under ambient conditions. A minimum of six constructs from each design were tested in dynamic axial compression. Each construct consisted of two UHMW polyethylene pucks simulating vertebral bodies, two screws and one rod (Figure 1). The constructs were tested under cyclic fatigue to develop



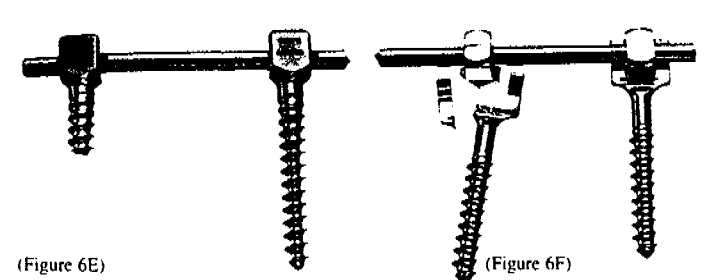
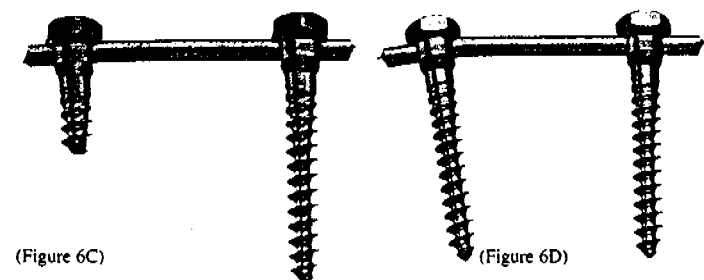
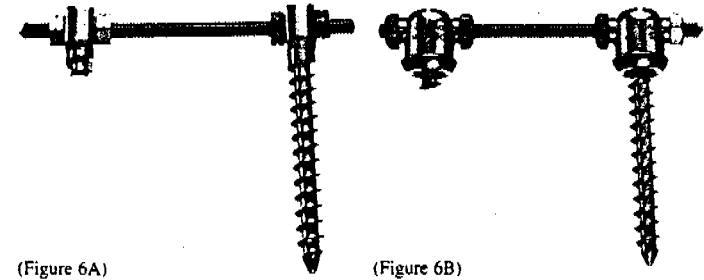
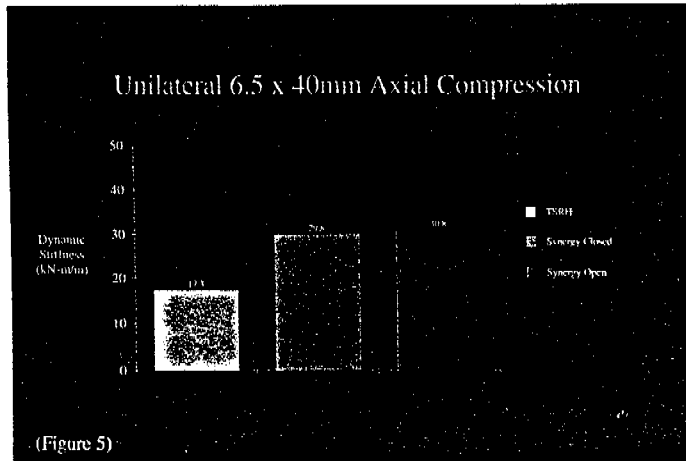
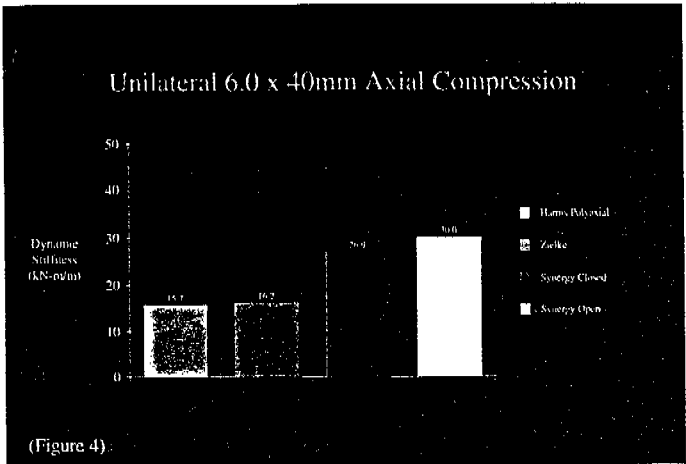
load/moment vs. number of cycles curves, and dynamic stiffness was determined within the first 1000 cycles of each test by capturing peak and valley points from both force and displacement sine waves. Differences were evaluated for statistical significance for dynamic stiffness in the standard manner ( $p=0.05$ ), and for FEL by determining if the 95% confidence limits fitted to each curve overlapped. The designs tested were Zielke 6 x 40mm top opening screws on a 4mm threaded rod, Harms 6 x 40mm polyaxial screws on a 4mm threaded rod, Synergy 6 x 40mm open screws on a 4.75mm rod, Synergy 6 x 40mm closed screws on a 4.75mm rod, TSRH 6.5 x 40mm goalpost screws on a 4.75mm rod, Synergy 6.5 x 40mm open screws on a 4.75mm rod, and Synergy 6.5 x 40mm closed screws on a 4.75mm rod.

RESULTS:

The load and moment vs. number of cycles curves for the 6mm screw constructs (Figure 2A-B) show significant differences in FEL between the Synergy Open and Closed screw constructs and the Zielke and Harms constructs. The Synergy Open screw construct developed a double curve with a screw breaking at the higher loads and the rod breaking at the lower loads. The 6.5mm screw fatigue curves (Figure 3A-B) show differences in FEL between the Synergy Open and Closed screw constructs and the TSRH construct, with all three significantly higher than the Zielke value.

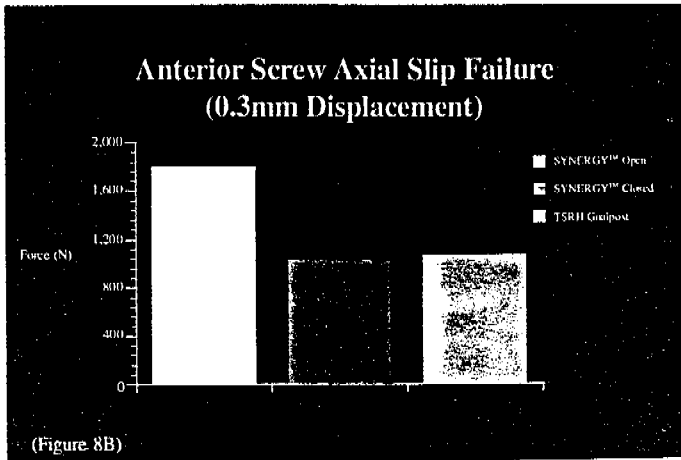
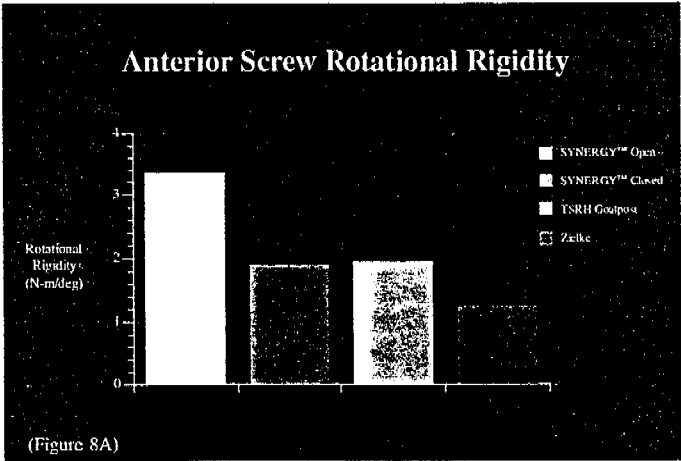
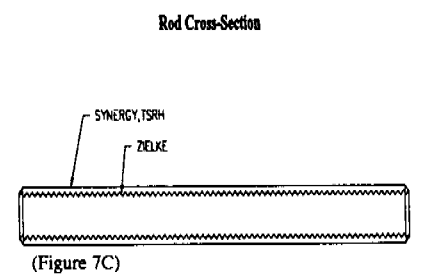
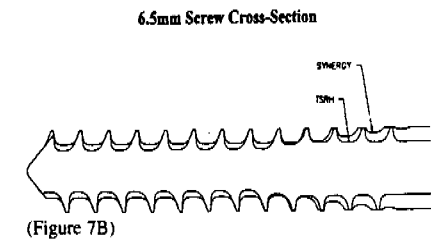
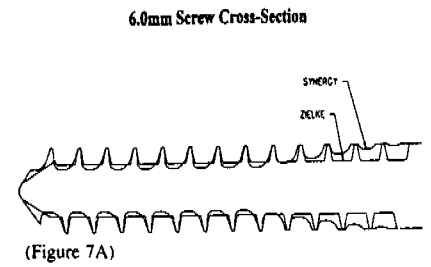


The dynamic stiffness values for 6mm screw constructs (Figure 4) show differences between the Synergy Open and Closed screw constructs and the Zielke and Harms constructs, while the 6.5mm screw constructs (Figure 5) show differences between the Synergy Open and Closed screw constructs and the TSRH construct. Typical failure modes for the different designs tested are shown in Figure 6A-F.



# CONCLUSIONS:

Stiffness and FEL's have improved as anterior screw/rod instrumentation for spinal deformity has evolved. The increases appear to be primarily due to enhanced rod & cancellous thread geometries (Figure 7A-C), and improved screw to rod clamping mechanisms (Figure 8A-B). Of clinical relevance, these increases should lead to reduced occurrences of instrumentation failure and loss of correction, and may contribute to higher rates of fusion.



## Ligament Strain and Ankle Joint Opening During Ankle Distraction

Randy Theken M.S., Paul Reiman, M.D., Glen Njus, Ph.D., David B. Kay, M.D., and Jeffrey Albert, M.D.

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**Summary:** To determine the efficacy of ankle distraction and to investigate possible complications of the procedure, the strain on four ankle ligaments and the tibiotalar joint opening resulting from distraction force and various foot positions were studied. We mounted strain gauges on the deltoid, calcaneofibular, tibiofibular, and anterior talofibular ligaments of six fresh human cadaver ankles. An Acufex ankle distractor was used to apply forces of 45, 90, 135, and 180 N at 20° dorsiflexion, neutral, and 10° plantar flexion. The ankle distractor proved to be effective in opening the joint space for better visualization, but complications of pin bending, excessive ligament strain, and bony destruction did occur within the clinically recommended range. Based on the observed results, the safest method of distraction was to use forces < 135 N in the neutral position. **Key Words:** Ankle distraction—Ankle joint—Ligament strain.

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The purpose of this study was to determine ankle ligament strain and tibiotalar joint opening as a function of distraction force and relative foot position.

Ankle arthroscopy has advanced from a medical curiosity to a valuable diagnostic and surgical procedure. The ankle joint presents a significant challenge to the arthroscopist because it is a small joint surrounded by neurovascular structures.

Distraction during arthroscopic surgery creates more space for visualization and maneuverability of instruments. Two methods of distraction are the simple Kerlix gauze sling (1) and the Acufex small-joint distractor, which utilizes a tibia and calcaneal pin for fixation. Potential complications are broken pins, infection, ligament injury, neurovascular damage, and fractures.

Guhl introduced an invasive distraction technique and found that the ankle joint could be dis-

tracted 7 to 8 mm for 45 to 60 min without significant injury to the ankle ligaments (2). Other studies have addressed the biomechanical properties of ankle ligaments but have not correlated them to ankle distraction (3,4).

### MATERIALS AND METHODS

Eight fresh foot and ankle specimens were used for this study. We used two in preliminary analysis to determine strain gauge placement, distractor mounting, and correct foot-ankle orientation for data collection.

The specimens varied in length and fibular and tibial shaft diameters. The length from the distal to the proximal end of the feet ranged from 18 to 29.5 cm, and tibia diameters ranged from 2.6 to 3.31 cm. The following four ligaments from each specimen were tested: anterior tibiofibular; anterior talofibular; and calcaneofibular on the lateral side; and the deltoid on the medial side. The posterior talofibular ligament was not tested because it would involve a technically difficult procedure requiring a larger dis-

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section than the other ligaments, which could have changed the data.

The strain gauges used in this study were liquid metal strain gauges (LMSG) (Parks Medical Electronics, Aloha, OR, U.S.A.) with an open length of 0.5 cm (5). Each LMSG was individually calibrated with the use of a dial caliper (Starrett, Athol, MA, U.S.A.) attached to the strain gauge. A bridge amplifier (Honeywell Accudata 218, Denver, CO, U.S.A.) provided gauge excitation voltage and amplification of the output voltage of the LMSG. An analog-to-digital converter (MetraByte, Taunton, MA, U.S.A.) installed in an IBM AT computer was used to collect and store analog voltages.

We made medial and lateral incisions transverse to the length of the foot and ~10 cm in length. These incisions were for access to the ligaments and for LMSG attachment. Each gauge was securely attached with a combination of 4-0 Dexon surgical suture and 22-gauge needle anchors. Care was taken in orienting the gauges so that the longitudinal gauge direction was parallel to the principle fiber directions of each ligament. In addition, each gauge was prestretched ~1 mm (20% strain) so that changes in the baseline strain could be measured for each ligament.

With the use of a handheld cannula and power drill, the ankle distractor (Acufex, Norwood, MA, U.S.A.) was attached 18 cm proximal to the ankle joint just behind the anterior tibial crest. Another 3/16 in pin was drilled distal to the ankle into the lateral aspect of the os calcis. This pin was placed adjacent to the peroneus longus tendon and into the os calcis ~13 mm anterior to its posterior border and ~13 mm above the inferior border. The ankle was drilled with a 20° distal inclination so that the pins were nearly parallel when distraction was complete. The pins were drilled only until good purchase was obtained and did not penetrate the medial cortex. The purpose of the cannula was to protect the soft tissues while drilling the pins. The distractor was positioned and secured with the locking nuts (Fig. 1).

We then placed the specimen into a Plexiglas holder capable of three preset positions: 10° plantar flexion; 20° dorsal flexion; and neutral position (90° orientation). The specimen was velcro-strapped to the holder for stability. The mercury strain gauge wires were then attached to the bridge amplifiers and coupled to the IBM computer for data collection. A 900 N load cell ring (A. L. Design, Amherst, NY, U.S.A.) was inserted between the tightening

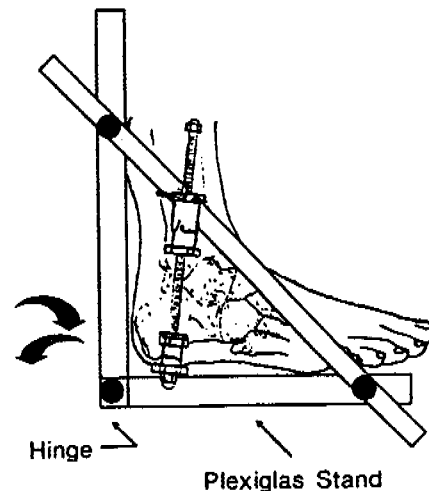


FIG. 1. Ankle Holder

ring and bottom face of the force scale on the distractor to obtain accurate and reproducible forces from the ankle distractor. While the specimen was strapped to the Plexiglas holder in a 90° orientation, the distractor ring was rotated until 45 N of distractor force was obtained on the load ring meter. It was held in this position for 10 s and then brought back to 0 N force and held again for 10 s. This procedure was repeated nine times to obtain ligament stabilization as verified from previous work (4). With the strain gauges and load ring voltages zeroed, the computer was programmed to collect data from the mercury strain gauges for 60 s. At time equal to 15 s, the distractor ring was rotated until 45 N of distractor force was obtained. The distractor was held at this position for 30 s, and then brought back to 0 N. At this point, the computer had finished data collection. The digitizing rate was 167 Hz with a 25-point running average routine for filtering. For a digitizing period of 60 s, this resulted in 100 data points per collected channel.

With the specimen in the same orientation as outlined above, the distractor ring was again rotated until 45 N of distractor force was obtained. A series of pins, incrementally ranging from 1 to 8 mm, were used as feeler gauges to determine ankle joint port-hole opening.

The same procedure as outlined above was performed at 10° plantar flexion, 20° dorsal flexion, and at 90 and 135 N distraction forces.

## RESULTS

A total of 24 ligaments were tested. Strain results are summarized in Table 1. Strain in the deltoid was

TABLE 1. Ligamentous strain (%)

	Dorsiflexion 20°			Neutral			Plantar flexion 10°		
	45 N	90 N	135 N	45 N	90 N	135 N	45 N	90 N	135 N
Deltoid	-1.3	-1.8	-6.6	0.4	2.0	4.3	-0.5	0.8	0.8
Calcaneofibular	5.2	7.6	4.4	4.2	3.2	6.6	3.5	5.4	6.2
Tibiofibular	1.2	2.6	4.6	0.3	0.7	2.1	1.4	1.2	4.4
Anterior talofibular	-2.2	0.2	2.5	-0.2	0.4	0.6	-0.6	-0.3	0.8

higher at each different force in the neutral position than in the 10° plantar flexion and 20° dorsiflexion positions. The strain was least in the dorsiflexed position and actually produced negative strain values because the ankle was inverted and closed down along the medial joint space. The differences in the strain of the deltoid were statistically significant ( $p < .02$ ).

The strain in the calcaneofibular ligament progressively decreased as the ankle went from 20° dorsiflexion to 10° plantar flexion. As the force increased at each given position, the strain on the calcaneofibular ligament also increased except in the 20° dorsiflexion position at 135 N. In this case, the strain went from a high value of 7.6% to 4.4%, respectively. In one of the ankles tested, the calcaneofibular ligament reached a high strain of 18.2% in the dorsiflexion position at 90 N.

The strain patterns for the tibiofibular ligaments showed a direct relationship to force of distraction applied. As the force increased, the strain also increased. The highest mean strain values occurred in the 20° dorsiflexion position; the lowest strains were in the neutral position. In one specimen, the maximum strain on the tibiofibular ligament was 10.3% in 20° dorsiflexion at 135 N.

The strain in the anterior talofibular ligament was lowest (-2.2) in the 20° dorsiflexion position at 45 N. But when the force reached 135 N, the strain on the anterior talofibular ligament became the highest (2.5).

Table 2 shows the results of portal opening in millimeters. The maximum joint space opening, 4.6 mm, was attained in the neutral position at 135 N. Using a paired statistical test, the neutral position

TABLE 2. Opening (mm)

	Neutral	Plantar flexion 10°
45 N	2.4 (0.21)	1.7 (0.55)
90 N	3.3 (0.67)	2.6 (0.31)
135 N	4.6 (0.97)	4.1 (0.77)

Standard deviations given in parentheses.

allowed a statistically significant, larger joint space opening at each given force of distraction when compared to the dorsiflexion and plantar flexion positions. When forces were increased in the neutral and plantar flexion positions, the increases in joint space opening were also significant ( $p < 0.05$ ). Pin bending and bony destruction of the calcaneus were consistent complications encountered with forces  $\geq 140$  N.

## DISCUSSION

Ankle arthroscopy is a valuable and prevalent surgical procedure. Ankle distraction is used to enhance the efficiency of the arthroscopic procedure. Different means of distraction, such as simple sling or invasive pin distraction, can be used. At the present time, no published studies describe the effects and impact of ankle distraction on ankle ligaments. This study was designed to determine the amount of joint space opening and to measure the strain on four ankle ligaments in three separate positions while subjected to various forces of distraction using the Acufex small-joint distractor.

The results of the forces and strains on the ankle ligaments are shown in Table 1. Strain in the calcaneofibular ligament increased when the ankle was dorsiflexed to 20°. These findings are consistent with Colville (6) and Rasmussen (7). An interesting significant clinical finding was a strain decrease of 3.2% (from 7.6 to 4.4%) while forces increased from 90 to 135 N. This indicated that the ligament reached yielding and that a ligamentous injury had occurred. However, it was not determined whether this injury occurred at the ligament-bone interface or within the substance of the ligament.

Therefore, it appears important for the arthroscopist to avoid distraction forces  $>90$  N while distracting the ankle in the 20° dorsiflexion position.

The strain pattern of the anterior tibiofibular ligament was highest in the 20° dorsiflexion position. This finding was consistent with the Kleiger study, which demonstrated disruption of the anterior ti-

biofibular ligament with dorsiflexion and external rotation of the ankle (8).

Strain in the anterior talofibular ligament was highest in the dorsiflexed position, just opposite the pattern of strain found by Colville (6) but similar to the report by Rasmussen (7). Negative strain patterns in the deltoid ligament in dorsiflexion suggested that the ankle distractor inverted the ankle. Neutral positions had similar but higher strain patterns than the plantar flexion positions.

The strain patterns of the four ligaments indicated that no damage was done while distracting the ankle in the three positions at the various forces. The exception was the calcaneofibular ligament, which developed strains sufficient to produce ligamentous injury in the 20° dorsiflexion position when forces applied were between 90 and 135 N. In addition, because the 20° dorsiflexion position resulted in the least amount of ankle joint opening, we suggest that this position be avoided during arthroscopic procedures.

The highest and safest force of distraction applied was 135 N. Beyond that point, pin bending and bony failure occurred in the calcaneus. However, because this experiment used cadaver bone, it may not reflect the possible differences in bony mechanics that depend on age and quality of bone. Pin bending, though, is independent of the specimen type.

The larger joint space openings in the neutral position, as compared with dorsiflexion and plantar flexion position, were significant using paired statistics. The maximum joint space opening obtained was 4.7 mm using 135 N in the neutral position. A further increase in the distraction forces did not increase the joint opening, which was probably due to the pin bending and bony failure. The bones of some specimens were experimentally supplemented with cement; however, failure still occurred at forces >135 N. In addition, we found that distraction techniques using less force still obtained joint opening measurements equal to and sometimes greater than those obtained with Acufex pin distraction. This happened because manual distraction applies a straight longitudinal force; Acufex distraction is a combination of longitudinal and inversional forces.

Based on these findings, we recommend that the arthroscopist avoid use of forces > 135 N to prevent complications. In addition, the ankle distractor calibration scale was found to be nonlinear—forces

<220 N were higher than actual readings and forces were lower than the actual readings >220 N.

Another important consideration is the size of the scope. The joint could only be safely distracted to <5 mm, which indicates that a 2.5-mm arthroscope would be less likely to cause articular cartilage damage than a 5.5-mm arthroscope. Also, manipulation of the ankle was difficult with the distractor in place.

In summary, this study addressed the biomechanical properties of ankle ligaments and correlated them with the clinical situation of ankle distraction. Joint distraction was found to be effective, with limitations. Specific parameters were defined for safe, effective joint distraction. This study required a considerable investment of time to define each plotted point on the stress-versus-strain graph. Therefore, only three positions and three forces on six cadaveric specimens were studied. However, this study provided a method for further investigation of ligamentous behavior during ankle distraction.

## CONCLUSIONS

1. The Acufex distractor was effective in opening the tibiotalar joint space for better visualization; complications did, however, occur.
2. Manual distraction was as effective as the Acufex distractor without the risks of pin bending and calcaneal bone destruction.
3. When using an invasive pin ankle distractor, forces >135 N should be avoided to prevent pin bending and bony calcaneal damage.
4. The neutral position of the ankle allowed statistically significant, larger joint space openings than did dorsiflexion or plantar flexion at the same given forces.
5. The 20° dorsiflexion position allowed the least amount of joint space opening.
6. Distractor forces >90 N in the 20° dorsiflexion position resulted in strains large enough to damage the calcaneofibular ligament.
7. Based on the data observed in the study, arthroscopes <4 mm should be used in ankle arthroscopy when using a small joint pin distractor.

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Surgical technique for anterior thoracolumbar corpectomy,  
graft placement and stabilization using the

## **University<sup>AM</sup> Plate Titanium Anterior System™**

**Howard S. An, M.D.**

Associate Professor

Director of Reconstructive Spine Surgery

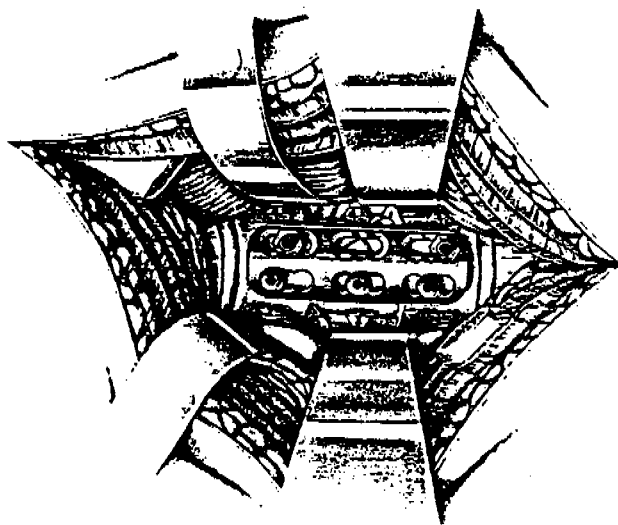
Medical College of Wisconsin

**Robert A. McGuire, M.D.**

Associate Professor of Orthopaedic Surgery

Chief of Spinal Surgery

University of Mississippi



### **Indications**

The University<sup>AM</sup> Plate Titanium Anterior System™ is indicated for treatment of anterior thoracolumbar spinal instability caused by trauma, tumor, severe disc degeneration, or anterior fusion following multiple posterior operations, including pseudarthrosis. The instrumentation is designed to treat affected vertebral segments from L3 through T10. The plate is not suitable for instrumenting across the L5 vertebral body, as no provision is made to anchor to the sacrum.

### **Contraindications**

The University<sup>AM</sup> Plate should not be used in cases of poor quality vertebral bone, including:

- overt infection of the involved vertebral bodies;
- severe osteoporosis, which may result in poor holding power of the screws and bolts; and
- widely disseminated metastatic tumors of adjacent vertebral bodies.

### **Pre-operation Evaluation**

Lateral and AP x-rays along with CT and MRI images are helpful in determining the degree of canal compromise, angular deformity, and potential instability. These images are also useful for preoperative planning including the approximation of plate size and screw/bolt length.

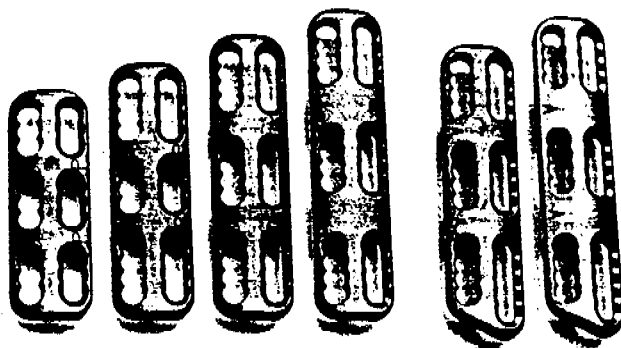


photo 1

## Implant Description

### Plates

Made of implant grade Titanium 6Al4V Alloy, University<sup>TM</sup> Plates have a contoured, low profile to match the curvature of the lateral aspect of the thoracolumbar vertebral column. The plates are intended to be attached to the lateral aspect of the vertebral body, and should not be attached to the anterior aspect. The three pairs of nested slots allow for a wide range of bolt and screw placement. Bolts are placed in the posterior slots, perpendicular to the plate. Screws are placed through the anterior slots. Their spherical countersink heads allow up to 15° of angulation.

Standard University<sup>TM</sup> Plates are available in 10mm increments from 70mm through 100mm. Distally tapered plates are available in 95mm and 105mm lengths and are designed to avoid contact with the common iliac vessels when a low lumbar application is required (Photo 1).

### Bolts

Fully threaded cancellous bone bolts with a 7.00mm thread diameter engage the posterior slots on the plates with the use of a tapered nut. Bolts are secured in place while tightening by seating the integral nut in the grooves on the underside of the plate (Photo 2). Bolts are available in 5mm increments from 30mm through 60mm in length (Photo 3).

### Screws

Spherical-head 6.25mm diameter cancellous bone screws nestle into the anterior slots on the plate and can be adjusted up to 15° off the mid-line of the anterior slot. The screws are available in 5mm increments from 30mm through 60mm (Photo 4).

photo 2

Anterior



Posterior

photo 3

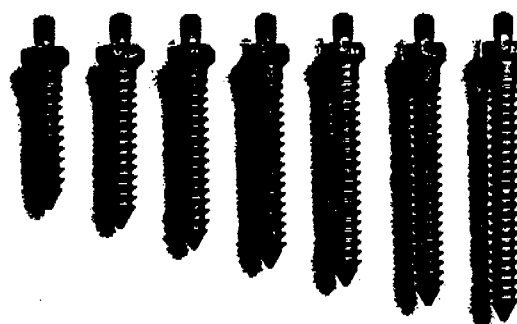
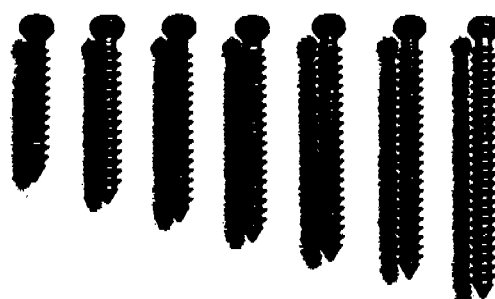


photo 4



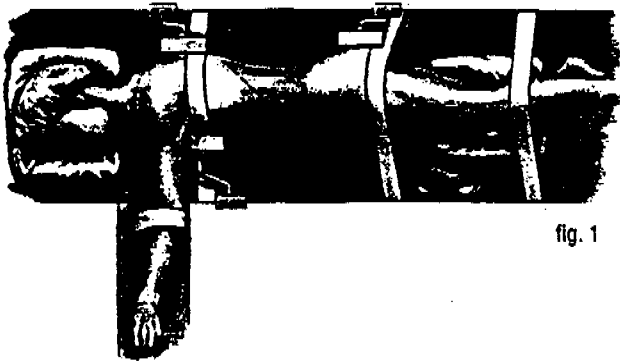


fig. 1

## Surgical Technique

Anatomic considerations including the location and ease of manipulation of the aorta, vena cava, and liver favor a left retroperitoneal or combined thoracolumbar approach.

### Position the patient

Access to the left flank is achieved by positioning the patient in a lateral decubitus position with the left side exposed. Radiographic verification of a true lateral position will show the spinous process centered between the pedicles. The patient is held securely with positioners and straps, and the peripheral nerves are protected (Fig. 1).

### Expose to the damaged segment

The level of the damaged segment will determine the incision site and the surgical approach. Segments above the thoracolumbar junction are most easily

reached through a thoracolumbar incision over the rib, two levels above the damaged segment. Lumbar segments are more easily exposed through a retroperitoneal approach.

Removal of the rib two levels above the damaged segment improves the exposure and provides autologous graft material.

The exposure may require deflating the lung or bisecting the diaphragm. Care should be taken to avoid damage to the genitofemoral nerve, the sympathetic nerves, the ureter, and the aorta.

Once the spine is exposed one level cephalad and one level caudal to the damaged segment, the level is confirmed radiographically, and the segmental vessels at all three levels are identified, isolated and ligated approximately one centimeter from the aorta (Fig. 2).

The disc material cephalad and caudal to the damaged segment is removed. If canal decompression is required, a corpectomy of the damaged segment is performed leaving the anterior and contralateral cortices intact if possible (Fig. 3).

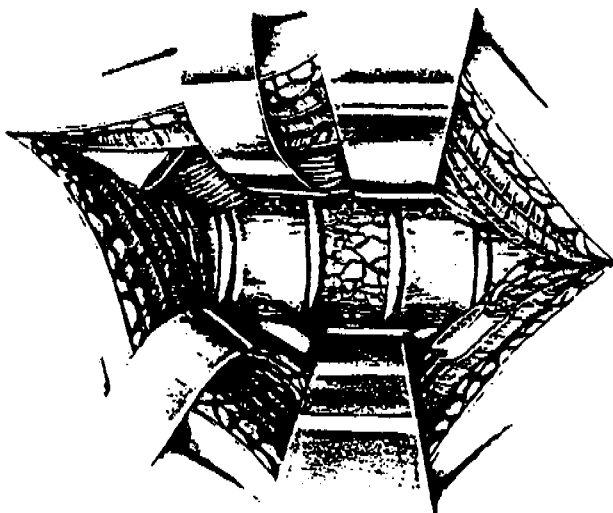


fig. 2

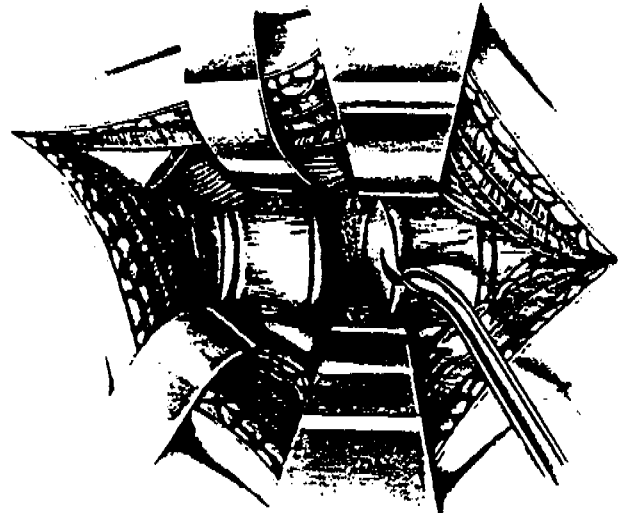


fig. 3

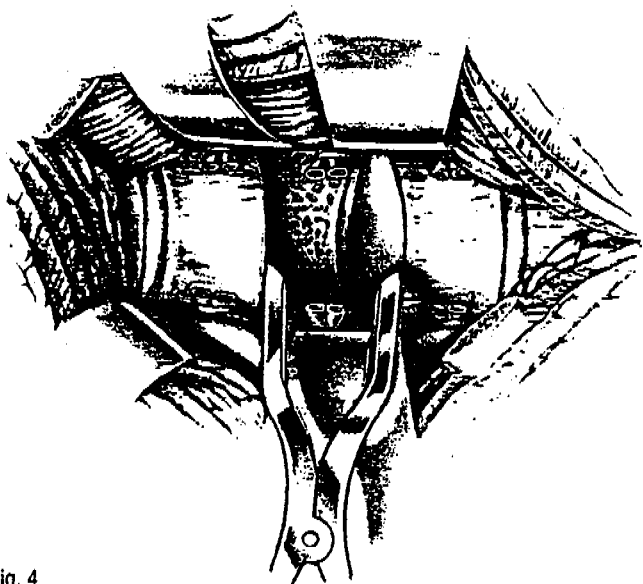


fig. 4

### Initial reduction and correction of alignment

A vertebral body spreader is placed inside the corpectomy site against the caudal endplate of the cephalad vertebral body and the cephalad endplate of the caudal vertebral body. The bodies are distracted to their correct anatomic location. A taut intact anterior longitudinal ligament serves as an excellent indication of correct vertebral height correction. (Fig. 4).

### Measure graft site

The graft site is measured from the endplate of the cephalad body to the endplate of the caudal body following complete removal of cartilage from endplates, leaving cortical bone intact (Fig. 5). Correct sizing of the graft is important to ensure that:

- the graft is placed in compression between the cephalad and caudal vertebral bodies;
- the anatomic load is accepted by the graft; and
- the correct anatomic orientation of the vertebral bodies is maintained.

While the corpectomy site is void of bone graft, the width of the endplates of the cephalad and caudal vertebral bodies should be measured in the coronal plane to gauge screw and bolt length.

### Prepare and place graft

An autologous tri-cortical iliac crest graft is harvested, shaped to fit precisely within the site created, and placed into the distracted corpectomy site (Fig. 6). Remove the vertebral body spreaders and allow the

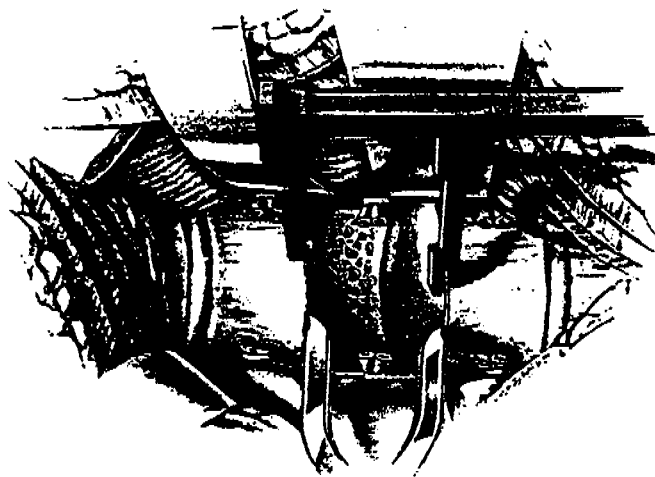


fig. 5

cephalad and caudal vertebral bodies to rest on the graft. Additional morselized graft material is placed anterior to the strut graft completely filling the void between the graft and the anterior longitudinal ligament.

No spinal instrumentation system will compensate for poor grafting technique. Insufficient graft material may lead to failed hardware and poor clinical results.

### Prepare implant site

The implant site is prepared by reducing the height of the lateral prominence of the vertebral endplates or osteophyte directly under the plate.

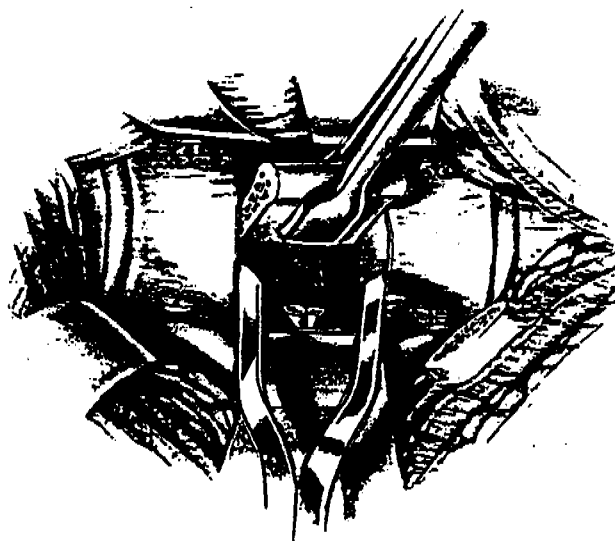


fig. 6

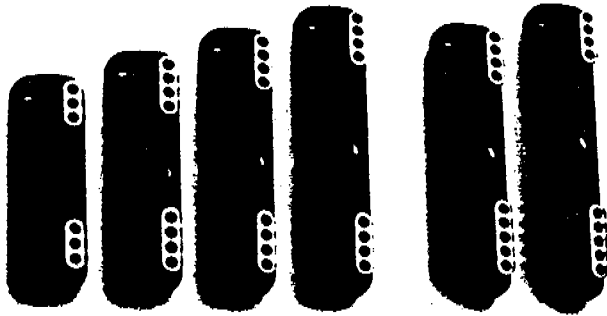


photo 5

### Select plate size and drill for posterior bolts

Drill guides are used as templates to select the plate length which extends to within several millimeters of the furthest endplate of the cephalad and caudal vertebral bodies without extending into the healthy disc spaces (Photo 5).

Once the appropriate plate length is selected, the corresponding drill guide is attached to the drill guide handle and placed on the vertebral bodies, spanning the graft site. The guide is located along the posterior edge of the lateral spine to prevent the instrumentation from extending into the anterior soft tissues. A slight anterior rotation of the guide will help to ensure a flush plate fit and help to prevent canal penetration by the posterior bolt. A flush fit is essential to assure correct bolt alignment. The letters "A" and "P" etched on the drill guide or the stainless steel drill sleeves on the posterior edge identify the anterior and posterior aspects of the guide.

The posterior drill guide positions correspond to the nests in the slot of the plate. A position is selected in the guide which will optimize bolt purchase in the vertebral body and allow for approximately one nest of compression after the bolt has been placed. A graduated 3.2 millimeter drill is placed through the appropriate drill guide position in either the cephalad or caudal vertebral body, and both cortices are penetrated (Fig. 7). The drill is removed and replaced by a pin which maintains the position of the drill guide while the second bolt site is prepared. The process is repeated for the remaining vertebral body. Bolt lengths can be measured directly from the graduated drill.

### Determine bolt length

The posterior bolt length may now be confirmed by placing a probe or k-wire into the prepared bolt sites. Sufficient length is allowed to assure that both cortices are captured.

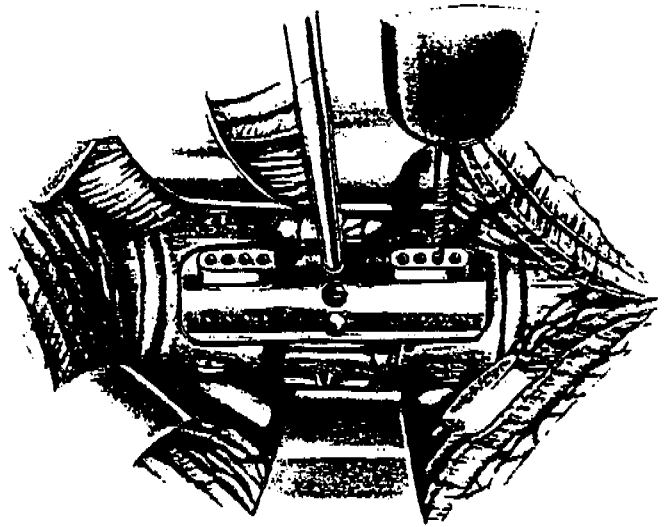


fig. 7

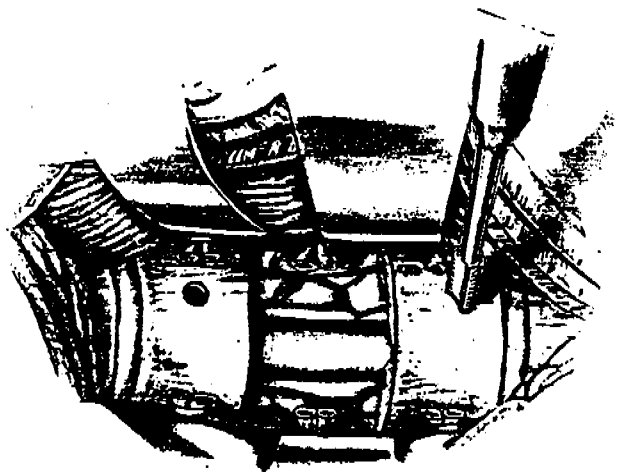


fig. 8

### Tap for cephalad and caudal posterior bolts

The posterior bolt sites are now tapped using bone taps. The taps are graduated and should not be advanced beyond the measured depth of the bolt site. The taps must be allowed to follow the path created by the previous drilling operation (Fig. 8).

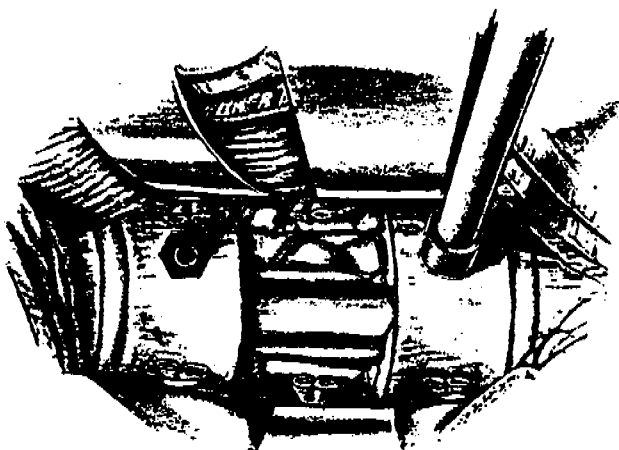


fig. 9

### Place the posterior bolts

The appropriate length bolts are selected and placed into the prepared sites with a 3/8 inch wrench. The integral nuts must engage the longitudinal slots in the bottom of the plate. To achieve this, the nut must be allowed to sit slightly above the vertebral body, and one set of parallel sides of the nut must be closely aligned with the longitudinal axis of the spine (Fig. 9). Bicortical penetration is confirmed radiographically or with direct palpation. If bicortical purchase is not obtained, remove the bolt and replace it with one of sufficient length.

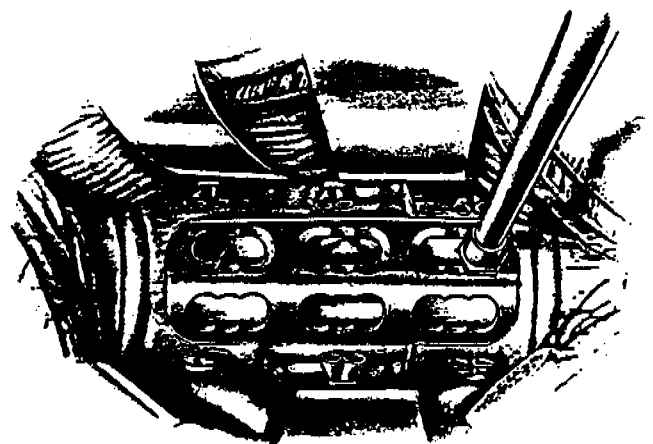


fig. 11

### Place the plate over the posterior bolts

The posterior aspect of the plate is identified by an etched letter "P". The plate is placed on the spine with the posterior nested slots fitting over the posterior bolts and the nests exposed (Fig. 10). Correct placement is critical to ensure alignment of the integral nut and the slot in the underside of the plate. This alignment prevents the bolt from advancing while the tapered nut is tightened.

### Place the nuts on the machine thread portions of the screws

The nut starter is used to locate the 3/8 inch tapered nuts on the exposed machine thread of each posterior bolt. The nuts are spun down to the plate, but not tightened securely (Fig. 11).

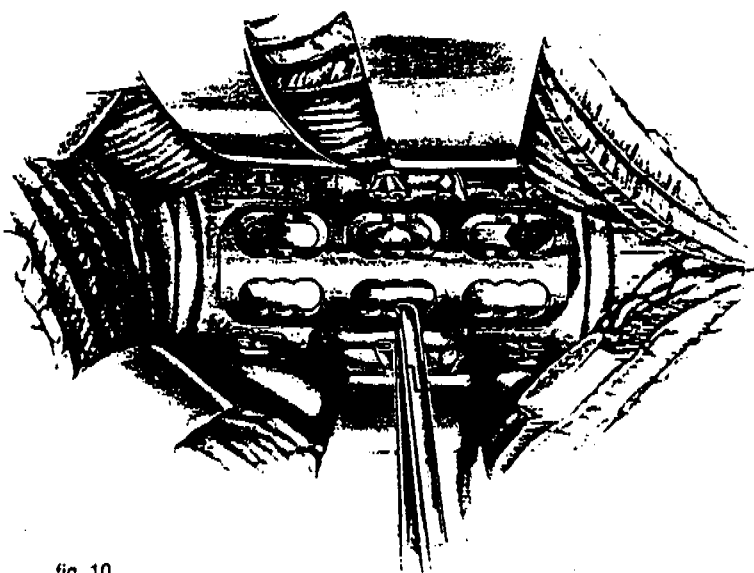


fig. 10

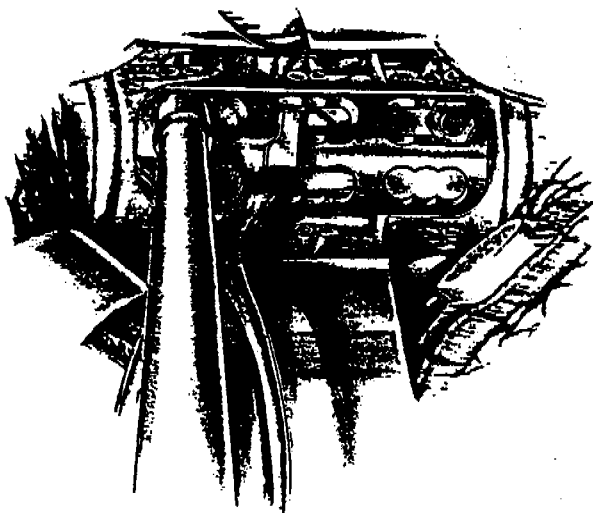


fig. 12

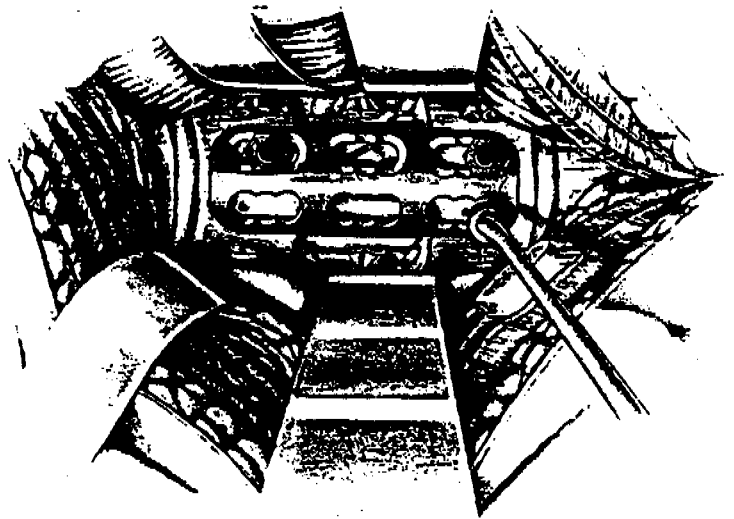


fig. 13

### Compress the graft

The plate is located in the final position relative to either the cephalad or caudal vertebral body, and the corresponding nut is tightened securely using the 3/8 inch wrench. The 3/8 inch wrench is then placed on the remaining loose nut, the compressor is placed to anchor its tabs in the middle nested slot and around the wrench, the bolt is compressed approximately one nest, and the nut is tightened to 100 inch pounds (Fig. 12).

### Place the anterior screws

An anterior nest is selected for both the cephalad and caudal vertebral bodies which maximizes purchase in the body, and allows the converging screw and bolt to pass within the body without impinging.

The cortices are penetrated immediately beneath the selected nests with a straight or angled awl (Fig. 13). The sites are tapped, penetrating the contralateral cortices. The depth of the site is confirmed with a wire probe, and the screws are placed with the 1/8 hex driver (Fig. 14). Bicortical purchase is confirmed radiographically or with direct palpation. If bicortical purchase is not obtained, remove the screw and replace it with one of sufficient length.

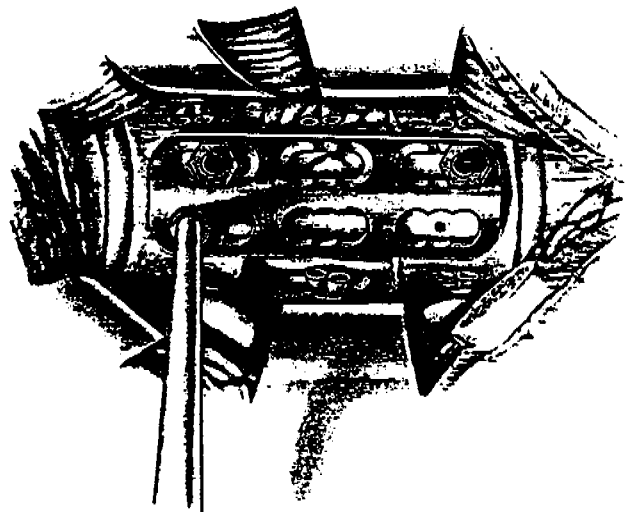


fig. 14



The 1/8 inch wrench is placed into either screw head. The compressor is placed with the tabs located in the middle anterior nested slot and around the wrench. The screw is compressed and tightened securely (Fig. 15). The process is repeated for the remaining screw.

### Place optional screws into the graft using the technique described above

A screw may be placed through the anterior middle slot into the graft material to stabilize that segment at the discretion of the surgeon.

### Construct assembly is complete (Fig. 16)

### Close the wound

Wound closure is dependent on surgical approach used and may involve repair of the diaphragm or placing a chest tube.

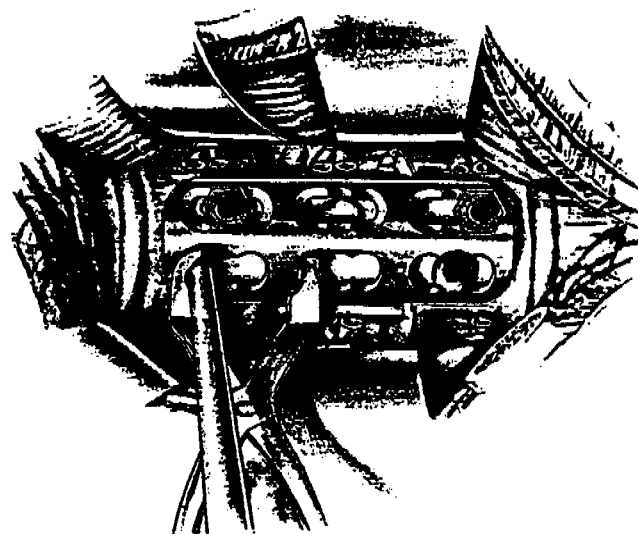


fig. 15

## Post-operation management recommendations

The patient is instructed to wear a Thoracolumbar Spinal Orthotic and to restrict activity for four to six months post-operation. A program of isometric muscle exercises is recommended.

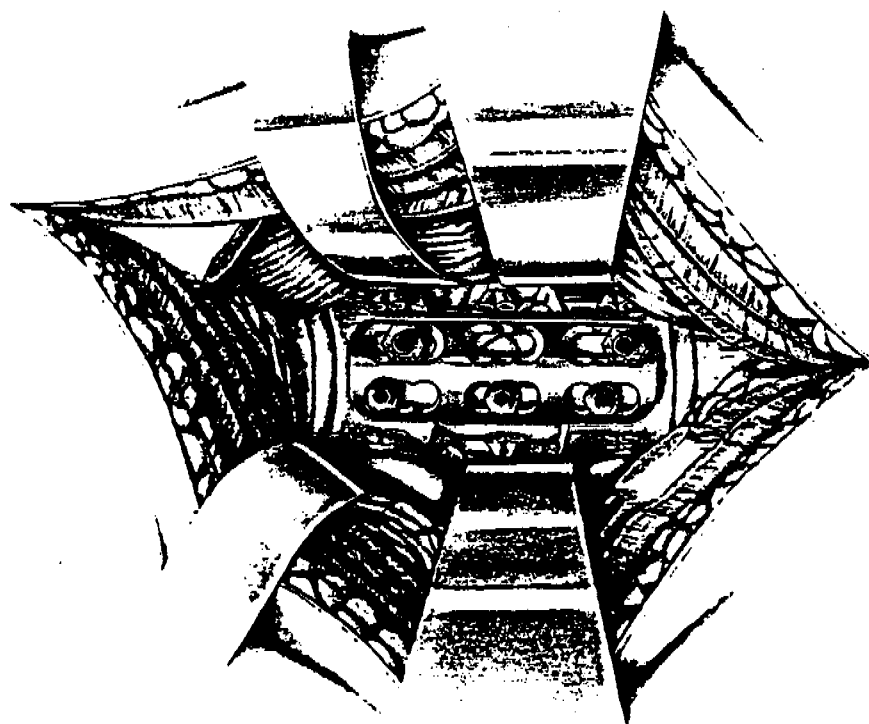


fig. 16

**Caution:** USA and Canadian law restricts these devices to sale by or on the order of a physician.

**Limited Warranty:** AcroMed standard catalog products are sold with a limited warranty to the original purchaser against defects in workmanship and materials; any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Please see the current price list for important warranty information.

The University<sup>™</sup> Plate Titanium Anterior System<sup>™</sup> is suitable for stabilization following:

1. anterior decompression and bone grafting of burst fractures;
2. vertebrectomy in tumor patients;
3. anterior fusion following multiple posterior operations, including pseudoarthrosis; and
4. anterior fusion following severe disc degeneration.

**CAUTION:** This system is intended for the T10 to L3 area and is not suitable for attachment to the sacrum. The plates are intended to be attached to the lateral aspect of the vertebral body, and **SHOULD NOT** be attached to the anterior aspect.

University<sup>™</sup> Plate Titanium Anterior System<sup>™</sup> implants are manufactured from Implant Grade Titanium Alloy as noted. All University<sup>™</sup> Plate Titanium Anterior System<sup>™</sup> instruments are manufactured from Stainless Steel unless otherwise noted.

The following patents apply to University<sup>™</sup> Plate Titanium Anterior System<sup>™</sup> implants and instruments: 5,261,910; 4,696,290.

Other U.S. and foreign patents pending.

**Notice:** There are labeling limitations in the use of AcroMed products. See the package insert supplied with all implant products for important information.

**Warning:** These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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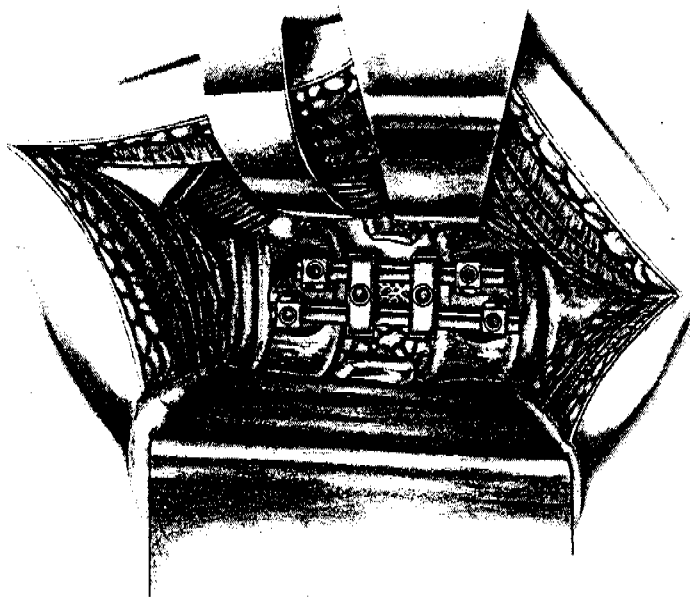
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Surgical technique for anterior thoracolumbar corpectomy,  
graft placement and stabilization using the

## **Kaneda SR™ Anterior Spinal System**

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### **Indications**

The Kaneda SR™ (smooth rod) Anterior Spinal System is an internal fixation system indicated for treatment of thoracolumbar spinal instability caused by fracture. Kaneda SR Anterior Spinal instrumentation is used as an adjunct to spinal fusion where corpectomy, decompression, and bone grafting are utilized to treat the unstable spine. The instrumentation is designed to treat affected vertebral segments from L3 through T10. The device is capable of spanning up to a maximum of four motion segments.

### **Contraindications**

The Kaneda SR System should not be used in cases of poor bone quality including:

- overt infection of the involved vertebral bodies,
- severe osteoporosis, which may result in poor holding power of the screws; and
- widely disseminated metastatic tumors of adjacent vertebral bodies.

All components of the Kaneda SR System must be positioned a minimum of one centimeter from all major vascular structures.

## Implant Description

Manufactured from implant grade 6Al4V Titanium Alloy, the Kaneda SR System utilizes tetra-spiked spinal plates, closed spinal screws, smooth spinal rods, and transverse couplers to create an anterior construct which allows:

- maximized surgical versatility
- uncomplicated compression and distraction
- biomechanical integrity.

### Tetra-Spiked Spinal Plates

Contoured spiked plates are designed to help the construct anchors resist axial forces, and serve as a guide for placement of the screws. The plates are available in three sizes (small, medium, and large) and are designed as pairs with specific caudal and rostral components. Each plate is clearly marked with anterior, posterior, and caudal/rostral indications to aid in proper placement on the spine (**Photo 1**).

### Anterior Spinal Screws

Available in five millimeter increments from 30 through 60 millimeters in length, the 6.25 mm diameter, cancellous thread closed screws serve to anchor the vertebral bodies to the longitudinal rods. The screw to rod connection utilizes AcroMed's VHGT™ (V-Groove, Hollow Ground) technology found on the ISOLA® Spinal System (**Photo 2**).

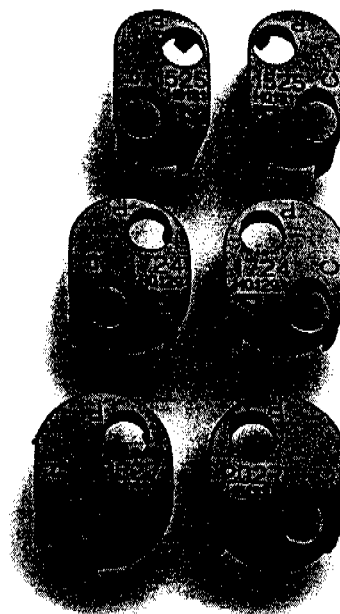


Photo 1

Small, 15mm x 26mm

Medium, 18.5mm x 25mm

Large, 20.5mm x 27mm

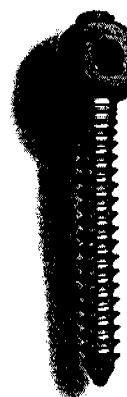


Photo 2

## Open Screws

The blending of the Isola and Kaneda technologies to create the Kaneda SR system provided, in addition to the VHG connection, the opportunity to provide "open" screws (**Photo 3**). The removable cap allows the rod to be introduced from directly above the open screw. This simplifies rod insertion for single segment or even multi segmental repairs. **Two open screws cannot be used together on the same spinal plate.**

Single level applications with the open screws utilizes the technique detailed above, modifying only the step involving placement of the rods. The open and closed screws are placed through the plates and aligned as described. The rod is then simply placed into the top of the open screw and slid through the closed screw. The screw caps are placed onto the screws in the direction of the arrows, and compressed into place with a parallel compressor. The previously described technique is utilized to compress the construct.

Multi segmental applications may also be performed using the open screws. Kaneda SR plates are placed one level rostral to and one level caudal to the defect to be repaired, and at each level to be instrumented. Open and closed screws are placed through the plate at each vertebral body along the repair. All of the screw heads are made to line up, with or without corrective action, and the rod is placed into the screw heads. Once the rod is properly placed, the caps are compressed into place, and the set screws are tightened to a minimum of 60 inch pounds.



Photo 3  
Open screw with cap

## Longitudinal Smooth Rods

The Kaneda SR System utilizes 6.35mm (1/4") diameter smooth rods incorporated from the ISOLA Spinal System. These 18" long rods are easily cut to length with the ISOLA Table-Top Rod Cutter. The system also features rods which are pre-cut from 45mm to 150mm in length. These rods feature smooth radiused ends designed to help prevent damage to surrounding soft tissue.



Bridge Width

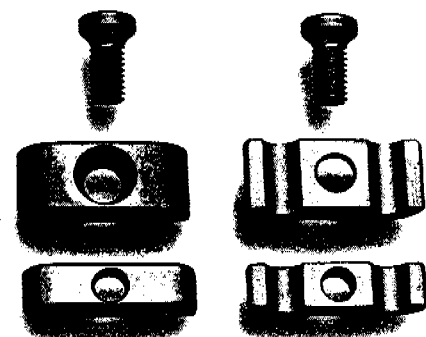


Photo 4

## Transverse Couplers

Transverse couplers add stability, contributing to the construct's ability to resist torsional loads. They are available in single millimeter increments, measured by the bridge width, from 13 through 16 millimeters in width. Two couplers are recommended for each construct (**Photo 4**).

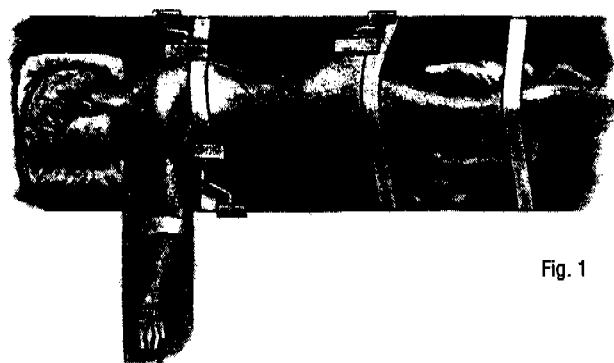


Fig. 1

## Surgical Technique

Anatomic considerations including the location and ease of manipulation of the aorta, vena cava, and liver favor a left retroperitoneal or combined thoracolumbar approach. Unusual anatomy or a need for extensive decompression on the right side may necessitate a surgical approach from the right side.

### Position the patient

Access to the left or right flank is achieved by positioning the patient in a lateral decubitus position with the left or right side exposed. The patient is held securely with positioners and straps. Any spinal deformity is corrected as completely as possible through careful patient positioning. The peripheral nerves are protected (Fig. 1).

### Surgical Exposure

The surgical approach and incision site are determined by the level of the damaged segment(s). Segments above the thoracolumbar junction are most

easily reached through a thoracolumbar incision over the rib, two levels above the damaged segment. Lumbar segments are more easily exposed through a retroperitoneal approach. The thoracolumbar junction is commonly approached through an incision over the tenth or eleventh rib.

The costal cartilage is split longitudinally, and the corresponding rib is removed to improve the exposure and provide autologous graft material. Blunt dissection separates the retroperitoneal fat and retroperitoneal structures from the iliopsoas muscle and spine. The great vessels are identified by palpation. The thoracic exposure is extended by either retropleural or intrapleural dissection. The lung may be deflated or the diaphragm bisected if necessary to improve exposure.

Once the spine is exposed one segment above and below the damaged segment(s), the segmental vessels at all involved levels are identified, isolated, closed, and ligated approximately one centimeter from the aorta. The iliopsoas muscle is bluntly dissected from all involved vertebrae (Fig. 2). Care should be taken to avoid damage to the genitofemoral nerve, the sympathetic nerves, the ureter, and the aorta.

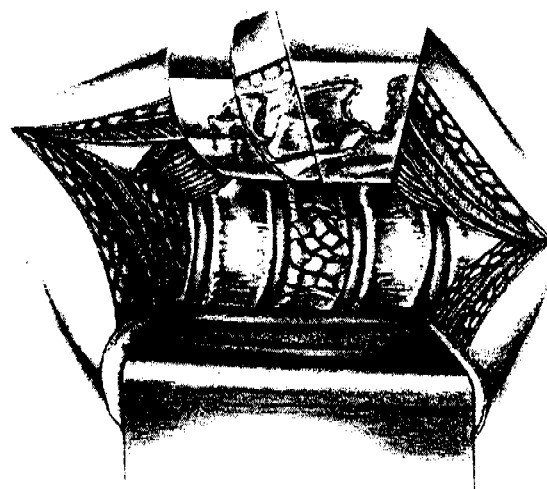


Fig. 2

## Corpectomy

The disc and endplate material rostral and caudal to the damaged segments(s) is excised and removed. A corpectomy is performed at all damaged segments, leaving the anterior and contra lateral cortices intact if possible. Bone removed from the corpectomy site(s) is morselized for use as autologous graft material. Any required anterior decompression is performed (Fig. 3).

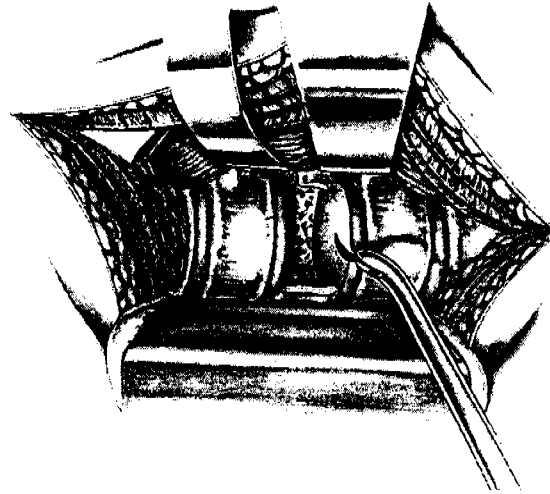


Fig. 3

## Placing spinal plates

Tetra-spiked Kaneda SR spinal plates serve as templates for placement of the Kaneda SR screws and are designed to help prevent the screws from migrating through the vertebral bodies under axial load. To avoid creating a parallelogram construct, the Kaneda SR plates are designed in pairs with a distinct caudal and rostral component. Each plate is marked with the letters A (anterior), P (posterior), and C/R (caudal/rostral) to aid in correct placement.

When placed correctly, the plates will allow for the rod in the anterior location to be longer than the rod in the posterior position. The plates are available in three sizes: small, medium, and large. Plate size is determined by selecting a plate which maximizes coverage of the lateral aspect of the vertebra with all four spikes located well within the margins of the vertebral body. The spikes should not be allowed to penetrate into the disc spaces rostral or caudal to the body. Correct size plates are selected, positioned on each vertebral body, and impacted (Fig. 4).

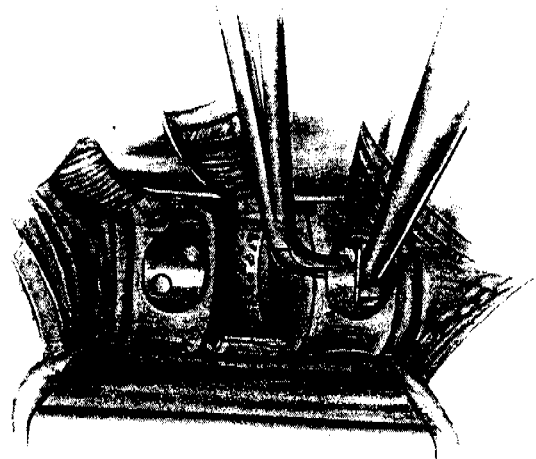


Fig. 4

## Placing spinal screws

Kaneda SR spinal screws serve as the anchors for the longitudinal rods. Each open or closed screw connects to the longitudinal rod with a VHGM (V-Groove, Hollow Ground) connection (Figures 5a, 5b, & 5c) and is secured with a set screw. This connection is exceptionally strong when the screw and rod are perpendicular to each other and the set screw is tightened to a minimum of 60 inch pounds. Failure to form a perpendicular relationship between the screw and rod or failure to securely torque the set screw can lead to construct failure.

The screws are 6.25 millimeters in diameter and are available in five millimeter increments from thirty millimeters through sixty millimeters in length. Two open screws cannot be used together on the same spinal plate.

Required screw length can be determined in many ways: utilizing measurements taken from pre-operative images; measuring through the corpectomy site(s); or measuring across the intact body with a gauge.

The posterior screws are positioned parallel with a vertebral endplate and angled approximately ten degrees away from the posterior wall of the body. The anterior screws are placed parallel with the same vertebral endplate and parallel with the posterior wall of the vertebral body. Utilizing a single vertebral endplate as a reference for placement of all screws will help to achieve a perpendicular alignment of all screws and rods.

The screw is driven until the head is recessed into the surface of the plates and the screw heads are aligned to allow rod passage (Fig. 6). Each blunt-tipped screw is allowed to extend beyond the contra-lateral cortex by approximately two millimeters to ensure secure bicortical purchase (Fig. 7). Confirmation of each screw's placement through direct palpation or x-ray is recommended in order to confirm bicortical purchase without excessive screw penetration.

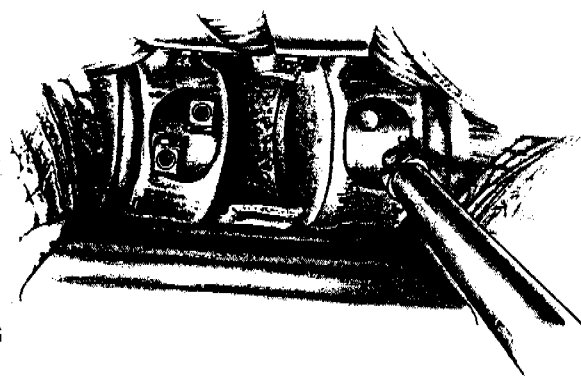
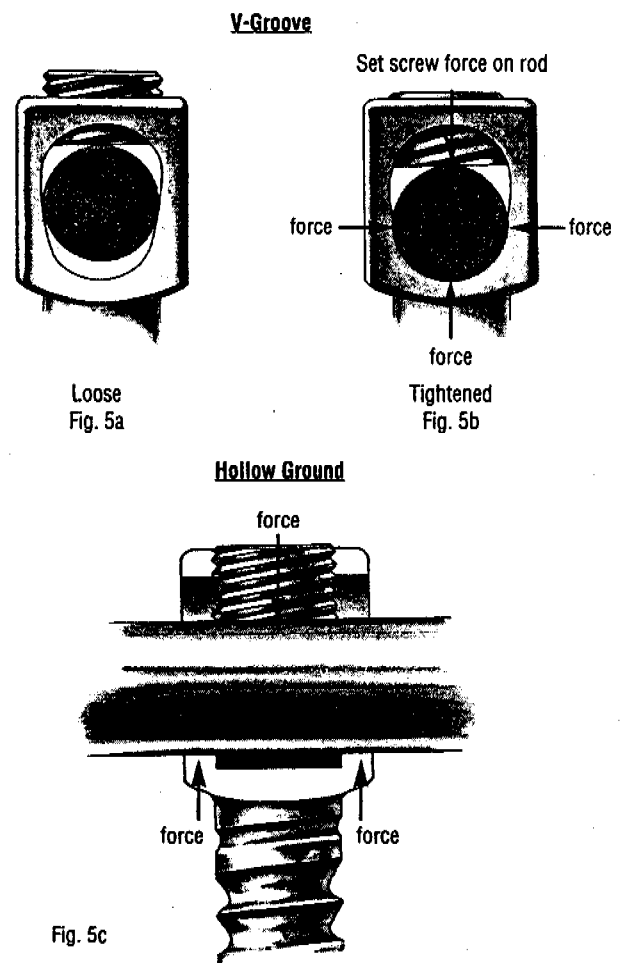


Fig. 6



## The VHGM Principle

The V-Groove Hollow Ground (VHG) junction by the ISOLA developers and is incorporated into all ISOLA connectors and hook bodies to produce a strong and durable connection to either straight or curved smooth rods. Unlike a conventional hole and set screw type of connection, the ISOLA V-Groove creates additional lateral gripping forces by compressing the rod into a smaller diameter hole. The hollow ground provides three-point fixation at the optimal location with the connector, even when the rod is contoured.

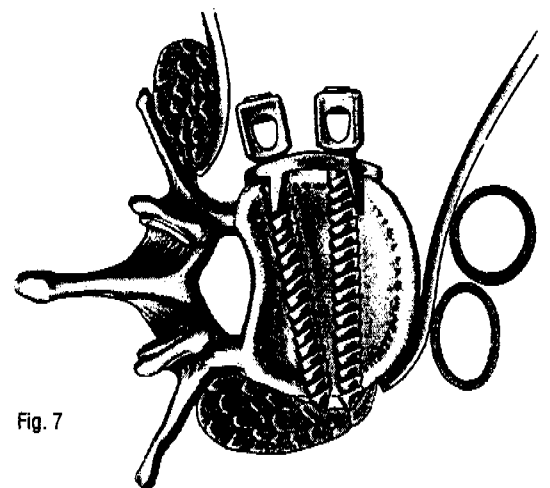


Fig. 7

### Deformity correction and grafting

The vertebral body spreader is placed between the heads of the rostral and caudal screws. Distraction is applied until the bodies have been returned to their anatomically correct location. A taut anterior or posterior longitudinal ligament is an excellent indication of correct vertebral height and lordosis/kypnosis correction. If the anterior longitudinal ligament prevents the correction of a kyphotic deformity, it may be divided.

The graft site is measured, and a tri-cortical graft segment of the appropriate length is harvested from the iliac crest. Correct sizing of the graft is important to ensure that:

- the graft is placed in compression between the rostral and caudal vertebral bodies;
- the anatomic load is accepted by the graft; and
- the correct anatomic orientation of the vertebral bodies is maintained.

Poor graft sizing can lead to failed hardware and poor clinical results.

The graft is positioned to place the cortical strut on the ipsilateral side and tapped into place (Fig. 8). The anterior wall of the spinal canal is protected and the rib struts are placed in the anterior portion of the defect (Fig. 9 insert). Additional morselized bone is packed into the remaining anterior defect, filling the entire defect (Fig. 9).

The distractor is removed.

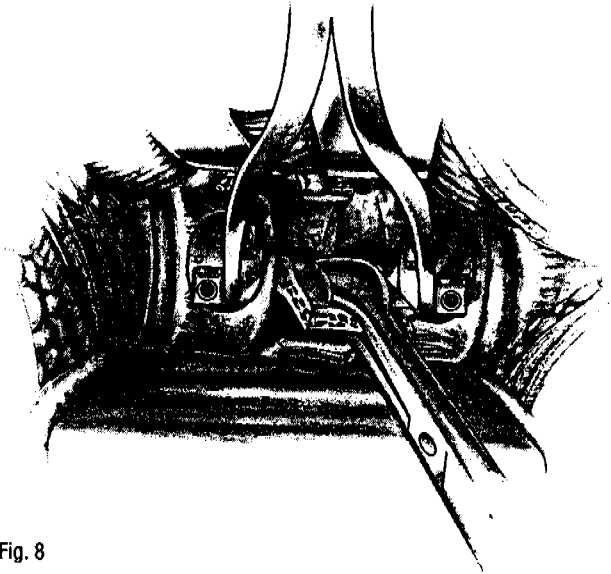


Fig. 8

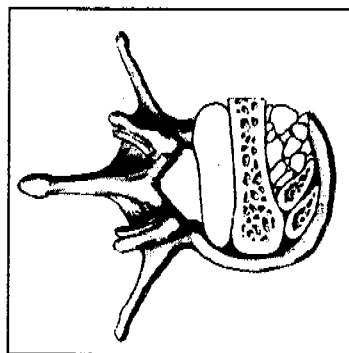
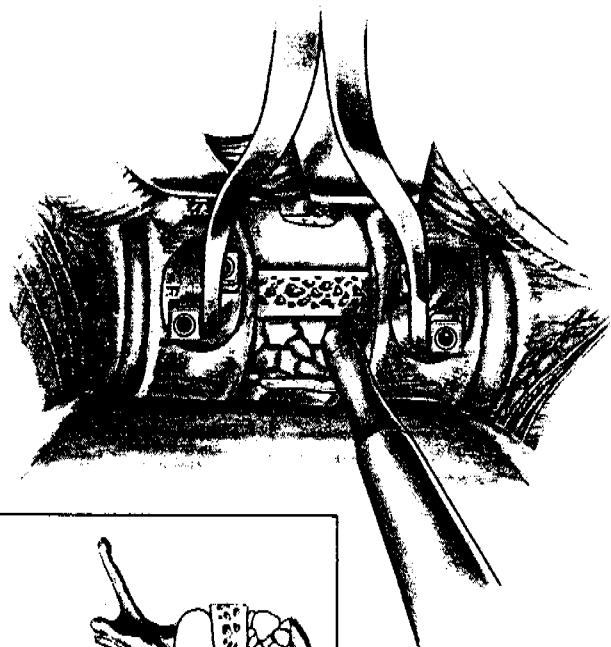


Fig. 9



## Placing the rods

A gauge is used to measure between the rostral edge of the posterior rostral screw and the caudal edge of the posterior caudal screw. Additional length is added to allow the rod to extend two millimeters from the edges of the caudal and rostral screw connections. A rod is cut to the indicated length and inserted, connecting the two posterior screws.

The set screws should be positioned such that they do not protrude into the VHG connection prior to rod insertion to prevent impingement with the rods. To aid in rod insertion, one screw is rotated slightly away from the longitudinal axis of the construct, the rod is inserted, then the screw is rotated back into the correct orientation. The process is repeated for the anterior screw pair (Fig. 10).

All set screws are positioned to locate the rod at the opening of the VHG, but none are tightened securely. The posterior rod is correctly positioned relative to either the caudal or rostral screw, and the set screw is tightened. A rod holder is clamped on the posterior rod approximately two centimeters from the unsecured screw to serve as a compression anchor. A compressor is placed across the loose screw and the rod holder. Firm compression is applied, and the set screw is tightened. The process is repeated for the anterior rod (Fig. 11).

Firm compression is required to ensure that the anatomic loads are passed through the graft rather than the construct. Failure to compress the graft can lead to hardware failure and poor clinical results.

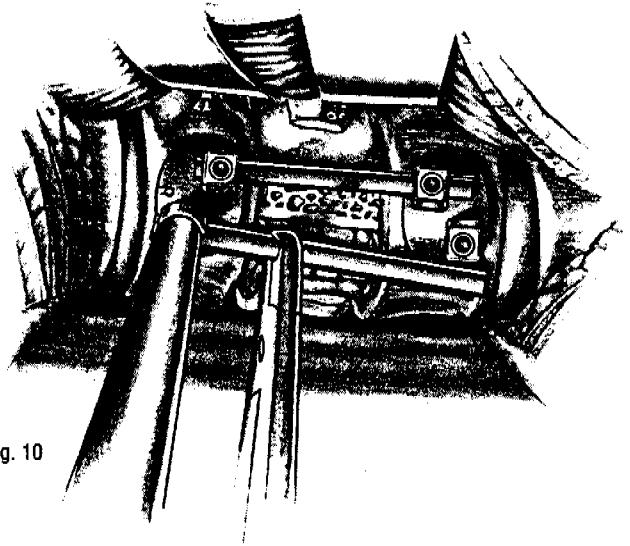


Fig. 10

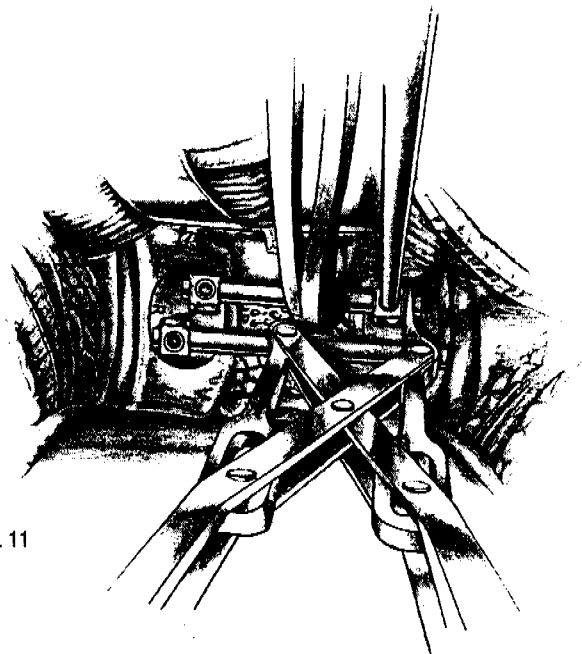


Fig. 11

### Placing the transverse couplers

The Kaneda SR transverse couplers serve to stabilize the construct. Two transverse couplers are recommended for each construct; one placed near the rostral end of the construct and one placed in a caudal position. The transverse couplers are available in single millimeter increments from thirteen millimeters through sixteen millimeters. The correct size transverse coupler is selected using the transverse coupler gauge.

An appropriately sized transverse coupler is loaded onto the self-retaining 1/8 inch wrench and the bolt is loosened. The upper and lower portions of the coupler are positioned such that they are perpendicular to each other, and the lower portion is introduced through the longitudinal rods (Fig. 12). The lower portion is rotated into its final position by rotating the 1/8 inch wrench or with a Penfield, and the coupler is moved to the rostral or caudal end of the construct. The lower portion is engaged onto the rod with gentle upward traction, and the bolt is tensioned loosely. Final tightening of the bolt is done with the modular 1/8 inch wrench. The process is repeated for the second coupler.

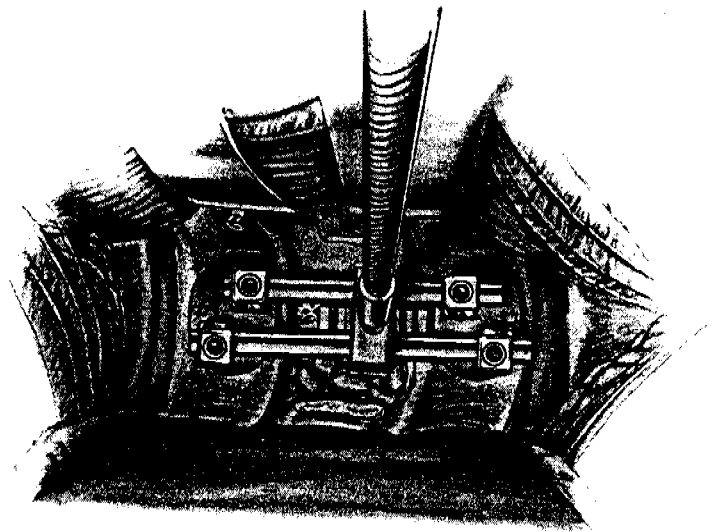


Fig. 12

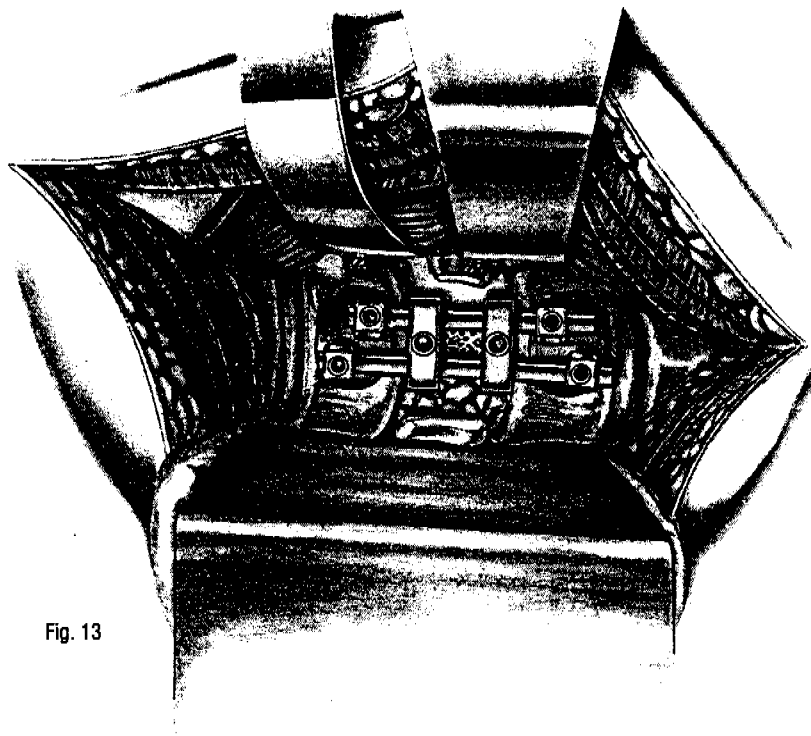


Fig. 13

#### **Revisiting set screws**

After the construct assembly has been completed, each set screw and transverse coupler bolt is again tensioned to a minimum of 60 inch pounds.

#### **Close the wound**

Wound closure is dependent on the surgical approach used and may involve repair of the diaphragm or placing a chest tube.

**Construct assembly is complete (Fig. 13).**

### **Post operation management recommendations**

The patient is instructed to wear a thoracolumbar spinal orthotic and to restrict activity for four to six months.

## **WARNINGS FOR ANTERIOR SPINAL IMPLANTS**

Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants. Possible neurologic injury risks include, but are not limited to, paresthesia, impotence, and retrograde ejaculation.

As with all surgical procedures, the surgeon must consider patient selection, patient bone quality, surgical technique, and the inherent limitations of internal fixation devices in the decision to use this product. Although the potential risks and adverse effects listed above and below are not necessarily all-inclusive, these and other risks known by the surgeon should be discussed with the patient prior to the surgical procedure.

## **WARNINGS, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES**

### **WARNINGS**

#### **1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.**

The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

**2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

**3. MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals.

**4. PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

- A. **The patient's weight.** An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.
- B. **The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
- C. **A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- D. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
- E. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

### **PRECAUTIONS**

**1. SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

**2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.

**3. REMOVAL OF THE IMPLANT AFTER HEALING.** Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

**4. ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and that physical activity and full weight bearing have been implicated in premature failure of metallic internal fixation devices by loosening, bending, or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

### **POSSIBLE ADVERSE EFFECTS**

1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Vascular and/or nerve damage due to surgical trauma.
8. Erosion of blood vessels due to proximity of the device, leading to hemorrhage and/or death.
9. Bursitis.
10. Paralysis.
11. Death.

### **NOTICE**

There are labeling limitations to the use of AcroMed products. See the package insert supplied with all implant products for important information.

### **FDA WARNING STATEMENT:**

WARNING: These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

### **GENERAL STATEMENT**

CAUTION: USA and Canadian Law restricts these devices to sale by or on the order of a physician.

## Basilar Crescentic Osteotomy A Three-Dimensional Computer Simulation

Randy Theken M.S., Glen Njus, PhD†,  
William Parrish, MD‡, and David B. Kay, MD\*

Treatment of the symptomatic bunion deformity is a controversial and complex subject. There are more than 130 various surgical procedures that have been described to treat this common foot deformity. These procedures generally fall into one of two categories. There are those procedures that rely solely upon soft-tissue releases and then there are those that combine the soft-tissue releases with an osteotomy. Osteotomies have been described at the base of the first metatarsal,<sup>9,11,16</sup> the diaphysis, the distal portion of the first metatarsal,<sup>5,7,21,23-25</sup> and the proximal phalanx.<sup>8,28</sup> The basilar crescentic osteotomy of the first metatarsal combined with the appropriate soft-tissue surgery, is advocated as an excellent method for correcting wide metatarsus primus varus that often is associated with hallux valgus.<sup>19,20</sup>

There is little guidance for the operating surgeon in the exacting method needed for performing this osteotomy (Table 1).<sup>15,20</sup> The current recommendations are to perform the osteotomy in the metaphysis, the saw blade should be concave distal and at right angles to the metatarsal shaft, with no medial or lateral deviation. The diaphysis should be predrilled and the osteotomy should be fixed with either Steinmann pins, Kirschner wires, staples, or an interfragmentary screw. When the osteotomy is performed in the oblique plane, there is little to guide the surgeon as to the final three-dimensional orientation of the first metatarsal head.<sup>19,20,26</sup>

The literature has been addressed to the varus position of the first metatarsal and very exact methods.<sup>27</sup> The weight-bearing anterior-posterior roentgenogram is the standard by which many of the decisions are based when selecting bunionectomy procedure. There has been mention of hy-

permobility of the first metatarsal and pronation of the great toe, although little has been done to quantify these deformities. When an osteotomy has been performed that elevates the metatarsal head, transfer metatarsalgia will occur.<sup>1,3,4,10</sup> If rotation should occur that increases the pronation of the metatarsal head, then the deformity will be worsened. This study will provide the surgeon with an understanding of the flexibility that is afforded by the crescentic osteotomy in correcting this multiplanar deformity.

There has been much interest in using computer simulation to visualize deformities and fractures about the pelvis. There also has been a great deal of interest in the three-dimensional anatomy of the clubfoot. These three-dimensional computer simulations are performed on large, mainframe computers, which involve extensive software development. Also, these simulations generally are used to view the deformity. The computer simulations may be used in fabrication of custom implants or in modification of existing allografts. There has been little data published on three-dimensional simulations and osteotomies. The computer simulations on which this study has been based have all been performed on a microcomputer. A microcomputer is readily available to many practicing orthopedic surgeons.

### METHODS

A model of the normal foot was constructed from serial CT sections spaced 3 mm apart. Serial sections were oriented normal to the plantar surface of the weight-bearing foot. An image analysis system (Data Translations, Marlborough, Massachu-

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Table 1. *Specific Guidelines for Performing the Crescentic Osteotomy\**

1. Biplanar radiographic evaluation using weight-bearing anterior or posterior and sesamoid roentgenograms.
2. Distal soft-tissue reconstruction.
3. Excision of the medial eminence *following correction* of the intermetatarsal angle by the basilar osteotomy.
4. Directing the saw blade in a proximal to distal direction.
5. Directing the saw blade in a lateral to medial direction.
6. Distal translation of the metatarsal when there is significant shortening.

\*New recommendations for performing the basilar crescentic osteotomy.

sets) using 256 gray levels was used to digitize the CT images. Bony surface contours were constructed from enhanced boundary gray level gradients. From the resulting cross-sectional areas, centroids were calculated, and the centroidal axes of the first and second metatarsal were determined by three-dimensional linear regression. An orthogonal, global-coordinate system, with the origin at the head of the first metatarsal (Fig. 1) was constructed, incorporating all serial sections. Subse-

quent computer-generated images of the foot (Fig. 2) were constructed using a three-dimensional computer-assisted design (CAD; Generic 3D, CA, Bothell, Washington) software package.

The crescentic osteotomy blade was modeled as a hemicylinder 2 cm in diameter. All osteotomies were simulated with a length of the first metatarsal as 66 mm, and the apex of the cutter oriented proximal and intersecting the X axis 1.5 cm distal to the first metatarsal head. Surgical corrections were such that the intermetatarsal angle was closed to 8 degrees.

The equations describing the crescentic osteotomy were determined as follows:

- A crescentic surface cut at a given orientation in the X-Y plane was modeled in the first metatarsal as described previously
- The distal segment of the first metatarsal then was rotated about the Y axis to obtain the desired surgical correction
- Rotations and translations then were made with respect to the X and Z axes such that the contact surfaces were maximized and the gap was minimized between the distal and proximal osteotomy surfaces

A saw kerf of zero (that is, identical radius of the curvature for the distal and proximal sections) was employed in this study, which resulted in a perfect mate between the osteotomy surfaces. This procedure resulted in a series of distal first metatarsal

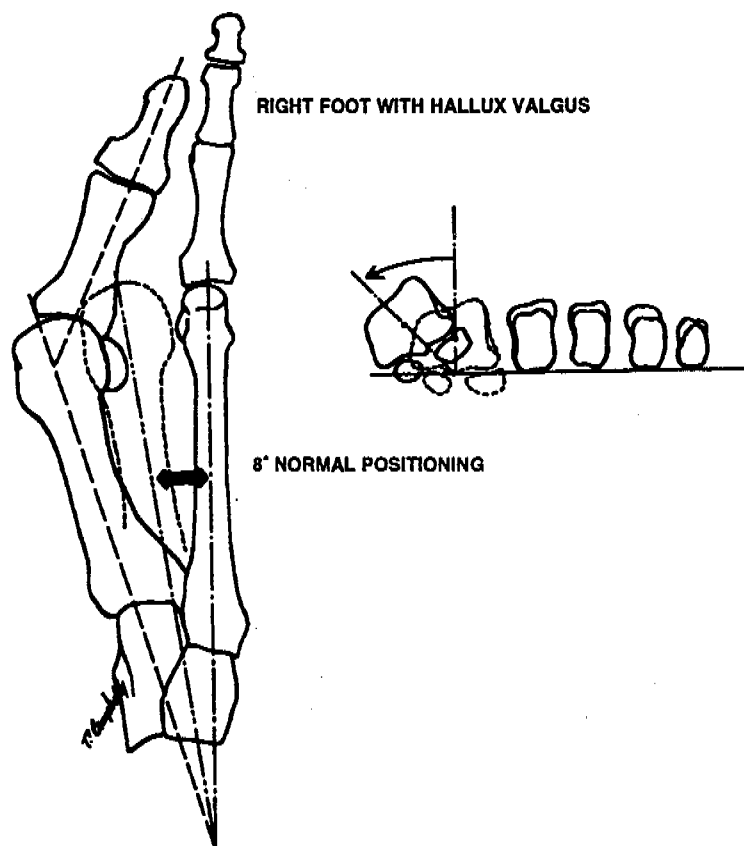


Figure 1. Representation of hallux valgus with a wide intermetatarsal angle and elevation and pronation of the first metatarsal head. The ghosted images demonstrate three dimensional final correction.

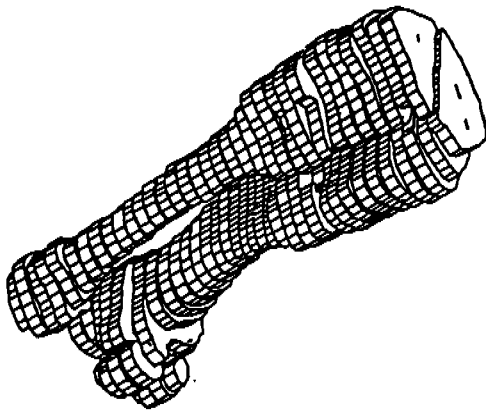


Figure 2. Three-dimensional reconstruction of the foot, generated from computerized tomographic images, obtained at 3-mm intervals.

orientations that varied as a function of the proximal - distal cutter angulation and surgical closure angle. Series approximation then was computed of the coupled rotations and translations. The resulting equations that were determined are as follows:

$$R(x) = \frac{1}{4} \cos(TR)^{1/2} * \frac{1}{4} \tan(TC)^{1/2} * \frac{1}{4} - TR^{1/2}$$

$$R(z) = \frac{1}{4} \sin(TR) * \tan(TC) * \frac{TR^{1/2}}{2}$$

$$T(x) = \frac{1}{4} \tan[R(z)] * \frac{\sin(TC)^{1/2}}{\frac{1}{4} \cos[R(z)]}^{1/2}$$

$$T(z) = -\frac{1}{4} \tan[R(x)] * \frac{\sin(TC)^{1/2}}{(\frac{1}{4} \times 2) * \cos[R(x)]}^{1/2}$$

Where TR = the surgical base closure, TC = the cutter angulation relative to the Z axis, R(x) = the coupled X-axis rotation (pronation-supination), R(z) = the coupled Z-axis rotation (elevation-depression) T(x) = the coupled X-axis translation of the osteotomy centroid, T(z) = the coupled Z-axis translation of the osteotomy centroid

Medial and lateral deviations of the cutter were modeled by transforming the above equations from the cutter-X plane to the global X-Y plane.

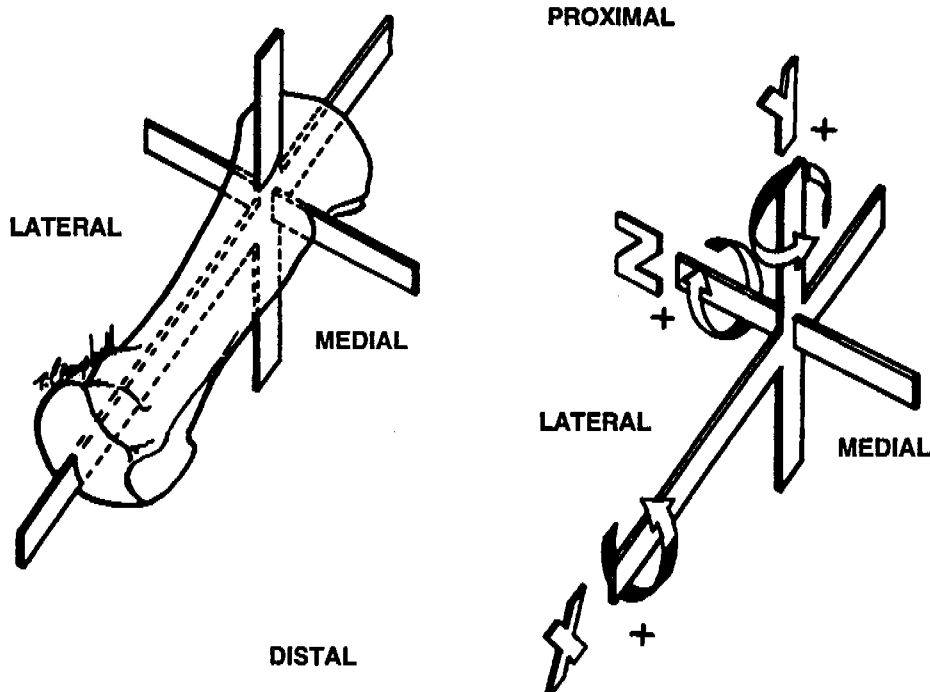


Figure 3. Demonstrates the axis system with the X axis being the long axis of the first metatarsal, the Y axis being the anterior to posterior axis, and the Z axis being the medial to lateral axis. Note that rotation about these axes may be positive or negative.

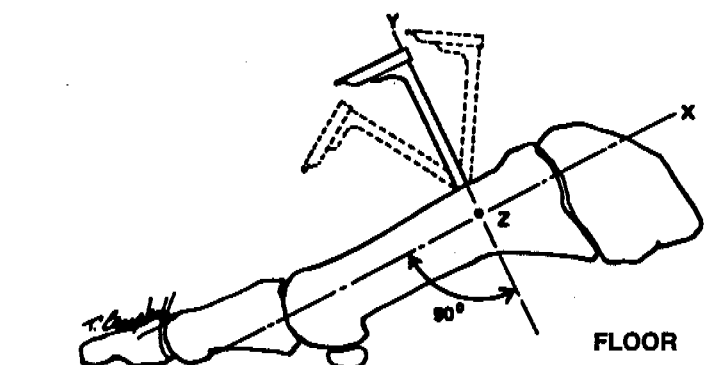


Figure 4. Demonstration that the saw blade may be directed at 90 degrees to the shaft of the first metatarsal or directed proximally or distally.

### RESULTS

There are an infinite number of possible osteotomy simulations. Three basic types of simulations will be presented with accompanying graphs (Figs. 1, 3 to 5).

When the saw blade is oriented at a right angle to the long axis with no medial or lateral deviation, only shortening of the metatarsal occurs as the intermetatarsal angle is closed (Fig. 6). The greater the correction, the more the shortening.

By directing the saw blade proximally or distally, and keeping the blade at 90 degrees to the long axis, the metatarsal head will pronate or supinate as the intermetatarsal angle is closed (Figs. 7 and 8 and Table 2).

Anterior or posterior, metatarsal head deflection occurs with medial or lateral directioning of the saw blade (Figs. 9 and 10 and Table 3). As in the other simulations, the length of the metatarsal will decrease proportionately with the amount of closure of the intermetatarsal angle.

Multiplanar changes will create dramatic changes in the metatarsal head's final position. An

exaggerated scenario would be as follows: the saw blade is oriented 45 degrees proximally and 45 degrees laterally (Fig. 11). When a 15-degree closure is accomplished, the metatarsal shaft shortens by 4.3 mm, the head elevates 15.4 mm and pronates 26 degrees. This is an unlikely surgical event, but it dramatizes the potential alterations that would not be apparent on an anterior-posterior roentgenogram.

### DISCUSSION

Treatment of the bunion deformity is a complex and controversial subject. Medial deviation and elevation of the first metatarsal head are commonly associated with hallux valgus. Clinically, these are evidenced by a widened forefoot and marked callus formation under the lesser metatarsal heads. This increased callusing is a result of decreased weight bearing of the first ray and increased weight bearing by the lesser metatarsals. As the first metatarsal deviates medially, it will also elevate. This occurs because of the shape of the

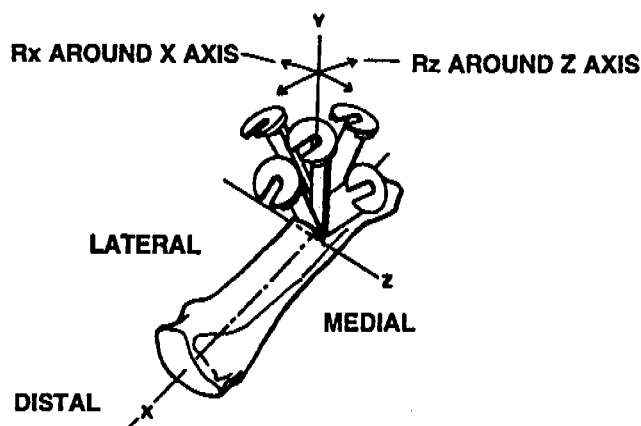


Figure 5. Multiplanar changes may occur with directing the saw blade either medial to lateral or distal to proximal directions.



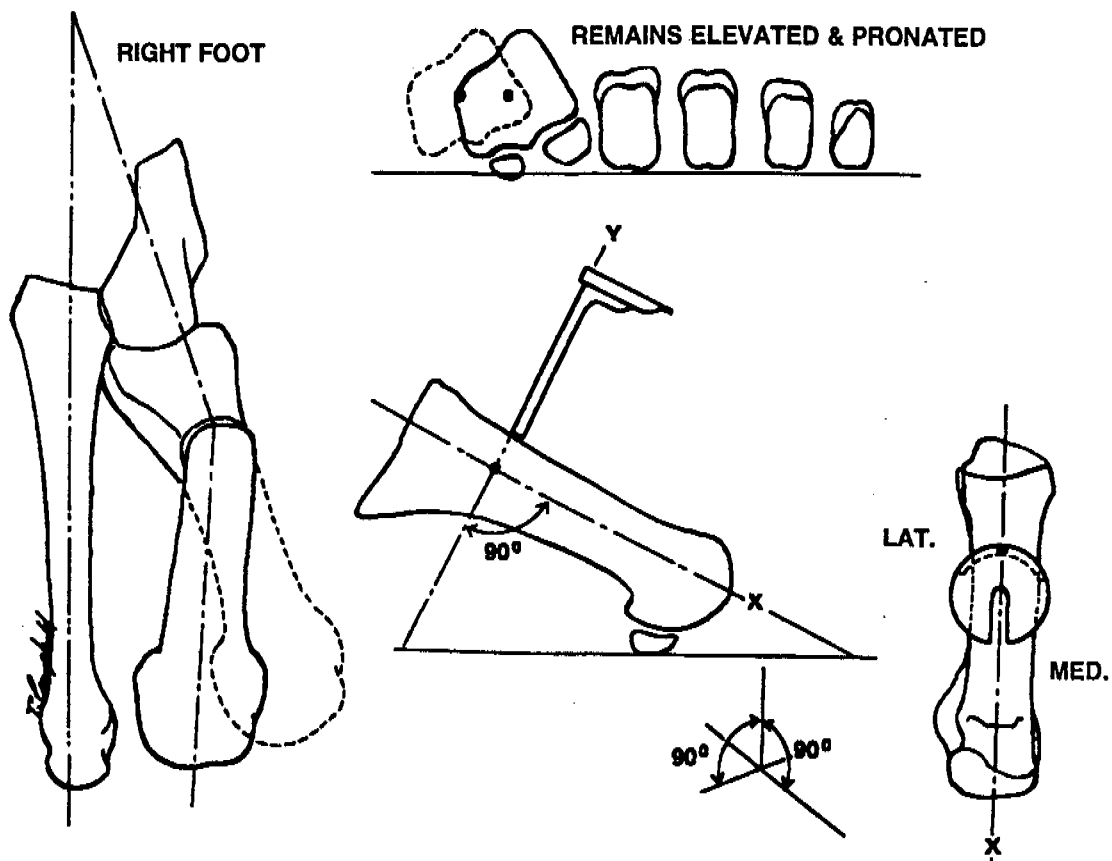


Figure 6. Graphic demonstration of Simulation 1. When the osteotomy is 90 degrees in both the proximal to distal direction and medial to lateral direction, then when closure of the intermetatarsal angle occurs, the head will remain at the same anterior-posterior level and no rotational changes will occur.

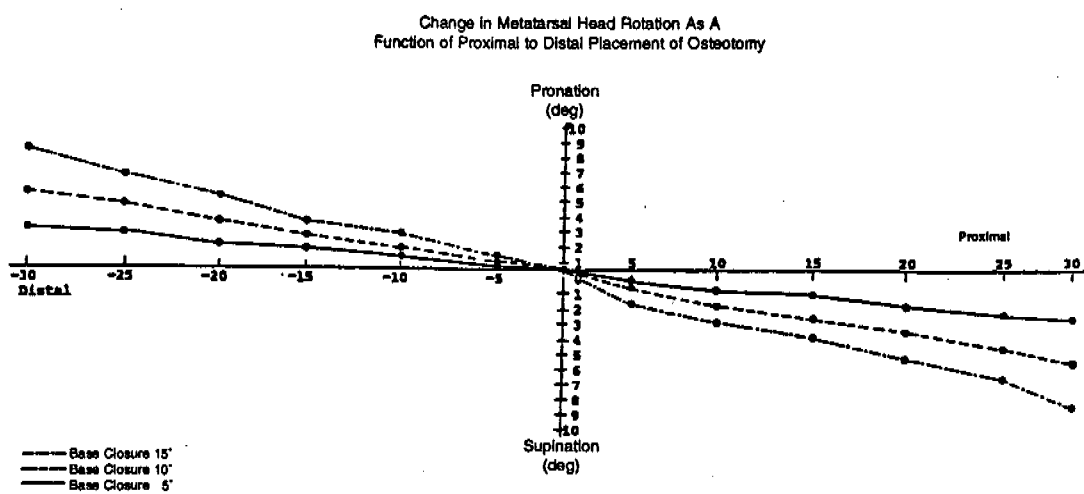


Figure 7. This is a graphic representation of Table 2. When the saw blade is directed proximally to distally, supination of the metatarsal head occurs. When the saw blade is directed distally to proximally, pronation of the metatarsal head occurs when the intermetatarsal angle is closed.

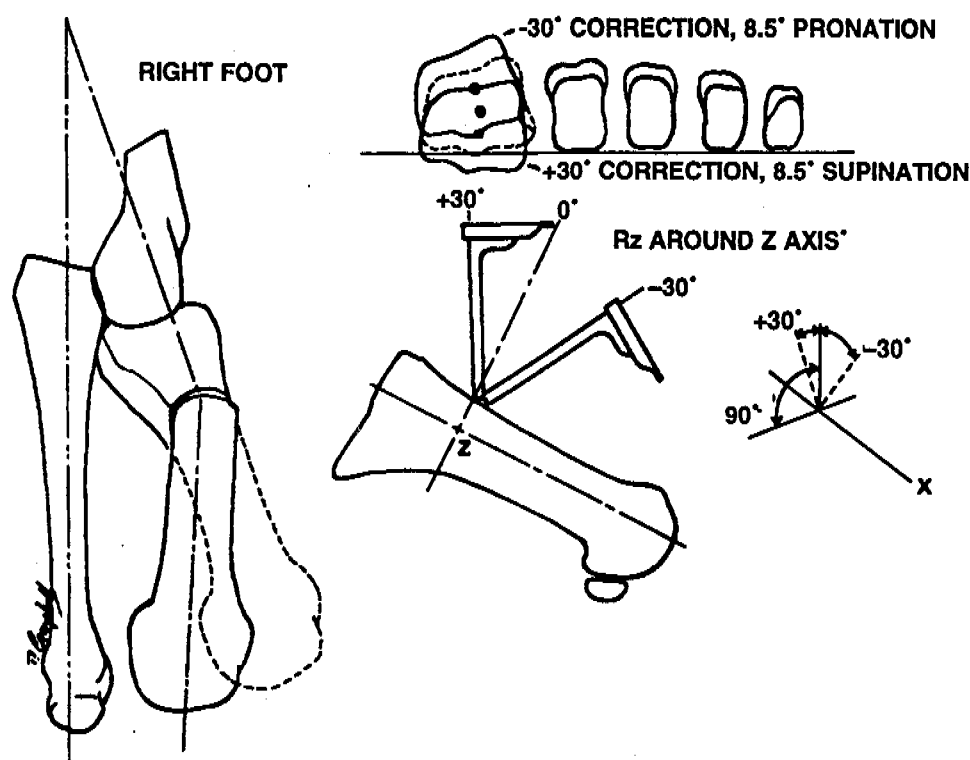


Figure 8. When the saw blade is directed distally to proximally then as the inter-metatarsal angle is corrected pronation will occur. When the saw blade is directed proximally to distally then supination of the metatarsal head occurs. Therefore, it would be most desirable to correct the pronated metatarsal head by directing the saw blade in a proximal to distal direction.

first metatarsocuneiform joint. The second metatarsocuneiform joint is a stable articulation and has little motion in the dorsoplantar or anterior-posterior planes. When sufficient forces are transferred away from the first metatarsal head, a symptom complex occurs. There is pain that is secondary to bursitis, synovitis, interdigital neuritis, or possibly stress fracture. One of the most important aspects of bunion correction is the return of normal weight bearing to the first ray. The pronation of the toe is secondary to the tethering of the proximal phalanx by the conjoined tendon and by rotation of the metatarsal head as it elevates. The pronation may be quantified by measuring the plane of a nail plate. The plane of the lesser toenails would serve as the reference point. The weight-bearing, sesamoid roentgenogram is used to determine the elevation of the metatarsal head. This roentgenogram is simple to obtain with a commercially available stand.<sup>17</sup>

A well-recognized cause of failure after bunion surgery is elevation of the first metatarsal head such that it no longer will participate in normal weight-bearing function. Therefore, it is impor-

tant to determine the preoperative head elevation. If the osteotomy is performed in such a fashion that an already-existing metatarsal head is elevated further, then failure will result. The anterior-posterior roentgenogram will not demonstrate this position of the metatarsal head. In fact, an excellent correction often is assumed when this roentgenogram is relied on solely. The weight-bearing lateral roentgenogram of the foot is not used to determine the head position because the overlap of the metatarsal heads makes it difficult to discern exact points. We would recommend using a weight-bearing, sesamoid roentgenogram in addition to the weight-bearing anterior - posterior roentgenogram as the standard radiographic evaluation of those undergoing surgical correction of the bunion deformity.

The ideal bunionectomy will not create mechanical imbalances in the foot secondary to a change in length of the first metatarsal following an osteotomy. When shortening of the first metatarsal occurs, it does not effectively participate in weight bearing. This is a well-known cause of transfer metatarsalgia and is seen in its most severe form

Table 2. Change in Metatarsal Length and Head Position as a Function of Proximal to Distal Placement of Osteotomy\*

Cutter Angle Proximal	BASE CORRECTIVE ANGLE—15°				BASE CORRECTIVE ANGLE—10°				BASE CORRECTIVE ANGLE—5°			
	Change in		Supination (+) Pronation (-)		Change in		Supination (+) Pronation (-)		Change in		Supination (+) Pronation (-)	
	Length (mm)	Elevation (+) Depression (-)	Length (mm)	Elevation (+) Depression (-)	Length (mm)	Elevation (+) Depression (-)	Length (mm)	Elevation (+) Depression (-)	Length (mm)	Elevation (+) Depression (-)	Length (mm)	Elevation (+) Depression (-)
+30	-1.37	-0.76 mm	-8.36	-0.35 mm	-0.62	-0.28 mm	-5.68	-0.16	-0.09 mm	-2.87	-0.16	-0.07 mm
+25	-1.38	-0.62 mm	-6.75	-0.22 mm	-0.62	-0.16 mm	-4.59	-0.16	-0.07 mm	-2.32	-0.16	-0.06 mm
+20	-1.39	-0.48 mm	-5.27	-0.16 mm	-0.62	-0.11 mm	-3.58	-0.16	-0.04 mm	-1.81	-0.16	-0.04 mm
+15	-1.39	-0.35 mm	-3.88	-0.11 mm	-0.63	-0.05 mm	-2.64	-0.16	-0.02 mm	-1.33	-0.16	-0.01 mm
+10	-1.40	-0.23 mm	-2.55	-0.05 mm	-0.63	0	-1.74	-0.16	0	-0.87	-0.16	0
+5	-1.40	-0.11 mm	-1.26	0	-0.63	-0.05 mm	-0.86	-0.16	+0.01 mm	-0.43	-0.16	+0.02 mm
0	-1.40	0	0	0	-0.63	-0.11 mm	0	-0.16	+0.02 mm	0	-0.16	+0.04 mm
-5	-1.40	+0.11 mm	+1.26	-0.05 mm	-0.63	-0.16 mm	+0.86	-0.16	+0.06 mm	+0.43	-0.16	+0.06 mm
-10	-1.40	+0.23 mm	+2.55	-0.11 mm	-0.63	-0.22 mm	+1.74	-0.16	+0.07 mm	+0.87	-0.16	+0.07 mm
-15	-1.39	+0.35 mm	+3.88	-0.16 mm	-0.63	-0.28 mm	+2.64	-0.16	+0.09 mm	+1.33	-0.16	+0.09 mm
-20	-1.39	+0.48 mm	+5.27	-0.22 mm	-0.62	-0.35 mm	+3.58	-0.16	+0.09 mm	+1.81	-0.16	+0.09 mm
-25	-1.38	+0.62 mm	+6.75	-0.28 mm	-0.62	-0.35 mm	+4.59	-0.16	+0.09 mm	+2.32	-0.16	+0.09 mm
-30	-1.37	+0.76 mm	+8.36	-0.35 mm	-0.62	-0.35 mm	+5.68	-0.16	+0.09 mm	+2.87	-0.16	+0.09 mm

\* Computer data from proximal to distal direction of the saw blade. Base corrective angle corresponds to the amount of closure of the intermetatarsal angle. Example: A postoperative IM angle of 4° from a preoperative 19° IM angle would provide a 15° base corrective angle. A proximal-to-distal direction will supinate the head, while distal-to-proximal direction pronates the head when the IM angle is closed.

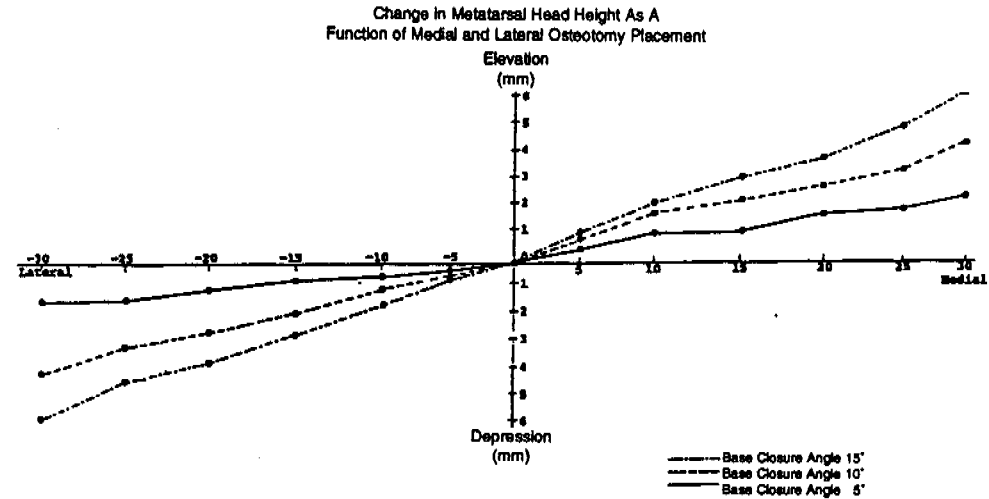


Figure 9. This is a graphic representation of Table 3. When the saw blade is directed in a lateral to medial direction, depression of the metatarsal head occurs. When the saw blade is directed in a medial to lateral direction, elevation of the first metatarsal head occurs.

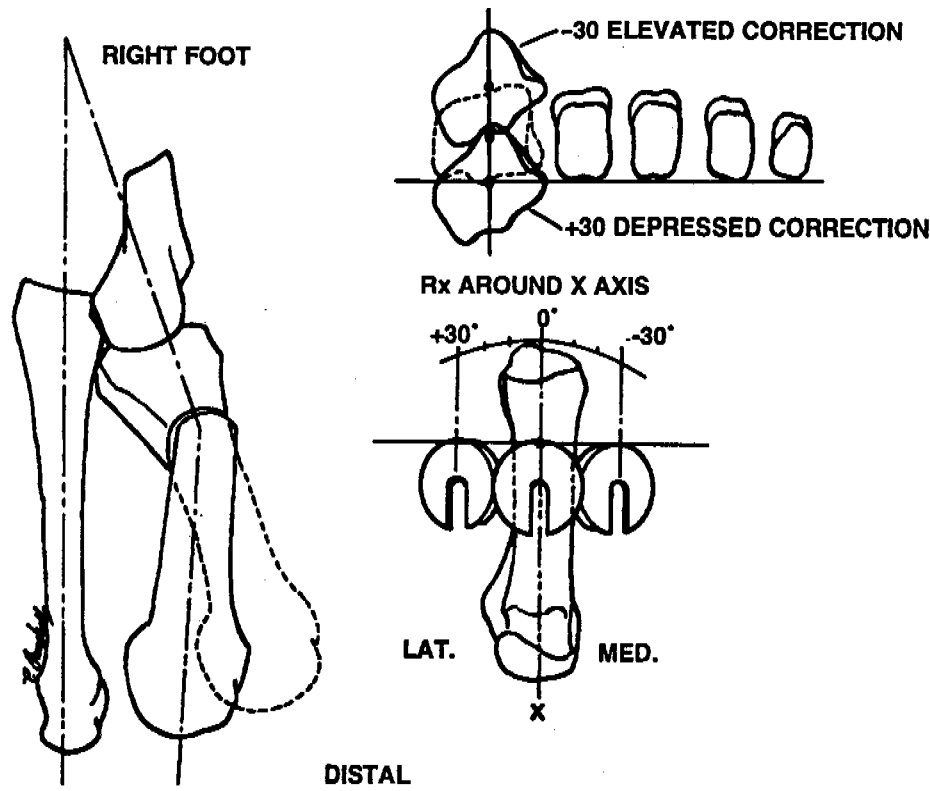
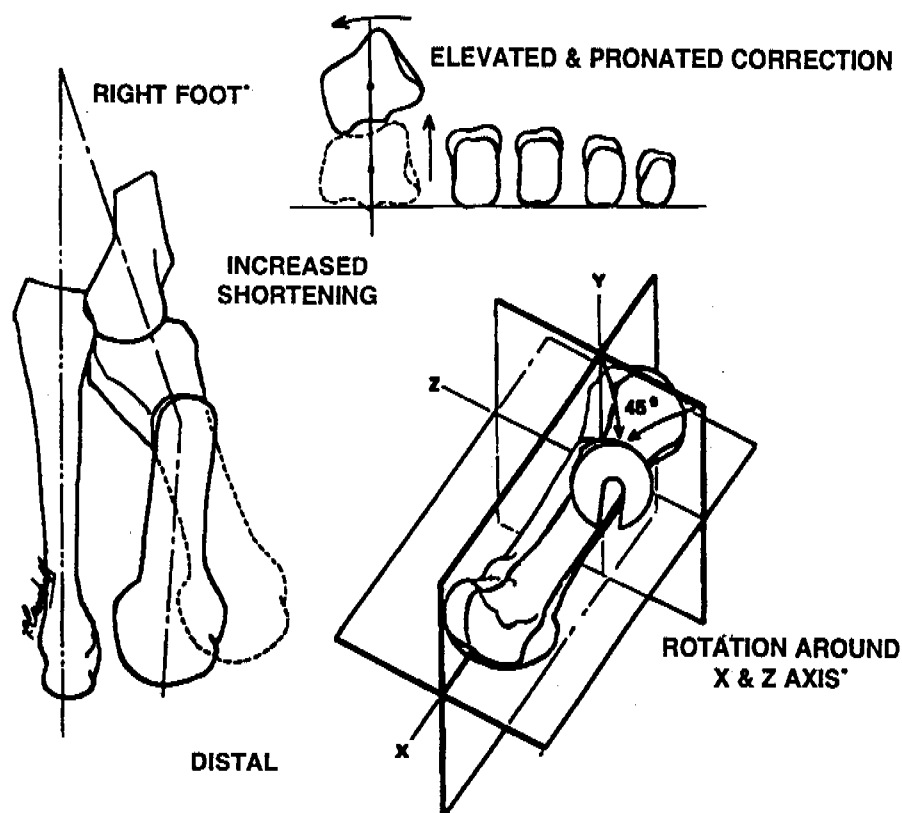


Figure 10. Graphic demonstration of directing the saw blade medially or laterally while maintaining the saw blade at 90 degrees to the long axis of the first metatarsal. When the intermetatarsal angle is corrected, then either elevation will occur when the saw blade is directed medially to laterally or depression of the metatarsal head will occur when directed laterally to medially.



**Figure 11** The saw blade is now directed 45 degrees distal to proximal, 45 degrees medial to lateral. When the intermetatarsal angle is closed then severe elevation and pronation of the metatarsal head will occur.

following the Mayo bunionectomy. Another possible sequela following osteotomy of the first metatarsal is lengthening. This can occur with an opening-wedge osteotomy. Two events have been noted following the lengthening of the first metatarsal. The first is that there may be an increase in the joint reaction force at the first metatarsophalangeal joint, leading to hallux rigidus. The second possible event is bowstringing of the soft tissue which may lead to a premature recurrence of the deformity. It is therefore desirable to maintain the neutral length of the first metatarsal. Shortening following the basilar crescentic osteotomy occurs for two reasons. First, there is loss of approximately 2 mm of bone that has been created by the saw blade. Second, shortening occurs with closure of the intermetatarsal angle. If a great deal of correction is needed and the osteotomy has been performed in a severely oblique fashion, then a great deal of shortening can occur. In the exaggerated 45-degree distal-to-proximal and medial-to-lateral saw blade orientation, 6.3 mm of shortening occurs. It is therefore recommended that, if a great deal of shortening is anticipated, then distal translation of the distal fragment may be necessary to return the metatarsal to its original length. This

translation creates a decreased amount of bone contact at the osteotomy site that otherwise might have caused instability, delayed union, or nonunion. It also is recommended that the obliquity be made in a proximal-to-distal angle. As previously noted, this orientation would supinate the first metatarsal head as opposed to a distal-to-proximal orientation, which would pronate the first metatarsal head.

Currently, it is recommended that the medial eminence of the first metatarsal head be excised before performing the basilar osteotomy. If the osteotomy has been performed at an oblique angle, then head rotation occurs as the intermetatarsal angle is closed. A previously well-trimmed metatarsal head will no longer exist if the rotation is significant. Therefore, trimming of the medial eminence should be performed after the basilar osteotomy has been completed. The osteotomy should be stabilized with either wire or screw fixation. It also is recommended that a motorized saw be used to excise the medial eminence because an osteotome may disrupt the basilar osteotomy's fixation.

The literature on three-dimensional orthopedic reconstructions typically has fallen into these areas: graphic representation of complex anatomic

Table 3. Change in Metatarsal Length and Head Position as a Function of Medial and Lateral Placement of Osteotomy\*

Cutter Position Medial	BASE CORRECTIVE ANGLE—15°				BASE CORRECTIVE ANGLE—10°				BASE CORRECTIVE ANGLE—5°			
	Change in Length (mm)	Elevation (+) Depression (—)		Supination (—) Pronation (+)	Change in Length (mm)	Elevation (+) Depression (—)		Supination (—) Pronation (+)	Change in Length (mm)	Elevation (+) Depression (—)		Supination (—) Pronation (+)
		Depression (—)	Elevation (+)			Depression (—)	Elevation (+)			Depression (—)	Elevation (+)	
+30	—1.80	+5.99 mm		0	—0.90	+4.26 mm		0	—0.23	+2.14		0
+25	—1.39	+4.77 mm		0	—0.76	+3.30 mm		0	—0.23	+1.81		0
+20	—1.39	+3.86 mm		0	—0.76	+2.67 mm		0	—0.16	+1.22		0
+15	—1.39	+2.92 mm		0	—0.76	+2.02 mm		0	—0.16	+0.92		0
+10	—1.40	+1.84 mm		0	—0.63	+1.24 mm		0	—0.16	+0.62		0
+5	—1.40	+0.92 mm		0	—0.62	+0.62 mm		0	—0.16	+0.31		0
0	—1.40	0		0	—0.63	0		0	—0.16	0		0
—5	—1.40	—0.92 mm		0	—0.63	—0.62 mm		0	—0.16	—0.31		0
—10	—1.40	—1.84 mm		0	—0.63	—1.24 mm		0	—0.16	—0.62		0
—15	—1.39	—2.92 mm		0	—0.76	—2.02 mm		0	—0.16	—0.92		0
—20	—1.39	—3.86 mm		0	—0.76	—2.67 mm		0	—0.16	—1.22		0
—25	—1.39	—4.77 mm		0	—0.76	—3.30 mm		0	—0.23	—1.81		0
—30	—1.80	—5.99 mm		0	—0.90	—4.26 mm		0	—0.23	—2.14		0

\* Computer data from medial or lateral direction of the saw blade. When the saw blade direction is medial to lateral, then elevation of the metatarsal head occurs as the IM angle is closed. When the saw blade is directed lateral to medial, then depression of the metatarsal head occurs.

structures, fabrication of complex implants and custom implants, and computer simulation of osteotomies.<sup>2,6,13,14,18,22,29,30,31</sup> Prior to this study, there was little information that was applicable to simulation of osteotomies for the practicing orthopedic surgeon. The computer simulation program that has been formulated can be used on a microcomputer, and is readily available to most orthopedic surgeons. This will allow an added avenue of precision when performing this osteotomy. The basilar crescentic osteotomy of the first metatarsal is a complex osteotomy that requires much in the way of preoperative planning.

### SUMMARY

A three-dimensional computer simulation of the basilar crescentic osteotomy has been presented. The bunion deformity consists of hallux valgus, an increased first and second intermetatarsal angle, pronation of the great toe, and elevation of the first metatarsal head. Every foot is different and some may have more or less of each of the above noted components. Because the deformity is multiplanar, at least two roentgenograms are needed to evaluate the deformity. The weight-bearing, anterior-posterior roentgenogram is the principle radiograph used in preoperative planning. The use of a weight-bearing, sesamoid roentgenogram is recommended to quantify the anterior-posterior deflection and rotation of the first metatarsal head. A computer model (based on a cylinder) of the first metatarsal has been formulated.

The osteotomy then was performed in a variety of scenarios in order to simulate the surgical correction. A great deal of flexibility is afforded by this osteotomy. The surgeon needs to be aware of the coupled motions that occur. That is, closure of the intermetatarsal angle may also cause head rotation, depression, or elevation. If the osteotomy is performed in an oblique multiplanar direction, then it is possible for the metatarsal head to elevate, pronate, and significantly shorten as the intermetatarsal angle is closed. If this scenario should occur, a poor surgical outcome will result. Excision of the medial eminence is recommended after the osteotomy has been completed and secured with stable fixation because of these rotational changes. The basilar crescentic osteotomy is an excellent method for correction of a marked metatarsus primus varus. It is important to pay close attention to a variety of anatomic considerations. The osteotomy must not be made in the diaphysis because of potential nonunion. There should be little dissection of the periosteum because of possible delayed union. As in any bunion surgery, it is essential to perform an adequate, distal, soft-tissue repair. Three dimensional preoperative planning is essential in obtaining correction of all components of a bunion. Specific guidelines, based on a three-dimensional computer model, are now available. An interactive computer program also is available to aid the surgeon in preoperative

planning. We hope there will be better understanding of this technically difficult but highly versatile osteotomy.

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## **A Theoretical Finite Element and Biomechanical Analysis of Transpedicular Screws for Fixation of the Spine**

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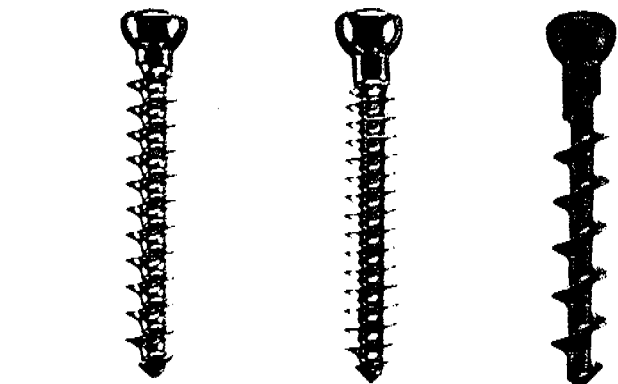
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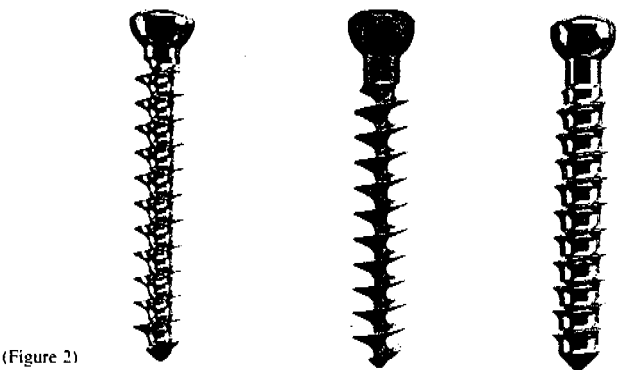
First presented at "The 2nd International Meeting on Advanced Spine Techniques" April 26-29, 1995.

INTRODUCTION:

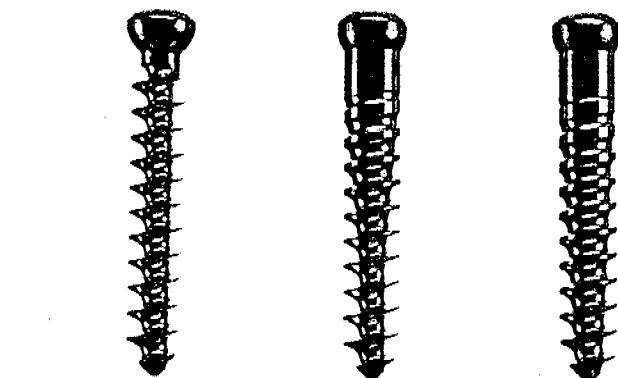
The choice of a transpedicular bone screw for fixation of the spine is made difficult by the variety of screws available which differ in material properties, dimensions and geometry. Above all, the choice is made difficult by a lack of scientific analysis on the bending strength, fatigue characteristics, stiffness, and pull-out strength with respect to the above variables. The purpose of this study is to develop and validate a theoretical Finite Element Analysis (FEA) model where the dimensional and geometrical properties can be independently varied, allowing for optimization of a screw design with respect to bending stiffness and pull-out strength. FEA enabled evaluation of the following variables independent of material and manufacturing variances: A) Pitch of 2.8, 2, and 5mm (Figure 1); B) Ratio between minor and major diameter (RMM) of 44, 25, and 75% (Figure 2); C) Taper over length of minor diameter of 0, 50, and 100% (Figure 3). These variables were evaluated both experimentally and using FEA with respect to bending stiffness and pull-out strength.



(Figure 1)



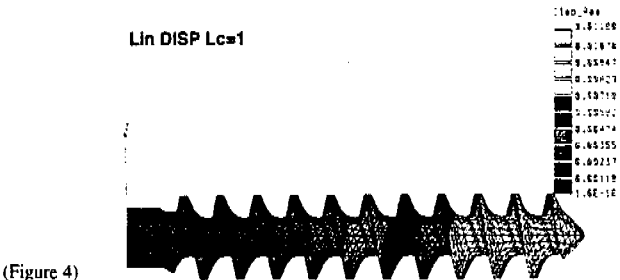
(Figure 2)



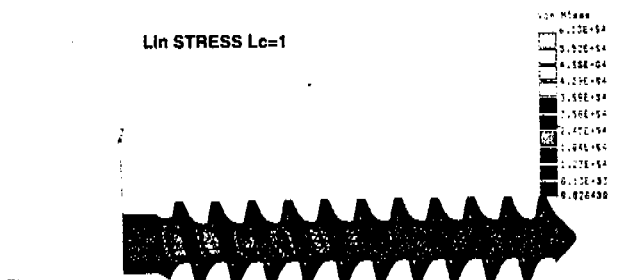
(Figure 3)

MATERIALS AND METHODS:

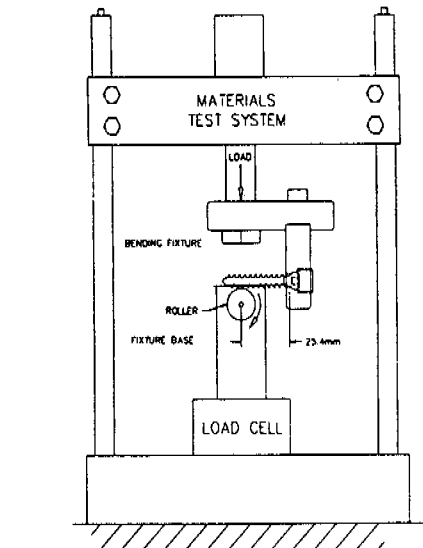
A standard 6.5 x 40mm 316L stainless steel (ASTM F138) AO bone screw was used as a control model, and material and mechanical properties for 316L were used for all models. The AO screw variables were 2.8mm pitch, 44% RMM, and 0% taper. First, a three dimensional (3D) FEA model of the AO screw was constructed and load stepped under cantilever bending to generate a force vs. displacement graph, from which stiffness was calculated (Figure 4), and a stress plot was produced to pinpoint the areas of highest stress (Figure 5). This model was validated experimentally by testing six (6) AO screws (Figure 6) under load control to generate six independent stiffness values, which were then averaged and compared to the FEA value. The remaining variables were evaluated in the same manner. Next, a two dimensional (2D) FEA model of the AO screw was constructed for pull-out strength, along with a simulated cancellous bone block. As a result of the 2D modeling, direct biomechanical comparison and validation of absolute pull-out force was not possible.



(Figure 4)

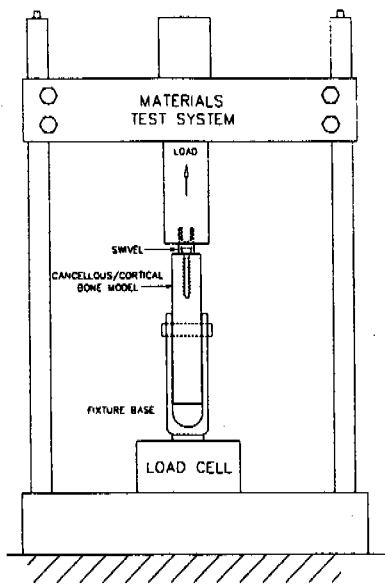


(Figure 5)



(Figure 6)

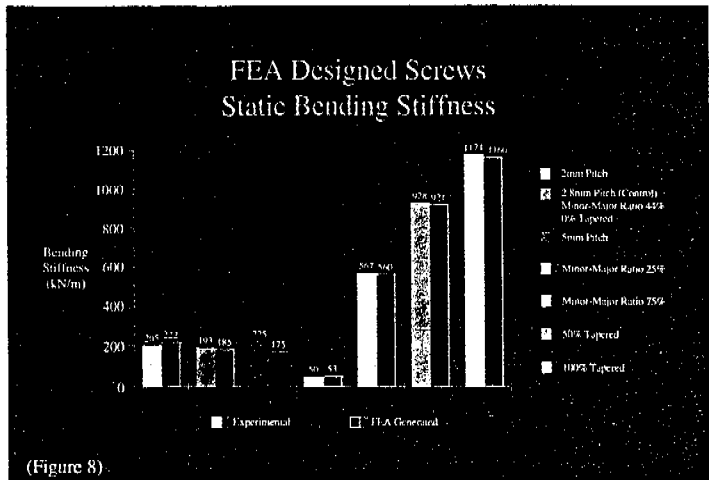
However, six (6) AO screws were tested for pull-out (Figure 7), along with samples produced to evaluate the remaining variables. If the statistical rankings of the FEA pull-out models matched the rankings of the experimental testing results, even though the specific values were not equal, the FEA model for pull-out was considered validated.



(Figure 7)

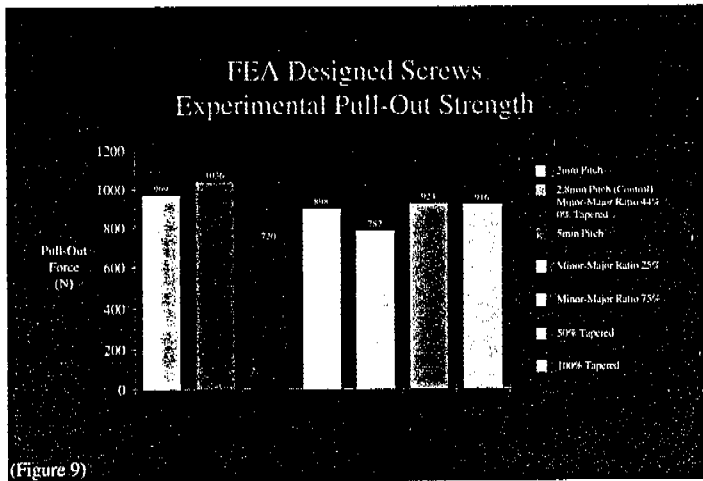
RESULTS:

Comparing the theoretical FEA and experimental stiffness values in cantilever bending for all variables yielded differences ranging from 0.7 to 22% (Figure 8), validating the FEA model. The percent difference between the lowest and highest values for all variables was 2250% (Figure 8). Statistical analysis showed that no differences exist in stiffness between the three pitches, but that differences do exist between the three RMM's and the three tapers.



(Figure 8)

Comparing the theoretical FEA and experimental values for pull-out showed identical rankings for all variables, validating the FEA model. The percent difference between the lowest and highest values for all variables was 44% (Figure 9). Statistical analysis showed that differences exist in pull-out between the three pitches and the three RMM's, while no differences exist between the three tapers.



(Figure 9)

CONCLUSIONS:

The results indicate that changing the variables of pitch, RMM and minor diameter taper affects the bending stiffness of the screw much more dramatically than it affects the pull-out strength. The pitch and RMM of the control screw are in the optimal range, but adding a minor diameter taper significantly improves the bending stiffness without sacrificing pull-out strength. Based on this study, optimum screw design relative to bending stiffness and pull-out strength is the 50 or 100% tapered screw. Of equal importance, further optimization can be readily performed using these validated FEA models.