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**STERGHOS, Peter, M.**; 5291 40th Avenue, St. Petersburg, FL 33709 (US).

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(74) Agent: **SLAVIN, Micheal, A.**; McHale & Slavin, P.A., 4440 PGA Blvd., Ste. 402, Plam Beach Gardens, FL 33410 (US).

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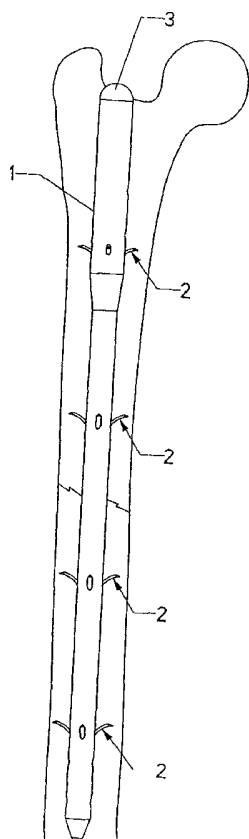
(71) Applicant: **BRAMLET, Dale, G.** [US/US]; 2044 Brightwaters Boulevard, N.E., St. Petersburg, FL 33704 (US).

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(72) Inventors: **COSGROVE, Patrick, J.**; 12200 4th Street E., Treasure Island, FL 33706 (US). **SODEIKA, John, A.**; 11650 Harborside Circle, Largo, FL 33773 (US).

[Continued on next page]

(54) Title: INTRAMEDULLARY NAIL



(57) Abstract: An intramedullary nail system for reducing and fixing fractures in long bones includes an elongated intramedullary nail having radial portals about the circumference. Tang assemblies are slidably telescoped inside the nail with resilient tangs which are deployed through the portals to interlock the nail and the portions of the bone.

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## INTRAMEDULLARY NAIL

### FIELD OF THE INVENTION

The present invention generally relates to an intramedullary nail system for reducing and fixing bone portions across a fracture therebetween providing a means of fixation through the use of tangs, screws or a combination of both.

### BACKGROUND OF THE INVENTION

In its most basic construct bones are formed of a relatively soft, spongy cancellous material surrounded by a much harder cortex. The cancellous bone yields under relatively low loading, while the much more dense cortical bone supports much higher loading. There have been a number of techniques used historically for treatment of fractures of the femur, humerus or tibia (referred to as the long bones). In early parts of this century, patients were merely placed in bed or in traction for prolonged periods, frequently resulting in deformity or death.

In the 1930s, the Smith-Peterson nail was introduced. This device was inserted into the intramedullary canal of the femur resulting in immediate fixation of hip fractures, early mobilization of the patient, and a lower morbidity and mortality. A number of nails have been introduced for intramedullary fracture fixation of long bones, including the Jewett Nail and Enders Nail.

Later intramedullary nails increased in diameter and surgeons/inventors began to experiment with cross section designs and radii of curvature along the nail's length. Since the femur curves slightly along its length, it was preferred that the nails have a similar long radius of curvature of, for example 50 inches. These nails were inserted down the entire length of the femoral canal to provide a basis for the construct. Fixation methods for certain types of fractures often required the nail to bear a portion of the

1 patient's weight during the recovery period. Threaded wires,  
2 standard bone screws or cannulated bone screws were then inserted  
3 through or along side the nail and into the outer cortex to provide  
4 enough fixation and rotational stability to bear weight during  
5 recovery.

6 As these intramedullary nails became longer other problems  
7 occurred. In longer nails the distal tip of the nail tends to rotate  
8 out of plane which forces the surgeon to target the distal screw  
9 holes using fluoroscopy by a method commonly known as "free-handing".  
10 Under this technique the surgeon utilizes fluoroscopic images in  
11 search of perfectly circular screw holes. Once found a mark is made  
12 on the patient, an incision is made and a pathway cleared to the  
13 cortical bone. A dimple is placed on the lateral cortex to reduce  
14 "drill walking" and the hole is then drilled and a screw inserted.  
15 Adjustments to this procedure are quite common; even to those skilled  
16 in the art of free handing.

17 Numerous patents, both domestic and foreign, have been granted  
18 citing devices which reduce the complications associated with distal  
19 screw targeting. The methods of accomplishing this task are varied,  
20 but the results are the same: Very few of the ideas have been  
21 developed and marketed as useful products. The majority of surgeons  
22 still return to free handing because there is a perceived time  
23 savings. Therefore, external methods for distal screw targeting have  
24 not gained favor.

#### 25 26 DESCRIPTION OF THE PRIOR ART

27 Newer devices and inventions explored additions to the nail to  
28 eliminate the need to locate the distal screw holes and improve the  
29 fixation. These newer devices are commonly classified as "expanding  
30 devices" and expand in size after placement to fill the  
31 intramedullary cavity. In the early 1980s, the Brooker-Wills Nail  
32 came on the scene and others soon followed. Freedland, U.S. Patent

1 No.s 4,632,101, 4,862,883 and 4,721,103, Chemello, U.S. Patent No.  
2 6,077,264, and Davis, U.S. Patent No. 5,057,103, describe methods of  
3 fixation which provide points which contact the internal cortical  
4 wall. In these patents a mechanism is actuated deploying arms or  
5 anchor blades through the cancellous bone to contact the inner  
6 cortical wall. These methods are complex and the arms are difficult  
7 to retract should the nail or lag screw assembly requires extraction.  
8 These arms do not deploy through the cortical bone.

9 Other expanding devices provide surface contact with the  
10 internal cortical wall resulting in a wedge effect. Kurth, U.S.  
11 Patent No. 4,590,930, Raftopoulos, U.S. Patent No.4,453,539, and  
12 Aginski, U.S. Patent No. 4,236,512, among others have described  
13 mechanisms which deploy or expand with a molly bolt concept. These  
14 methods are complex and the devices are difficult to retract should  
15 the nail require extraction. Neither do these devices deploy through  
16 the cortical bone.

17 Bolesky, U.S. Patent 4,275,717, was the first to discuss  
18 engagement within the cortical wall. However, Bolesky's invention  
19 does not address controlled penetration into the wall and required  
20 permanent implantation of the actuation rod. In addition, Bolesky  
21 does not address the fundamental problem of the actuation rod's  
22 protrusion extramedullarly into the surrounding musculature.

23 In U.S. Patent No.s 5,976,139 and 6,183,474B1, Bramlet et al  
24 describe a surgical anchor which has deployable tangs. These tangs  
25 are simple in design, internally positioned, yet easily deployed  
26 into, and if desired through, cortical bone providing improved  
27 purchase for compression of a proximal femur fracture, especially in  
28 osteogenic bone. These tangs are just as easily retracted should the  
29 device require explantation.

30

31

1     SUMMARY OF THE INVENTION

2             The intramedullary nail system according to this  
3     invention is especially suitable for installation within the  
4     medullary canal of a fractured long bone, such as a femur,  
5     humerus, or tibia and subsequently interlocking the nail and  
6     bone thereby preventing axial translation and axial  
7     rotation.

8             The intramedullary nail is, preferably, roughly  
9     circular in cross section and elongated although any number  
10    of cross sectional shapes may be used. The nail is,  
11    preferably, cannulated and anatomically curved to fit the  
12    shape of a bone.

13            The cannulated intramedullary nail allows passage of  
14    one or more anchoring tang assemblies. These anchoring tang  
15    assemblies are inserted from the proximal end and telescoped  
16    through the axial bore towards the distal end by a  
17    insertion/deployment/retraction instrument. An alternate  
18    embodiment has a retracted tang mounted on a tang assembly  
19    that is permanently placed within the intramedullary nail  
20    and is deployed and retracted by the above mentioned  
21    instrument.

22            The proximal end of the nail contains a securing  
23    arrangement for a tool for driving and extracting the nail.  
24    The tool advantageously cooperates with a slot in the  
25    proximal end of the nail so that the desired angular  
26    disposition of the nail is indicated and easily maintained  
27    during insertion of the nail.

28            When the intramedullary nail is placed into position,  
29    the anchoring tang assembly is actuated to deploy the tangs  
30    outwardly from their stowed position through the portals and  
31    into the cortical bone. The interlocking of the  
32    intramedullary nail to the cortical shell of the long bone

1 may be achieved, at least once, using at least one screw or  
2 at least one tang assembly. In the preferred embodiment,  
3 several tang assemblies would be positioned longitudinally  
4 within the nail based on the fracture location and the  
5 surgeon's assessment for proper fixation. The tangs are  
6 deployed to any desired position thereby achieving a desired  
7 fixation and rotation prevention based upon the quality of  
8 the bone. Should the system require additional load  
9 carrying capability, cortical screws may be placed to  
10 further secure the nail with the surrounding bone.

11 The anchoring tang assembly contains arcuate shaped  
12 tangs that are permanently attached to the tang assembly  
13 body. These tangs are initially formed into a prescribed  
14 position for storage. As the assembly is actuated, the  
15 tangs deploy and are formed into their final shape through  
16 interaction with the portal in the nail.

17 The end cap preferably contains a coating of ultra-high  
18 molecular weight polyethylene (UHMWPE) within the threads.  
19 This provides constant positive engagement between the end  
20 cap external threads and the intramedullary nail internal  
21 threads preventing loosening of the end cap due to bodily  
22 forces.

23 Should the situation arise in which the surgeon  
24 requires removal of the intramedullary system, the tangs are  
25 completely reversible. The end cap is removed and the tang  
26 assembly insertion/deployment/retraction instrument is  
27 inserted through the axial bore. When the first tang  
28 assembly is encountered, a force is exerted on the  
29 instrument against the tang body causing the body to move  
30 longitudinally resulting in the tangs engaging the portal  
31 and pulling away from the bone and returning inside the  
32 nail. Once the tangs are completely inside the axial bore,

1 the tang assembly is free to slide within the intramedullary  
2 nail. Force is continually applied, to the instrument,  
3 telescoping the instrument and tang assembly further along  
4 the nail until another tang assembly is encountered. The  
5 first tang assembly will "nest" with the second tang  
6 assembly. Upon continued pressure, the entire assemblage  
7 telescopes through the axial bore until the last tang  
8 assembly has been retracted and rests against the bottom of  
9 the axial bore of the intramedullary nail. The nail can  
10 then be extracted from the bone.

11 In one embodiment of the present invention, the  
12 intramedullary nail system is combined into a kit which  
13 includes several intramedullary nails of differing lengths  
14 and/or diameters and/or shapes, each having an axial bore,  
15 radial bores and portals which allow passage of different  
16 sized locking screws and anchoring tangs through the nails  
17 into the surrounding bone. The intramedullary nails have a  
18 distal end and a proximal end with internal threads in the  
19 proximal end. Several like-sized end caps are provided in  
20 the kit, each with external threads to cooperate with the  
21 internal threads in the proximal ends of the nails.  
22 Different sized tang assemblies are in the kit for selective  
23 telescoping movement through like-sized axial bores of the  
24 several nails. The tang assemblies may differ in diameter  
25 and/or in the length of the tangs carried by the tang  
26 assemblies. Also in the kit are several different sized  
27 cortical screws for use in conjunction with the nails. One  
28 or more insertion/deployment/retraction instruments are  
29 provided in the kit to manipulate the tang assemblies in the  
30 axial bore of a nail to deploy the tangs through the portals  
31 into a bone. The instrument is of a length that it may be  
32 manipulated at the proximal end of the nail to deploy or



1 retract tangs at the distal end of the nail. The kit allows  
2 the surgeon flexibility in selecting the proper nail system  
3 for the fracture presented by the patient. The entire kit  
4 may be sterilized and presented in the operating room or  
5 some choices may be made earlier as to the elements to be  
6 used in a particular situation.

7 Finally, once the intramedullary nail is locked into  
8 the bone a condition known as stress shielding is typically  
9 inherent in the bone. As the bone heals these stresses need  
10 to be relieved. The bone can heal in a pre-stressed  
11 condition and re-fracture at a later date or the nail  
12 rotates with respect to the bone and repeated loading causes  
13 screw failure.

14 Clearly a need exists for a system that offers the ease  
15 of insertion and superior performance of existing  
16 intramedullary nails while minimizing the surgical insult to  
17 the human body and eliminates the need for distal screw  
18 targeting. Such a system would include a simple, effective  
19 and controllable fixation device which allows greater  
20 purchase of the bony fragments, provides a means of  
21 rotational stability in the femoral shaft, and offers to  
22 minimize, if not eliminate the need for additional distal  
23 incisions to locate and place locking screws. This system  
24 would be designed to allow the surgeon a choice of  
25 penetration distance within the femoral shaft and fixation  
26 based upon the injuries presented and the desired level of  
27 treatment. Finally, this system would allow explantation to  
28 occur as easily as implantation.

29  
30 BRIEF DESCRIPTION OF THE DRAWINGS

31 FIG. 1 is a perspective view, partially in cross section, of the  
32 intramedullary system placed in a bone;

FIG. 2 is a perspective view, in partial longitudinal cross section, showing cortical screws;

FIG. 3A is a perspective of the intramedullary nail and tang assembly of FIG.1;

FIG. 3B is a longitudinal cross section of the nail shown in FIG. 3A;

FIG. 4A is a longitudinal cross section of the nail showing the nested tang assemblies;

FIG. 4B is an enlarged partial cross section of FIG 4A;

FIG. 5A is a side perspective of the intramedullary nail;

FIG. 5B is a front perspective of FIG. 5A;

FIG. 5C is a longitudinal cross section along line 5C-5C of FIG. 5B;

FIG. 6A is an enlargement of a deployed tang assembly of FIG. 3A;

FIG. 6B is an enlargement of tang assembly of FIG. 6A in the stowed state;

FIG. 6C is a top view of FIG. 6B;

FIG. 7A is a top view of the end cap of FIG. 3A; and

FIG. 7B is a perspective of the end cap of FIG. 7A.

#### DETAILED DESCRIPTION

The individual components of the assembly, as illustrated in FIG.1 and FIG. 2, are constructed of implantable grade stainless steel alloys in the preferred embodiment but could also be constructed of implantable grade titanium alloys as well. These components consist of the nail body 1, the tang assembly 2, the end cap 3, and the optional cortical screws 4.

The nail body, of FIG. 5 A, B, C, is anatomically designed for antegrade insertion into the intramedullary canal of a long bone. However, retrograde insertion into the intramedullary canal is

possible with a nail body of similar function, but different anatomical shape. The proximal outside diameter W of the nail body 1 is greater than the distal outside diameter M to improve the fit within the proximal bone. Applications within other long bones may result in the proximal outside diameter W being equal to the distal outside diameter M. Along the length of the nail body 1 are multiple sets of four tang portals 5, as shown in FIG.s 3A and 3B. A lesser or greater number of circumferential tangs and portals may be employed with the intramedullary nail system (not shown). Each set of four tang portals 5 are located on a 90 degree radial spacing penetrating from the leading outside diameter M into the distal bore 6, on axes which form an angle J to the distal outside diameter M. This angle J is critical to the proper formation and exit of the tang 16. The clearance holes 9 of FIG. 5C pass through the distal outside surface and wall into the distal bore 6 and continue on the same axis through the opposite wall and outer diameter. Their diameter is such as to allow passage of the threaded portion of the cortical screw 4 shown in FIG. 2. A frusto-conical surface 10 (FIG. 5C) provides a transition between the circular bore 6 and the bore 11. The bore 11 serves three purposes: It provides clearance through the leading end of the nail body 1 for passage of a guide pin, used during fracture alignment and installation of the nail body 1 into the intramedullary canal, it provides a sliding fit for the forward protrusion 18 (FIG. 6A) of tang assembly 2, and it acts as a "vent" hole for any organic material within the bore 6 which is being pushed ahead of the tang assembly 2 during tang assembly 2 installation. It must be noted that the forward most clearance holes 9 also intersect the frusto-conical feature 10 and will act as vents for organic material during tang assembly 2 insertion after the protrusion 18 has engaged and filled bore 11. The internal threads 13 at the trailing end of the nail body 1 provide for instrument interface, as do slots 14. The threads 13 are used for attachment and the slots 14 for radial

1 alignment. The internal threads 13 also engage the external threads  
2 23 shown in FIG. 7A of end cap 3.

3 The tang assembly 2 has four equally sized and radially spaced  
4 tangs 16 which are preformed to radius R. The radius R (FIG. 6B) on  
5 each tang 16 results in a dimension between the trailing ends of  
6 opposing legs which is greater than the outside diameter of tang body  
7 15 and the bore diameter 6 of nail body 1. The tang body 15 is  
8 circular in cross section and sized for a sliding fit within nail  
9 body bore 6 with a leading edge chamfer 17 which transitions into the  
10 leading protrusion 18 which has a square cross section and leading  
11 end taper 19. Tang body 15 contains an internally threaded bore 20  
12 which is the instrument interface for the  
13 insertion/deployment/retraction instrument 25 used to insert and  
14 deploy the tang 16 of tang assembly 2. It must be noted that  
15 threaded bore 20 is not needed for tang retraction. FIG. 6A  
16 illustrates the deployed shape of tang assembly 2 which is the shape  
17 it assumes after the tangs have been forced through the tang portals  
18 5 of nail body 1.

19 Insertion/deployment of the tang assemblies 2 occurs after  
20 insertion of the nail body into the intramedullary canal. The  
21 insertion/deployment instrument is threaded into the threaded bore 20  
22 of the most distal tang assembly 2. The most distal tang assembly 2  
23 is now inserted through nail body proximal bore 7 and into nail body  
24 distal bore 6. Since the distance between opposing tangs 16 is  
25 greater than the bore diameter 6 due to radius R, the interference  
26 with bore 6 forces the tangs 16 inward in an elastic manner and  
27 insertion continues. As the tang travels down bore 6, any organic  
28 material which has accumulated in bore 6 is pushed ahead and forced  
29 out through bore 11 of nail body 1 and through clearance holes 9.  
30 Further insertion causes the tang assembly 2 leading taper 19 to  
31 contact the bore 11 of the nail body 1. Since both cross sections  
32 are matched, no engagement will occur until they are radially aligned

1 which may or may not occur without some slight rotation of the tang  
2 assembly 2 using the insertion/deployment instrument. After  
3 alignment occurs and by virtue of this alignment, the tang leading  
4 protrusion 18 will slide freely in bore 11 and the tangs 16 and the  
5 nail body 1 tang portals 5 will now be aligned. The tang assembly 2  
6 continues past tang portals 5 and is fully inserted when the tang  
7 body leading edge chamfer 17 makes contact with the nail body frusto-  
8 conical feature 10 at point C FIG. 4B. In this position, the leading  
9 end of tang assembly 2 protrudes through the end of nail body 1 to  
10 point A and the trailing end of the tangs 16 are just past tang  
11 portals 5. The tang is now in position to be deployed. To deploy the  
12 tang, an axial force is exerted by the insertion/deployment  
13 instrument in the opposite direction as for insertion. This causes  
14 the tang assembly 2 to translate back up bore 6 and the sharp ends of  
15 tangs 16 to encounter tang portals 5. Since the tangs 16 were  
16 resiliently compressed inward by bore 6 they will now spring outward  
17 forcing the sharp end of tangs 16 into tang portals 5. Further  
18 translation of the tang assembly 2 forces the tangs 16 through the  
19 tang portals 5. Due to the diameter and angle of the tang portals 5,  
20 the tangs 16 are formed in such a manner as to emerge almost  
21 perpendicular to the femoral cortex at a final radius S. Continued  
22 translation of the tang assembly 2 causes the tangs 16 to penetrate  
23 the femoral cortex. During this time, tang leading protrusion 18 is  
24 still engaged by the nail body bore 11 thus preventing rotation of  
25 tang assembly 2 in bore 6 during deployment and preventing unwanted  
26 twisting of the tangs 16. The tang assembly 2 can be deployed fully  
27 or partially and is self locking in any position due to the almost  
28 perpendicular entry angle into the cortex. After deployment, the  
29 insertion /deployment instrument is unthreaded from tang threaded  
30 bore 20 and removed. The nail body 1 is now fixed axially and  
31 rotationally in the intramedullary canal. FIG.3B shows the tang  
32 assembly 2 in the fully deployed position having translated a

1 distance from point A FIG. 4B to point B FIG. 3B. The tangs 16 are  
2 fully retractable. Tangs 16 are retracted by applying a force on the  
3 tang assembly 2 with instrumentation in the opposite direction as  
4 deployment until the tang assembly 2 comes to rest at points C and A  
5 FIG. 4B.

6 Placement of additional tang assemblies 2 and deployment of  
7 tangs 16 is accomplished in much the same manner as that described  
8 above. As the more proximal tang assemblies 2 are added the  
9 insertion/deployment instrument 25 plays a more important role in  
10 obtaining proper alignment with the respective tang portals 5. FIG.  
11 1, 3A and 3B show deployment of multiple tang assemblies 2.

12 Distal fixation of the nail body 1 can be accomplished without  
13 use of tang assembly 2. This is accomplished by using the cortical  
14 screws 4 (FIG.2). The cortical screws 4 are placed through the  
15 lateral femoral cortex and through clearance holes 9 in the nail body  
16 1, then through the medial femoral cortex FIG. 2. The cortical  
17 screws are not used in conjunction with distal tang fixation and  
18 cannot be passed through clearance holes 9 if there is a tang  
19 assembly 2 inserted into nail body 1 at that location.

20 The end cap 3 is inserted into the proximal end of nail body 1  
21 until external threads 23 (FIG.7B) contact the internal threads 13 of  
22 nail body 1. The end cap 3 is then rotated clockwise by means of  
23 hexagonal recess 21 to engage the threads. End cap 3 contains a  
24 coating of ultra high molecular weight polyethylene (UHMWP) 24 which  
25 acts as a thread locking element to help prevent unwanted loosening  
26 of end cap 3. The top surface 22 of end cap 3 is rounded to provide  
27 an anatomic fit with the surrounding bone, thus eliminating  
28 irritation against the surrounding musculature.

29  
30

## 1 CLAIMS

2  
3 We claim:  
4

5 1. An intramedullary nail for reducing and stabilizing  
6 fractures in long bones comprising an elongated body sized and  
7 shaped for insertion in the intramedullary canal of said bone,  
8 said elongated body having a proximal end and a distal end,  
9 said proximal end to be disposed on one side of a fracture and  
10 said distal end to be disposed on the other side of a  
11 fracture, said elongated body having an axial bore throughout  
12 the length, said proximal end having a plurality of radial  
13 bores extending through said axial bore and said elongated  
14 body normal to said axial bore, said distal end having a  
15 plurality of radial bores extending through said axial bore  
16 and said elongated body normal to said axial bore, said  
17 proximal end having at least one portal extending through said  
18 elongated body from said axial bore, said distal end having at  
19 least one portal extending through said elongated body from  
20 said axial bore, a tang assembly disposed in said axial bore  
21 for longitudinal movement therein, said tang assembly  
22 including a resilient tang for radial deployment, said tang  
23 resiliently extending through one of said portals upon  
24 longitudinal movement of said tang assembly.

25  
26 2. An intramedullary nail of claim 1 wherein said tang is  
27 arcuate in shape upon radial deployment to apply compression  
28 between said proximal end and said distal end of said  
29 elongated body.  
30  
31

1 3. An intramedullary nail of claim 2 wherein an end cap is  
2 removably connected to said proximal end of said elongated  
3 body.

4  
5 4. An intramedullary nail of claim 3 wherein at least one  
6 cortical screw is inserted through said bone and one of said  
7 plurality of radial bores to provide additional load carrying  
8 capability.

9  
10 5. An intramedullary nail of claim 1 wherein said distal end  
11 axial bore has a reduced cross section, said tang assembly  
12 having a leading end and a trailing end, the shape of said  
13 leading end corresponding to said reduced cross section of  
14 said distal end axial bore preventing rotational movement of  
15 said tang assembly during longitudinal movement.

16  
17 6. An intramedullary nail of claim 5 wherein a retraction  
18 instrument is telescoped through said axial bore of said  
19 elongated body, said retraction instrument having a leading  
20 end and a trailing end, said leading end of said instrument  
21 temporarily engaging said trailing end of said tang assembly,  
22 said trailing end of said instrument extending outwardly from  
23 said proximal end whereby manipulation of said trailing end of  
24 said instrument causes longitudinal movement of said tang  
25 assembly and deployment of said tang.

26  
27 7. An intramedullary nail of claim 6 wherein said  
28 manipulation of said trailing end of said instrument is  
29 rotational.

30  
31



1 8. An intramedullary nail of claim 6 wherein said  
2 manipulation of said trailing end of said instrument is  
3 longitudinal.  
4

5 9. An intramedullary nail of claim 1 wherein said distal end  
6 has a plurality of portals, said proximal end has a plurality  
7 of portals, a plurality of tang assemblies disposed in said  
8 axial bore of said distal end corresponding to said plurality  
9 of portals in said distal end, a plurality of tang assemblies  
10 disposed in said axial bore of said proximal end corresponding  
11 to said plurality of portals in said proximal end, said tangs  
12 of each of said tang assemblies extending through said  
13 corresponding portals of said distal end and said proximal  
14 end.  
15

16 10. An intramedullary nail of claim 9 wherein at least one  
17 tang assembly is disposed in said axial bore of said distal  
18 end and at least one tang assembly is disposed in said axial  
19 bore of said proximal end, said tang of said tang assembly  
20 disposed in said axial bore of said distal end extending  
21 through a portal of said plurality of portals in said distal  
22 end and said tang of said tang assembly disposed in said axial  
23 bore of said proximal end  
24 extending through a portal of said plurality of portals in  
25 said proximal end whereby said tangs may be selectively  
26 deployed along said elongated body.  
27

28 11. An intramedullary nail kit for fixing bone fractures  
29 comprising a plurality of different sized elongated bodies  
30 shaped for insertion in the intramedullary canal of a long  
31 bone,  
32

1       each elongated body having a proximal end for disposition  
2       on one side of a fracture, a distal end for disposition  
3       on the other side of a fracture and an intermediate  
4       portion connecting said proximal and distal ends,  
5       said elongated body having an axial bore throughout;  
6       a plurality of end caps adapted for insertion in said axial  
7       bores in said proximal end of said different sized elongated  
8       bodies;  
9       each end cap and said proximal end having  
10       cooperating structure for removably securing said  
11       end cap to said elongated body;  
12       said proximal ends of said different sized elongated bodies  
13       having at least one radial bore extending through said axial  
14       bores and normal thereto;  
15       said distal ends of said different sized elongated bodies  
16       having at least one radial bore extending through said axial  
17       bore and normal thereto;  
18       at least one portal in said proximal ends of said different  
19       sized elongated bodies;  
20       at least one portal in said distal ends of said different  
21       sized elongated bodies; and  
22       at least one portal in said intermediate portions of said  
23       different sized elongated bodies;  
24       said portals each including at least one bore  
25       extending from said axial bore at an obtuse angle;  
26       a plurality of tang assemblies adapted to slidably traverse  
27       said axial bores of said different sized elongated bodies,  
28       each of said plurality of tang assemblies having at  
29       least one resilient tang, some of said tang assemblies  
30       having a different sized resilient tang, each of said  
31       resilient tangs adapted to be deployed through one of  
32       said portals into a bone;

1 a plurality of different sized cortical bone screws adapted to  
2 traverse a bone and said radial bores in said distal end and  
3 said proximal end of said plurality of different sized  
4 elongated bodies; and  
5 an instrument for movably engaging one of said plurality of  
6 tang assemblies;

7 said instrument adapted to slide said tang assembly  
8 through said axial bore and manipulate said tang assembly  
9 to deploy said tang;

10 whereby a particular sized intramedullary nail having  
11 particular sized tangs may be selected from said kit to fix a  
12 fracture in different sized bones, said instrument slides at  
13 least one particular sized tang assembly through said axial  
14 bore and manipulates said tang assembly to deploy said  
15 particular sized tang into the bone, said instrument is  
16 removed from said axial bore and an end cap is removably  
17 secured in said axial bore at said proximal end to close said  
18 axial bore.

19  
20 12. An intramedullary nail kit of claim 11 wherein said tang  
21 assemblies have at least two tangs on opposite sides of said  
22 tang assembly and said portals have at least two obtuse bores  
23 on opposite sides of said axial bore.

24  
25 13. A method of reducing and fixing fractures in long bones  
26 comprising the steps of

27 a) providing an intramedullary nail having an elongated  
28 body with an axial bore, said elongated body having a proximal  
29 end and a distal end, said proximal end having a plurality of  
30 radial bores extending through said axial bore and said  
31 elongated body normal to said axial bore, said distal end  
32 having a plurality of radial bores extending through said

1 axial bore and said elongated body normal to said axial bore,  
2 said proximal end having a plurality of portals in said  
3 elongated body, said distal end having a plurality of portals  
4 in said elongated body, each of said portals comprised of a  
5 plurality of circumferential bores through said elongated  
6 body,

7 b) inserting said intramedullary nail into the  
8 intramedullary canal of a fractured long bone with said  
9 proximal end disposed on one side of said fracture and said  
10 distal end on the other side of said fracture,

11 c) providing a retraction instrument having a size and  
12 shape to be telescoped through said elongated body, said  
13 instrument having a leading end adapted to be disposed  
14 adjacent said distal end and a trailing end adapted to be  
15 disposed adjacent said proximal end, said leading end  
16 including deployment structure,

17 d) providing a tang assembly having a tang body with  
18 cooperating structure for engaging said deployment structure  
19 and a plurality of tangs disposed about the circumference of  
20 said body, said tangs sized and shaped to extend through said  
21 circumferential bores of said portals,

22 e) inserting a tang assembly in said axial bore at said  
23 proximal end and longitudinally displacing said assembly  
24 toward said distal end of said elongated body with said  
25 retraction instrument,

26 f) manipulating said trailing end of said retraction  
27 instrument to engage said deployment structure and said  
28 cooperating structure to extend said tangs through said  
29 circumferential bores into said bone securing said distal end  
30 about said radial and said axial axes,

31 g) disengaging and removing said retraction instrument,

32

1           h) repeating steps e)-g) to insert a plurality of tang  
2 assemblies including inserting tang assemblies in said  
3 proximal end of said elongated body,

4           i) providing an end cap sized and shaped to close the  
5 axial bore in said proximal end of said elongated body and  
6 securing said end cap in said axial bore.

7  
8       14. A method of claim 13 including the step of inserting a  
9 cortical screw through said bone and through one of said  
10 plurality of radial bores.

11  
12       15. A method of claim 13 including removing said tangs from  
13 said bone by unsecuring said end cap from said axial bore of  
14 said proximal end, removing said end cap, inserting said  
15 retraction instrument in said axial bore, engaging a tang  
16 assembly and longitudinally displacing a first said tang  
17 assembly toward said distal end of said elongated body thereby  
18 causing said first tangs to retract into said axial bore,  
19 further longitudinally displacing said first tang assembly to  
20 contact a second said tang assembly, further longitudinally  
21 displacing said first and second tang assemblies to cause said  
22 tangs of said second tang assembly to retract into said axial  
23 bore and continuing said longitudinal movement toward said  
24 distal end until all tangs are retracted into said axial bore.

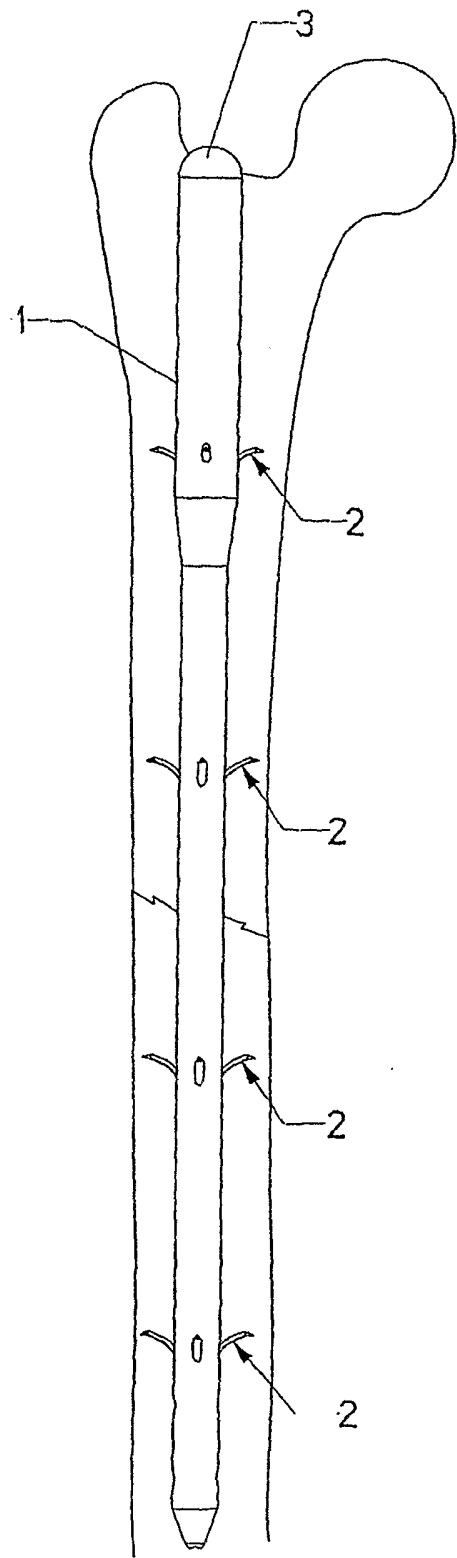


FIG. 1

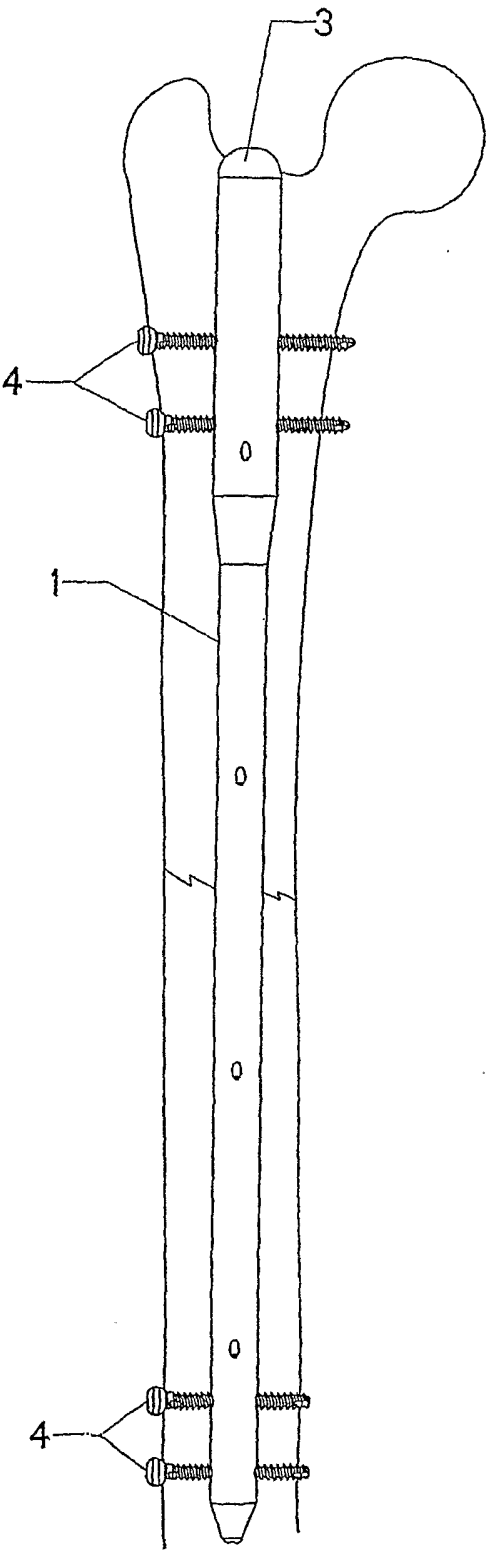


FIG. 2

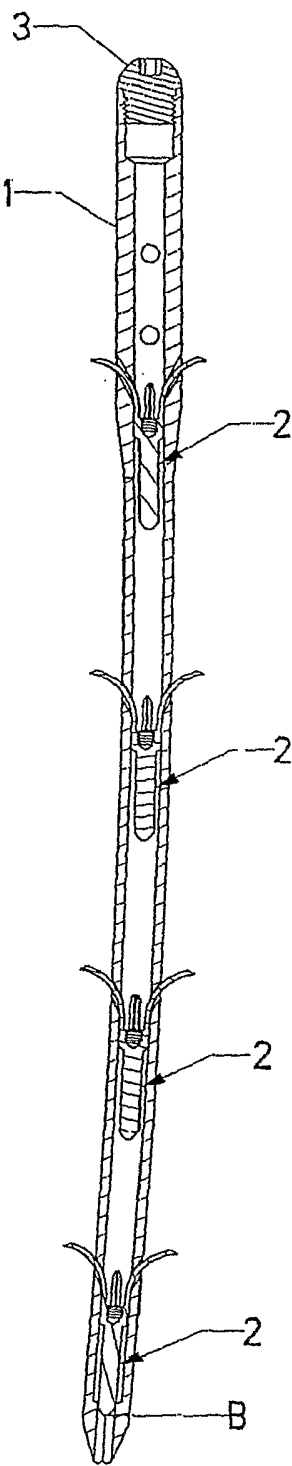


FIG. 3B

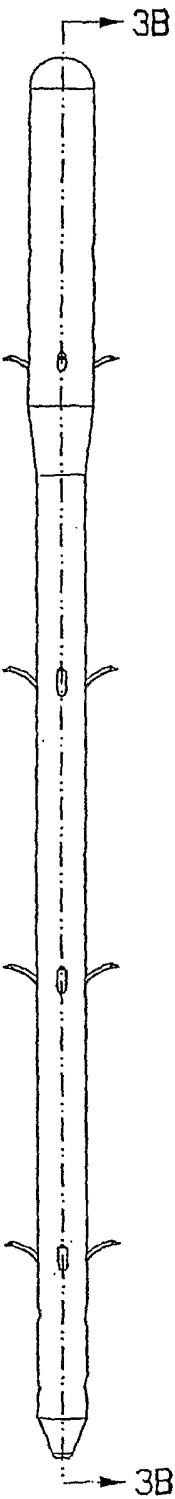


FIG. 3A

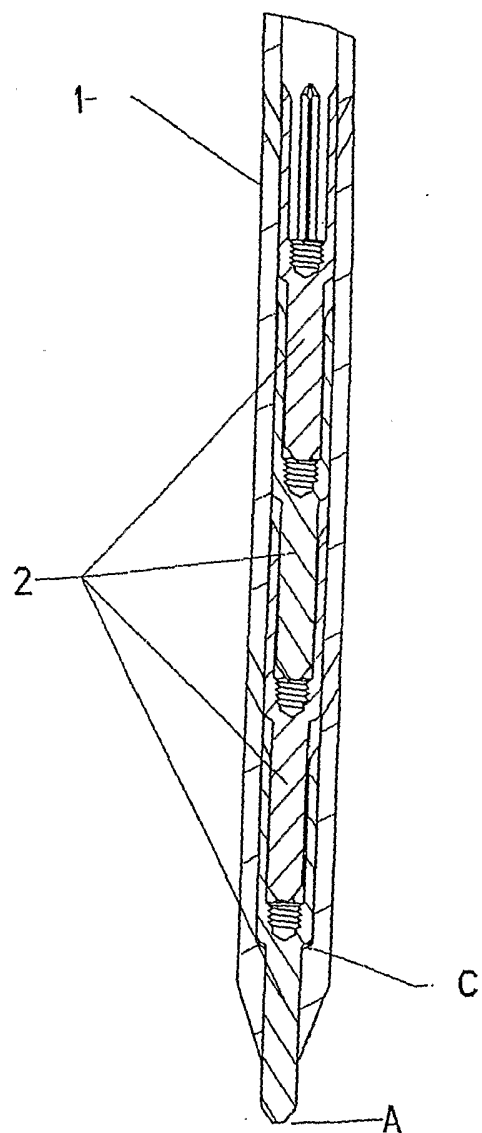
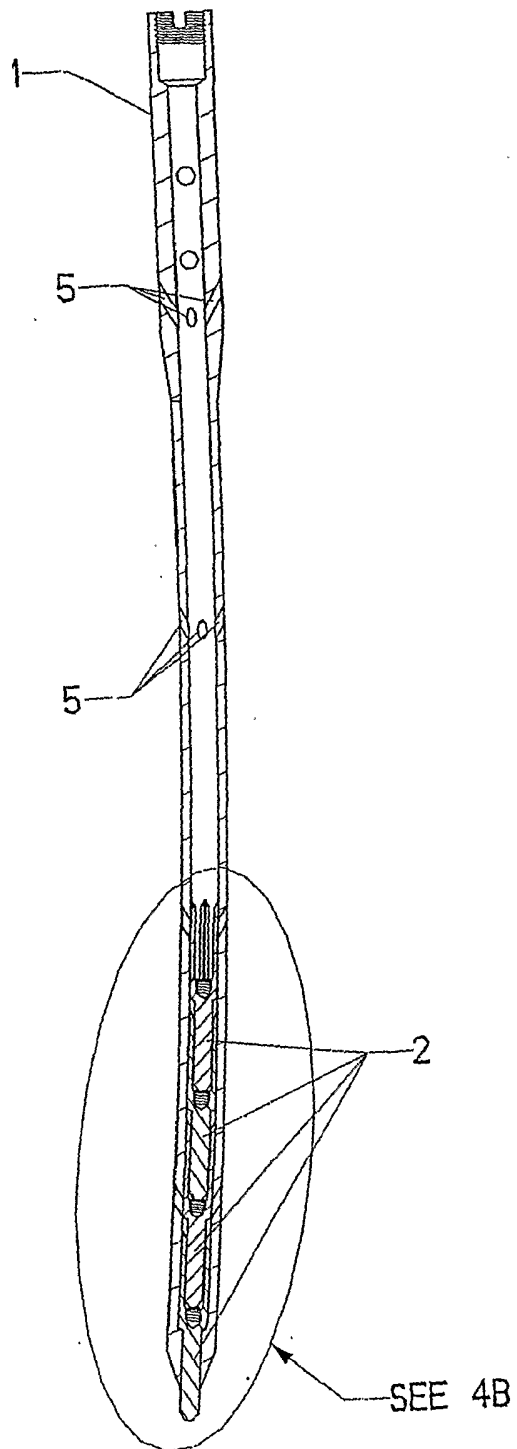






FIG. 5A

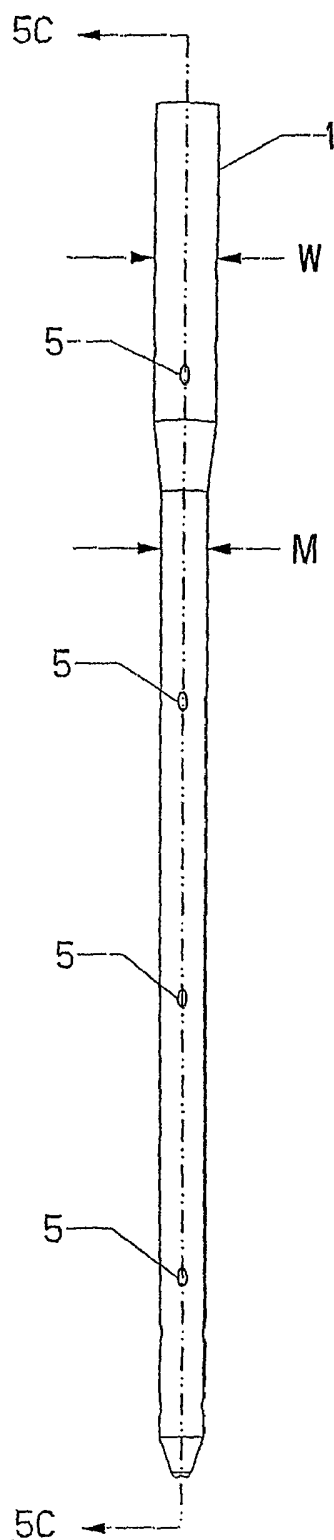


FIG. 5B

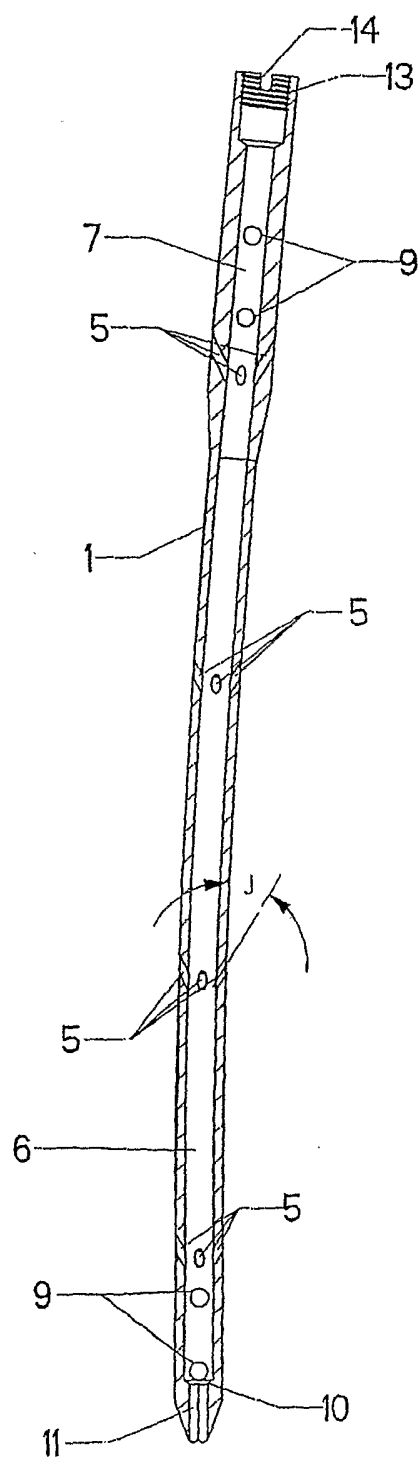


FIG. 5C

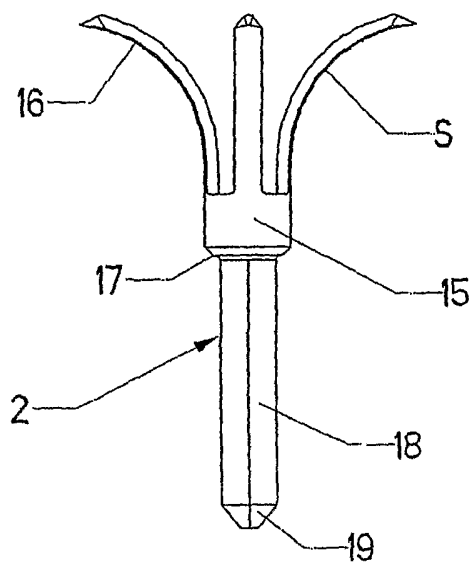


FIG. 6A

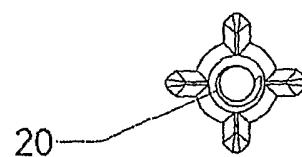


FIG. 6C

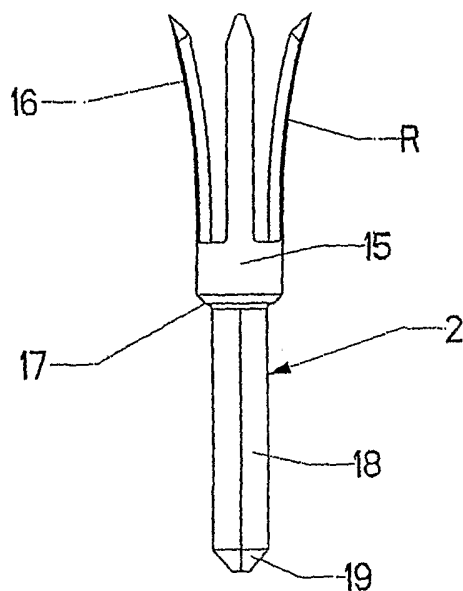


FIG. 6B

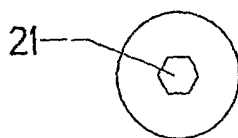


FIG. 7A

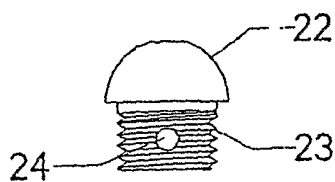


FIG. 7B

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/15036

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/72

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 077 264 A (CHEMELLO ANTONIO) 20 June 2000 (2000-06-20) cited in the application abstract; claims 1,4,14,15,20; figures 3-5,10,11	1-4,9-12
A	column 4, line 49-54 ---	6-8
X	EP 0 922 437 A (ORTOMEDICAL S P A) 16 June 1999 (1999-06-16) abstract; claim 1; figures 4,10,11 ---	1,9,10
X	DE 24 04 441 A (DAWIDOWSKI GERHARD) 31 July 1975 (1975-07-31) claim 1; figures 1,2 ---	1,2,9,10
A	---	11
X	DE 22 60 839 B (SCHILGEN, LUDGER) 27 June 1974 (1974-06-27) claims 1,3; figures 1,2 ---	1,2
A	---	9-12
	-/--	

☒ 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

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\*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.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

26 August 2002

Date of mailing of the international search report

03/09/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Macaire, S

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/15036

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 34 13 690 A (DAWIDOWSKI GERHARD) 17 October 1985 (1985-10-17) abstract; claim 1; figure 1 -----	6,7

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 02/15036

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-15  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

ional Application No

PCT/US 02/15036

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6077264	A	20-06-2000	IT VI960054 A1	06-10-1997
			AT 208588 T	15-11-2001
			AU 725703 B2	19-10-2000
			AU 2383597 A	29-10-1997
			BR 9708761 A	08-08-2000
			DE 69708280 D1	20-12-2001
			DE 69708280 T2	18-07-2002
			DK 892624 T3	11-03-2002
			EP 0892624 A1	27-01-1999
			JP 3169967 B2	28-05-2001
			JP 2000507475 T	20-06-2000
			RU 2149598 C1	27-05-2000
			CA 2249664 A1	16-10-1997
			CN 1219857 A	16-06-1999
			WO 9737606 A1	16-10-1997
			ES 2166539 T3	16-04-2002
			PT 892624 T	31-05-2002
EP 0922437	A	16-06-1999	IT MI972744 A1	11-06-1999
			EP 0922437 A1	16-06-1999
DE 2404441	A	31-07-1975	DE 2404441 A1	31-07-1975
DE 2260839	B	27-06-1974	DE 2260839 B1	27-06-1974
DE 3413690	A	17-10-1985	DE 3413690 A1	17-10-1985