PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :		(11) International Publication Number:
A61F 2/32	A1	WO 89/10730
		(43) International Publication Date: 16 November 1989 (16.11.89)

(21) International Application Number: PCT/US89/02020

(22) International Filing Date: 11 May 1989 (11.05.89)

(30) Priority data:
193,118 11 May 1988 (11.05.88) US

(71)(72) Applicants and Inventors: DALL, Desmond, M. [ZA/US]; SCHMOTZER, Johann, F., A. [DE/US]; 5698 Holly Oak Drive, Los Angeles, CA 90068 (US).

(74) Agents: FARBER, Michael, B. et al.; Sheldon & Mak, 201 South Lake Avenue, Suite 800, Pasadena, CA 91101 (US).

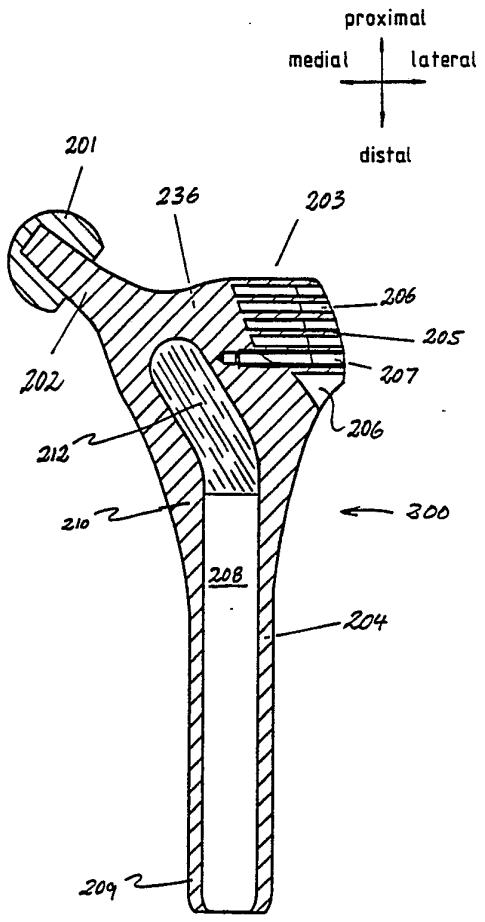
(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: HIP JOINT FEMORAL PROSTHESIS

(57) Abstract

A femoral prosthesis for hip arthroplasty provides means for extending into the trochanter for facilitating engagement of the prosthesis with the abductor muscles and attachment of the prosthesis with the trochanter. This restores the abductor loop forces and minimizes shear stresses between the femur and the prosthesis. The protrusion is at the femoral proximal end adjacent to the neck of the stem and includes ribs (205) and bridges (206) to be edged into the spongiosa bony structure of the greater trochanter. A hollowed shaft (204) of different cross-sections and open at the end improves flexural matching between the femur and the prosthesis.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MR	Mauritania
BB	Barbados	GA	Gabon	MW	Malawi
BE	Belgium	GB	United Kingdom	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IT	Italy	RO	Romania
BJ	Benin	JP	Japan	SD	Sudan
BR	Brazil	KP	Democratic People's Republic of Korea	SE	Sweden
CF	Central African Republic			SN	Senegal
CG	Congo	KR	Republic of Korea	SU	Soviet Union
CH	Switzerland	LI	Liechtenstein	TD	Chad
CM	Cameroon	LK	Sri Lanka	TG	Togo
DE	Germany, Federal Republic of	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

HIP JOINT FEMORAL PROSTHESIS

BACKGROUND

This invention relates to a femoral prosthesis for hip arthroplasty which includes hemiarthroplasty or total hip replacement. In particular, the invention is directed to a device for implanting into the femur so as to achieve a stable long-term fixation of the prosthesis by producing an improved physiological stress-strain environment at the bone implant interface and obtaining improved flexural matching between the prosthesis and the femur.

The invention also includes securing an artificial articular surface or joint head to the femur. The articular surface is carried on one end of the prosthesis stem. The remaining portion of the prosthesis, namely the neck and shaft is fully or partially embedded and in contact with the bone of the femur.

Known hip prosthetic stems are either solid or hollow and have a variety of cross-sectional shapes, for instance, circular, oval, diamond, trapezoidal, square, rectangular, or
I-beam. Fenestrations and variations in surface structure may be present. The prosthesis is inserted into a prepared bone bed or cavity usually in the medullary canal of a long bone and fixed either by grouting with acrylic bone cement or by press-fitting them into the bony cavity.

It is generally accepted that an exact initial fit is required in order to achieve good short term results. Further, for good long term results to be obtained the deformation of the stem should be similar to the deformation of the bone during loading, for instance, walking.

Presently known stems are either very stiff, especially the press-fit variety which attempts to fill the whole bony canal with the stem to obtain a line-to-line contact between prosthesis and strong outer cortical bone of the femur, or, if flexible, are too weak to withstand the cyclic loads. In the former situation, the stiff stem results in stress shielding of the bone, affecting the physiological bone turnover and resulting in bone resorption. The latter situation may lead to fatigue fracture of the stem. Attempts to overcome this problem have focused on the use of materials with increased elasticity and strength. Thus far, the changes have not proven to provide improved long term results.

A more recently known stem uses a metallic tubular shaft, where the outer wall is of constant thickness and is the main load-bearing structure. The stem is closed ended and the cavity in the shaft may be empty, or partially or totally filled with one or more other types of material. This stem, however, while it may provide variable loading stresses along the femoral canal, does not provide a mechanism for load transfer to produce an improved physiological stress-strain environment in the femur.

In another known stem the outer wall is apertured. This however provides the potential for bone ingrowth into the stem making subsequent revision extremely difficult.

Furthermore the apertures produce stress risers which may lead to implant failure.

In yet a further known stem, there is a partial split tube shell and a fin directed laterally at the stem neck. The fin has apertures for bone ingrowth; however, the narrow width does not permit for abductor forces to be transmitted to the fin, and thereby the stem, in compression. Instead these forces are at best effected on the fin in shear. This is undesirable since shear forces are not well tolerated by bone.

SUMMARY

It is an object of the present invention to provide a femoral stem which restores the continuity of an abductor force loop and provides good flexural matching of the stem and the bone, thereby creating a more natural loading environment of the shaft of the femur. The abductor force loop exists through the head, neck and greater trochanter of the femur, pelvis and abductor muscles.

According to the invention a femoral prosthesis comprises a stem with a proximal end and a distal end, an elongated shaft between the proximal and distal ends, and a neck towards the proximal end. The stem includes means for extending into the trochanter for facilitating engagement of the abductor muscle with the stem thereby to transmit force from the abductor muscle directly to the stem. The extending means facilitates attachment of the stem with the trochanter. Preferably, the shaft is at least partly hollow.

The extending means is located at the body adjacent the neck and includes a protruding element on the lateral side. The protruding element includes a series of transverse ribs extending between an anterior side and a posterior side of the body and are spaced apart along the elongated shaft. This depth across the transverse direction provides a compressive force on the bone at the interface with the transverse ribs, as opposed to a shear force at the interface. This effect produces a prosthetic procedure which can have effective short and long term results. The extension in the lateral direction is relatively more or less or the same as the extension in the transverse direction thereby to maximize bone contact and minimize shear forces at the interface. Rather the force is a compressive force and this acts to restore the abductor force loop.

The proximal extending means of protruding element or feature is provided to the shaft of the stem at the body of the stem for attachment to the greater trochanter. With this structure the abductor muscle engages directly to the stem and permits for continuity of the abductor force loop. The extending means is a protruding element which provides the potential for becoming an integral part of the trochanter to enable the abductor muscles to act directly on the prosthetic stem.

The hollow shaft for the stem allows for flexurally matching the deformation behavior of the stem to that of the femur. The shaft of the stem presents a wall of variable thickness in axial and radial directions thereby to facilitate for flexural matching.

In other preferred embodiments the stem may be solid, or partly tubular or hollow. The cross-sectional geometry of the stem can vary according to the strength and deformation requirements. The prosthesis implant, or its component parts is made of suitable bio-compatible material e.g. metals, ceramics, polymers or composites; singly or in any combination. As required filler material can be provided for at least partly filling a hollow stem, which may be open at its distal end.

The outer surfaces of the stem can be smooth or porous and may be coated with other materials. The surfaces can be regular or have irregular contours, interstices, apertures or can be fenestrated. The prosthesis is selectively formed as an integral unit or as several component parts.

The prosthesis implant is inserted directly into the bone or with an interposing material, for instance, acrylic bone cement, namely polymethylmethacrylate.

Accordingly the tubular stem allows for variation of the inner and outer diameter of the implant to attain flexural matching. Both the stiffness and the surface strain can be engineered to values tolerated by the bone. By choosing ideal material and geometry combinations bone growth can be stimulated and the normal physiological bone turnover maintained. Stress shielding and bone resorption is thereby prevented.

DRAWINGS

The invention is further described with reference to the accompanying drawings.

Figure 1a illustrates a diagrammatic force relationship of a natural femur and pelvis, showing the abductor force loop.

Figure 1b illustrates the force relationship with a prior art prosthesis in the femur.

Figures 2 to 9 shows an invented prosthesis or implant for a left femur. A prosthesis for the right femur would be a mirror image of the shown implant. The figures are detailed below.

Figure 2 is a longitudinal, anterior-posterior sectional view through a femoral prosthesis in accordance with the invention along the line I-II of the section indicated in Figure 3.

Figure 3 is a lateral-medial view of the prosthesis of Figure 2.

Figure 4 is an isometric view of the prosthesis in a proximal to distal direction.

Figure 5 is a diagrammatic partial side view of an alternative means for extending into the trochanter.

Figure 6 is a diagrammatic partial side view of another alternative means of extending into the trochanter.

Figure 7 is a diagrammatic partial side view of a further alternative means for extending into the trochanter.

Figure 8 are diagrammatic partial side and end views of another alternative means of extending into the trochanter.

Figure 9 are diagrammatic partial side and end views of another alternative means of extending into the trochanter.

DESCRIPTION

In a normal femur a high resultant joint force is counteracted and largely compensated by the abductor muscles inserting into the greater trochanter. This force mechanism occurs in the proximal region of the femur with its structured trabecular or spongiosa bony arrangement. A diagrammatic force model is illustrated in Figure 1a.

The joint force passing in the proximal region via the head 10, neck 11 and trochanter 12 regions of the femur is balanced by the abductor muscles 13 which arise from the pelvis 14. Simplistically this could be modelled as a closed loop, namely the abductor force loop 15, 16, 17 and 18 in these structures 10, 11, 12, 13 and 14 respectively. The result is that the tubular, cortical shaft 19 of the femur 20 is loaded by the axial net force equal to the partial body weight 21 and the moment due to the offset 22 between the center of gravity 23 and the femoral shaft 19. The fulcrum 24 is loaded on the one side by the partial body weight 21 acting on lever 25, and on the opposite side by

the abductor muscle 13 acting on lever 26. The consequence of this abductor force loop is that the shaft 19 of the femur 20 is exposed to predominantly axial forces, bending moments and torque.

The insertion of a prosthesis 27 of the prior art is illustrated in Figure 1b. This insertion involves removal of the femur head 10 and replacement with the artificial articular surface 28 with an elongated shaft 29 being inserted in the femur cortical shaft 19 of the femur 20.

Although total hip replacement has enjoyed effective results in the short term, a problem of long term loosening of the prosthesis 27 relative to the femur 20 remains unresolved. This problem is due to many factors including, in the case of the femoral shaft 29, an altered loading of the proximal medial cortex 31, which is less than the physiological requirements to maintain equilibrium of bone turnover and mechanical properties. Additionally, there is an abnormal shear loading as indicated by force lines 32 and 33 at the prosthesis implant-bone interface 134. Both these factors can be attributed largely to the insertion of the shaft 29 into the femoral canal 30. This changes the mechanism of load transmission as indicated by the abductor force loop in Figure 1a from the hip joint to the femoral canal as illustrated in Figure 1b, and particularly as illustrated by the force lines 32, 34 and 33.

The resultant joint force is transmitted via the neck 35 of the prosthesis 27 into the stem 29. This force has to be transmitted into the femur 20. This takes place at the interface 134 between the shaft 29 and the tubular

shaft 19 of the femur 20. This is different to the normal situation as illustrated in Figure 1a. Firstly, the resultant bending moment in the prosthesis 27 is insufficient to achieve physiological loading of the proximal medial cortex 31. This is particularly the case with most known stems which have large cross-sectional dimensions proximally and therefore a high stiffness in bending. Secondly, and probably more important, a piston-like effect is produced during each load cycle as the shaft 29 is pushed in a distal direction into the femoral canal 30 while the bone is pulled in a proximal direction towards the pelvis 14 by the action 17 of the abductor muscles 13. This is illustrated by the opposing force lines 32 and 33 and results in high shear forces at the implant-bone interface 134.

Referring to Figure 2, the prosthesis includes a stem 200 which is composed of essentially four components; namely an articulating surface called the head 201, a central portion or body 236 including the neck 202, an extending or protruding element or feature 203 extending proximally and laterally to achieve direct attachment of the greater trochanter to the stem 200, and a tubular hollow shaft 204 extending distally. The components 201, 202, 203 and 204 may be made individually from different or similar materials and permanently or exchangeably attached to each other or may be parts of an integral stem 200 without clear separations between them. This is shown in the Figures 2 to 8.

The function of the stem 200 is to transmit the loads as indicated in the abductor loop as modified by prosthetic implant between the head 201, trochanter protruding element or attachment feature 203 and the shaft

204. A combination of different structural materials for these components 201, 202, 203, 204 and 236 depending on individual variation in requirements is possible. The protruding element consists of several ribs or lamellae 205 which are laterally connected by one or more bridges 206. The ribs or lamellae 205 can be solid or have apertures or holes to allow for bone ingrowth by the greater trochanter. The ribs 205 extend from the anterior to posterior sides over a sufficient in width extent to ensure that a physiologically acceptable compressive stress is applied to the bone and the abductor muscles engage the protuberance thereby to input force from the abductor muscle directly to the stem.

A screw hole 207 is provided for securing the greater trochanter with a screw or bolt 211 or for attaching an external feature such as a hook or washer which engages the trochanter and facilitates reattachment of the trochanter. The screw 211 is an auxiliary device to enhance trochanteric fixation and bony union between the greater trochanter 12 and the shaft 19 of the femur 20 when the trochanter 12 is osteotomised during surgical exposure.

Alternative means for the protruding element 203 as a trochanteric attachment are fibre sponges, meshes, interstices, fenestrations, have apertures or contain irregular protuberances which are firmly attached to the stem. Figures 5 to 9 show a variety of options to achieve direct, mechanically sound integration of the attachment feature 203 into the trochanter 12.

Figure 5 also shows a different option to achieve short term fixation of the trochanter 12 until the process of integration is successfully completed. The attachment

feature 203 is used together with or is completely in the form of a cage 213. The cage 213 consists of a network of intersecting fibers, wires or cables 214 of any kind of material. The cage 213 is either firmly attached to a base plate 215, which in turn rests against a face 216 of the stem 200 or is directly attached to the stem 200. The cavity under the cage 213 may be filled with bone graft or other osteo-inductive materials.

The short term fixation system consists of one or more pairs of wires or cables 217 and 218. Wire 217 is attached to the prosthesis proximally of the trochanter attachment feature 203, and the other wire 218 is attached distally to the feature 203. To achieve fixation the proximal wire 217 is threaded through the tendinous insertion of the abductor muscles 13. The two cables or wires 217 and 218 are then inserted into a sleeve 219 in such a way that the ends 220 of the cable point in opposite directions. After tensioning, the sleeve 219 is crimped and the wire or cable ends 220 are cut. If more than one pair 217 and 218 is used, the cables or wires 217 and 218 may be linked cross-wise. The opposite ends 224 fit into apertures 225 in the protrusion 203.

Figure 6 shows the feature 203 made from a porous material 221. It has the structure of open cell foam 222; namely, the cells 222 are continuous with each other. The cell diameter may vary, and probably will be in the range of about
1 mm to 3 mm. At the time of insertion the cells or pores 222 may be filled with bone graft or an osteo-inductive material. The outer surface may be regular or have grooves 223, tissues, lamellae 205 or other roughening or irregularities.

In Figure 7 curved or circumferential grooves 226, are cut into the feature 203. The ribs 205 are cut in such a way that the distally facing surface 232 is perpendicular or undercut in relation to the elongated axis 233 of the prothesis so as to represent a saw tooth type front face 234. The circumferential grooves and ridges may be continuous or interrupted by axially directed bridges, grooves or ridges 206. The ridges or teeth may have sharp edges 227 or may be rounded 228.

In Figure 8, pins 229 of variable number and size extend laterally from the surface 230 of the feature 203. This effectively presents a surface with multiple interstices, fenestrations or apertures 232.

Figure 9 shows a form of the feature where circular or ellipsoidal, concentric rings 231 extend from the lateral surface 230. The rim of these rings may be sharp for cutting or blunt ended.

A system for initial fixation on the external surface 230 may be used with any of the options of Figures 7 to 9 even though not shown in detail. In Figure 9 the components of the stem 200 are shown as separate parts 235.

Ribs 205 or bridges 206 can be wholely or partly curved. The protruding element 203 can be filled or coated with bone graft or man-made materials such as hydroxyapatite, which have osteo-inductive potential to enhance the process of integration of the protruding element 203 into the trochanter 12 and to facilitate engagement of the abductor muscles 13 with the stem 200.

The axis of the stem 200, as viewed in the lateral-medial illustration of Figure 3 has an anterior tilt, firstly, to follow the geometry of the natural bone and secondly to position the protruding element or attachment feature 203 optimally for integration of the trochanter 12 and the engagement of the abductor muscles 13.

The shaft 204 is generally cylindrical in cross-section. In different embodiments the cross-section and its geometry can vary as the cross-sectional shape of the femoral canal 30 changes along its elongated axis. The shaft 204 can be selectively hollowed where the bone dimensions allow a stronger stem 200 than required to sustain fatigue failure of material. This is likely the case at the junction between the shaft 204 and the neck 202. As necessary the hollow shaft can selectively have a solid or foamed polymer filler 212 material such as polyethylene or polyurethane for reinforcement. The filler may partly fill the bore 208 of the shaft 204, and the shaft 204 is open at the distal end. The wall thickness 209 at the distal end is narrower than at the proximal medial end 210.

The above description is given only by way of example and does not limit the field of the invention, the replacement of details described by any other equivalents not departing from the scope thereof.

We claim:

1. A femoral prosthesis comprising a stem with a proximal end and a distal end, an elongated shaft between the proximal and distal ends, a neck towards the proximal end, the stem including means for extending into the trochanter for facilitating engagement of the abductor muscle with the stem thereby to transmit force from the abductor muscle directly to the stem.

2. A prosthesis as claimed in claim 1 including a medial side and lateral side, the extending means being located adjacent to the neck and including a protruding element on the lateral side.

3. A prosthesis as claimed in claim 2 wherein the extending means includes a portion directed for a preselected elongated distance at the proximal end.

4. A prosthesis as claimed in claim 3 wherein the protruding element includes a series of transverse ribs extending between an anterior side and a posterior side below the neck and are spaced apart along the elongated shaft.

5. A prosthesis as claimed in claim 4 including at least one bridge directed longitudinally between at least two of the ribs.

6. A prosthesis as claimed in claim 5 including means for receiving an anchorage for securing the trochanter to the stem.

7. A prosthesis as claimed in claim 5 including a bolt for receiving an anchorage for securing the trochanter to the stem, the bolt being adapted for screw threaded location in the protruding element and a member engaging the bolt for facilitating engagement with the abductor muscle.

8. A prosthesis as claimed in claim 1 wherein the shaft is at least partly hollow.

9. A prosthesis as claimed in claim 8 wherein the shaft is open at the distal end.

10. A prosthesis as claimed in claim 8 wherein the shaft is at least partly filled with a filler material.

11. A prosthesis as claimed in claim 1 wherein the stem is selectively constituted by multiple components.

12. A prosthesis as claimed in claim 1 wherein the stem is selectively made of a metal, a composite material, a ceramic, polymer material or combination of such materials.

13. A prosthesis as claimed in claim 8 wherein the hollow shaft selectively includes a wall of different thickness and of different cross-sectional shape.

14. A prosthesis as claimed in claim 1 wherein the stem includes an outer surface at least partly roughened.

15. A prosthesis as claimed in claim 1 wherein at least part of the body includes a material having osteo-inductive potential.

16. A prosthesis as claimed in claim 1 wherein a bone cement is adapted to be located about at least part of the stem.

17. A prosthesis as claimed in claim 2 wherein the protruding element is at least partly a mesh configuration.

18. A prosthesis as claimed in claim 2 wherein the protruding element includes at least partly sharpened edges for facilitating entry into the trochanter.

19. A prosthesis as claimed in claim 5 wherein the ribs or bridges are selectively partly curved or straight.

20. A prosthesis as claimed in claim 2 wherein the protruding element selectively contains multiple interstices, fenestrations, or apertures.

21. A femoral prosthesis comprising a stem with a proximal end and a distal end, an elongated shaft between the proximal end distal ends, a neck towards the proximal end, the stem including means for extending into the trochanter for facilitating attachment of the trochanter with the stem.

22. A prosthesis as claimed in claim 21 including a medial side and lateral side, the extending means being located adjacent to the neck and including a protruding

element on the lateral side, and extending between an anterior side and a posterior side adjacent to the neck.

23. A prosthesis as claimed in claim 21 wherein the protruding element includes a series of transverse ribs are spaced apart along the elongated shaft, and are adapted to facilitate engagement with the abductor muscle.

24. A femoral prosthesis comprising a stem with a proximal end and a distal end, an elongated shaft at least partly hollow between the proximal and distal ends, a neck towards the proximal end, the stem including means for extending into the trochanter for facilitating engagement of the abductor muscle with the stem and attachment to the trochanter.

25. A prosthesis as claimed in claim 24 including a medial side and lateral side, the extending means being located adjacent to the neck and including a protruding element on the lateral side, and extending between an anterior side and a posterior side adjacent to the neck.

26. A prosthesis as claimed in claim 25 wherein the protruding element includes a series of transverse ribs extending and are spaced apart along the elongated shaft, and at least one bridge directed longitudinally between at least two of the ribs.

27. A prosthesis as claimed in claim 26 wherein the shaft is open at the distal end.

28. A prosthesis as claimed in claim 27 wherein the shaft selectively includes a wall of different thickness and of different cross-sectional shape.

29. A prosthesis as claimed in claim 1 including a head located at the proximal end of the neck.

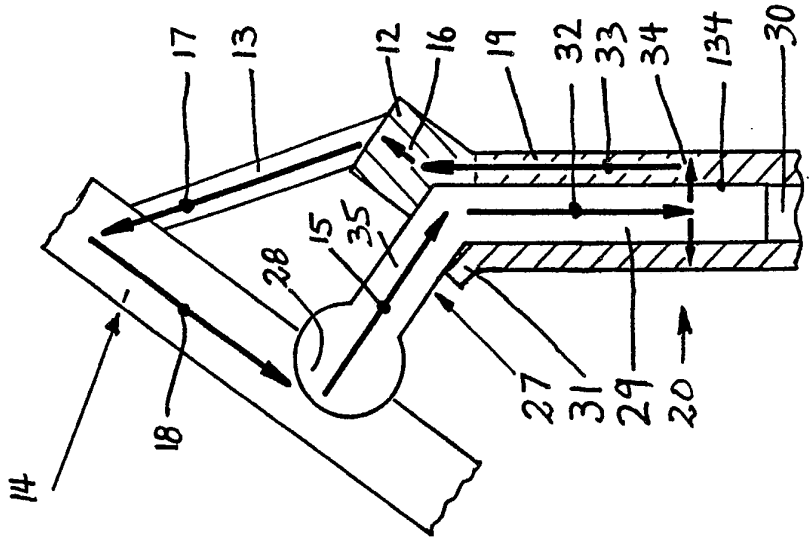


Fig. 1b
PRIOR ART

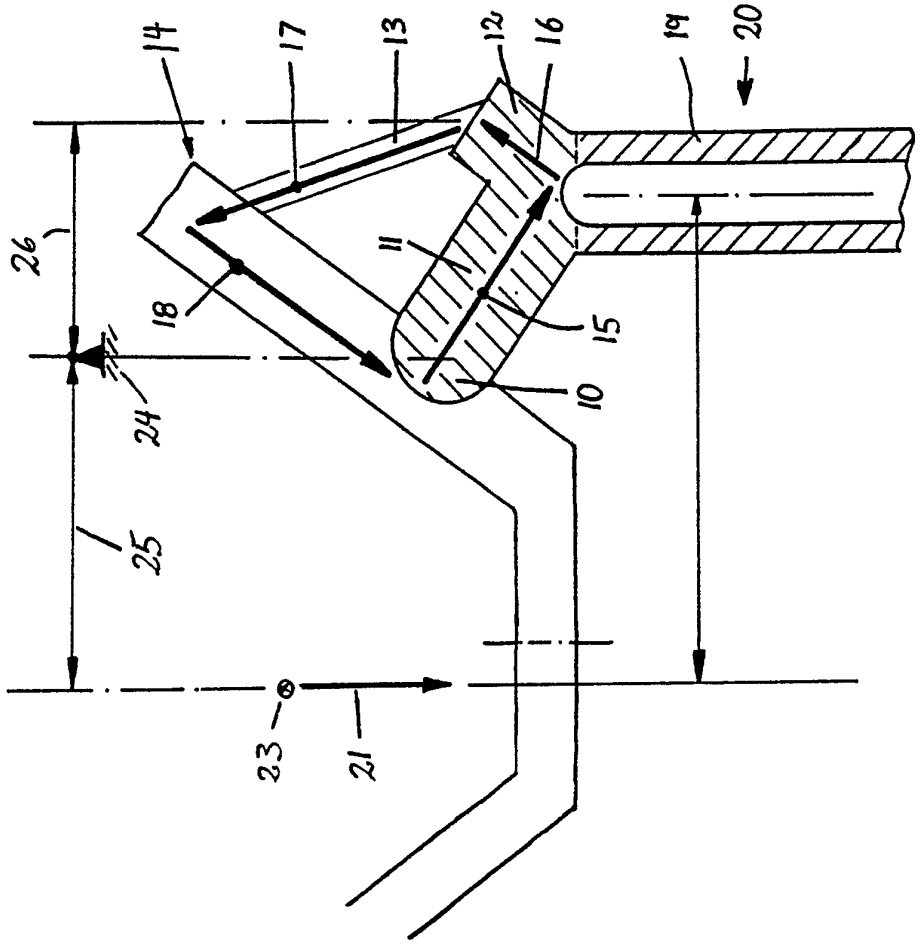


Fig. 1a

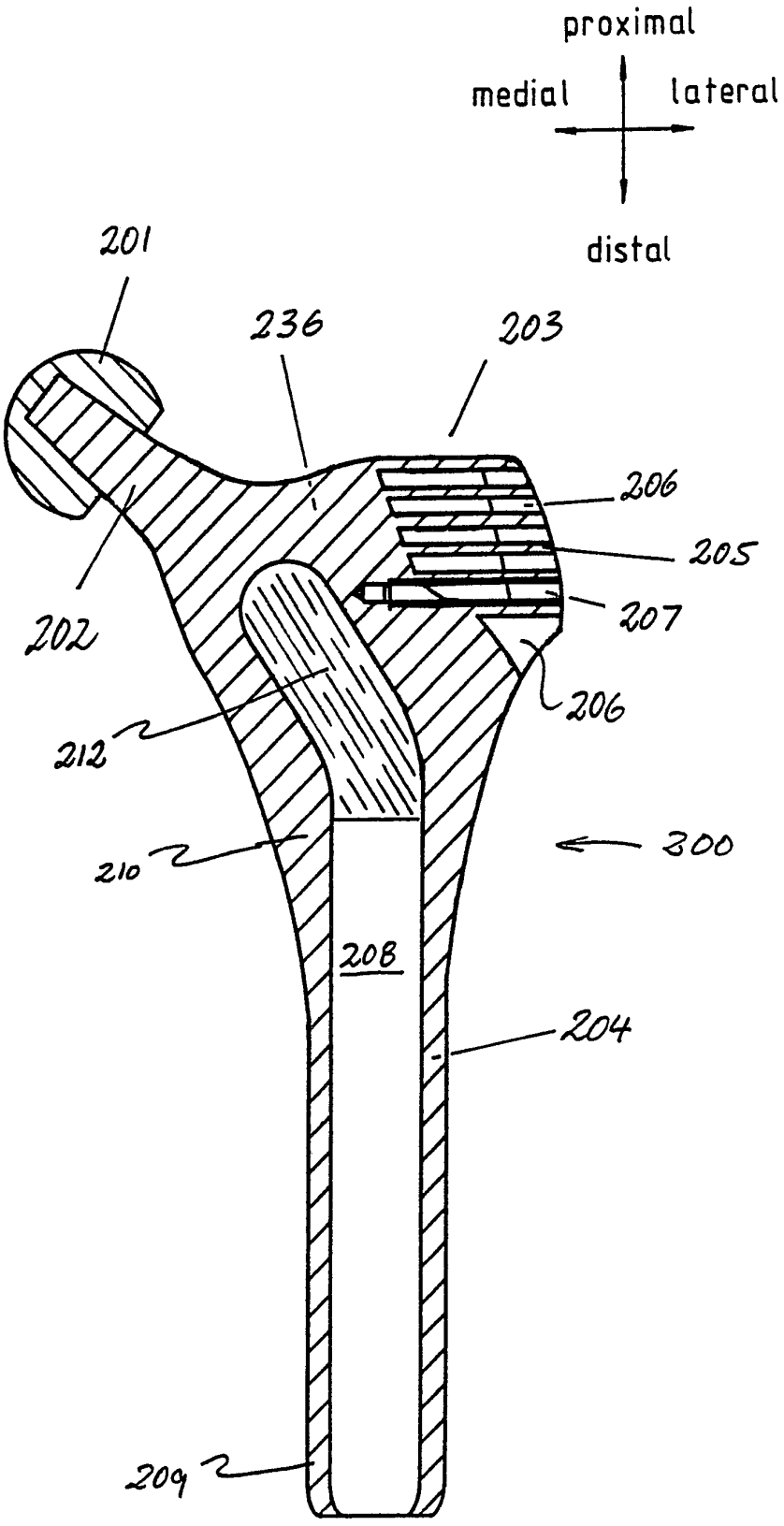

proximal
medial
lateral
distal
201
236
203
206
205
207
206
202
212
210
300
208
204
209

Fig. 2

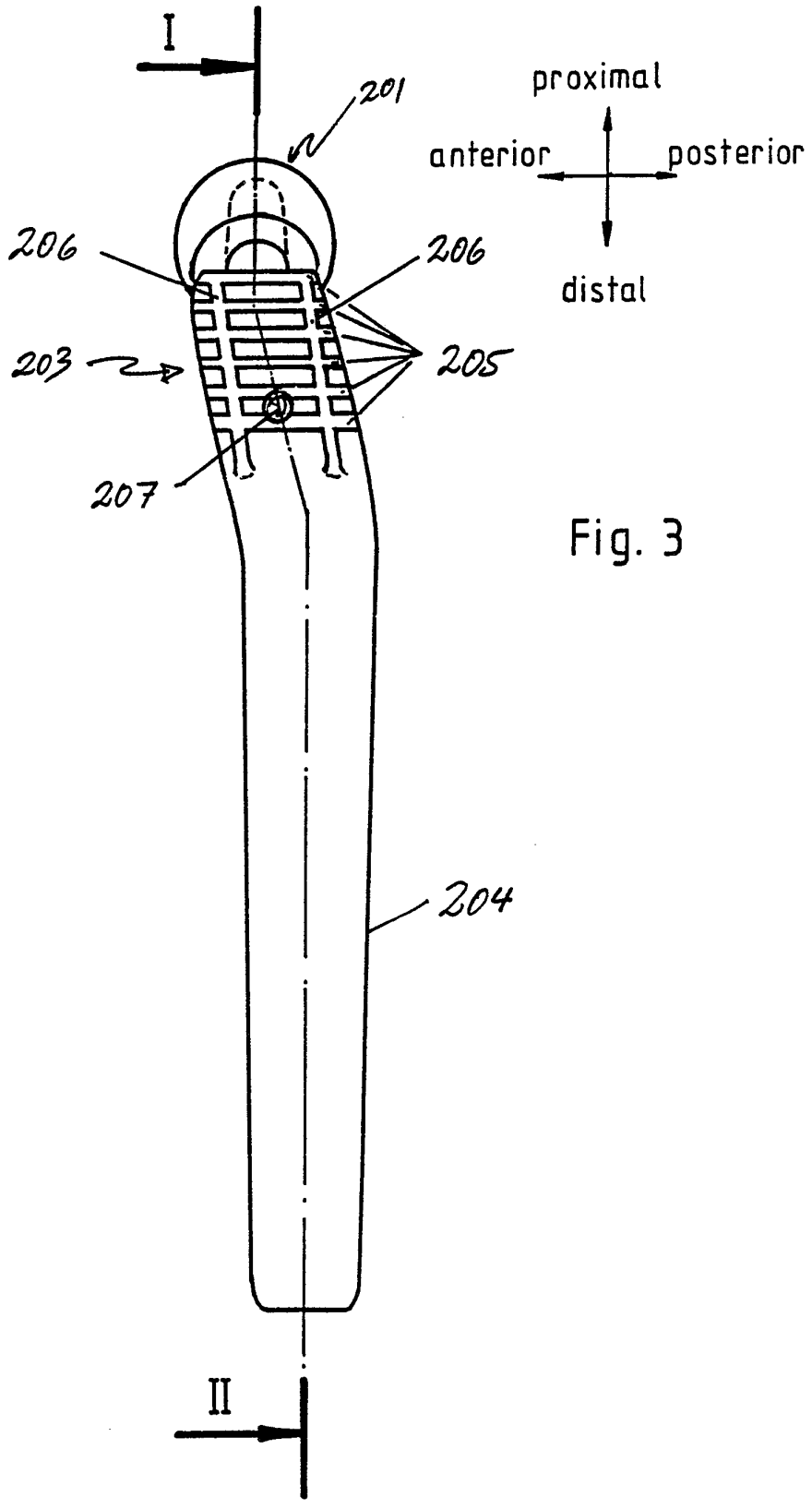

I
201
proximal
anterior
posterior
distal
206
206
203
205
207
204
II

Fig. 3

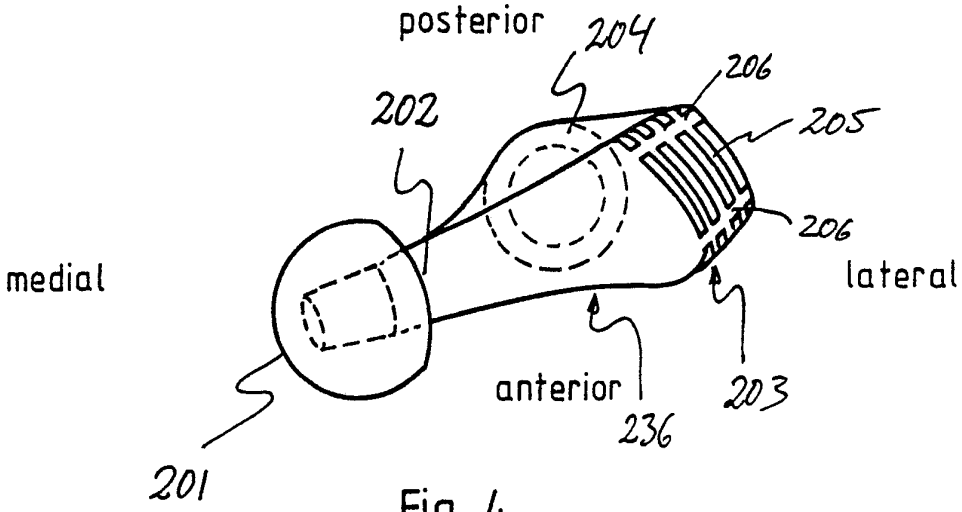

posterior
204
206
202
205
206
medial
lateral
anterior
203
236
201

Fig. 4

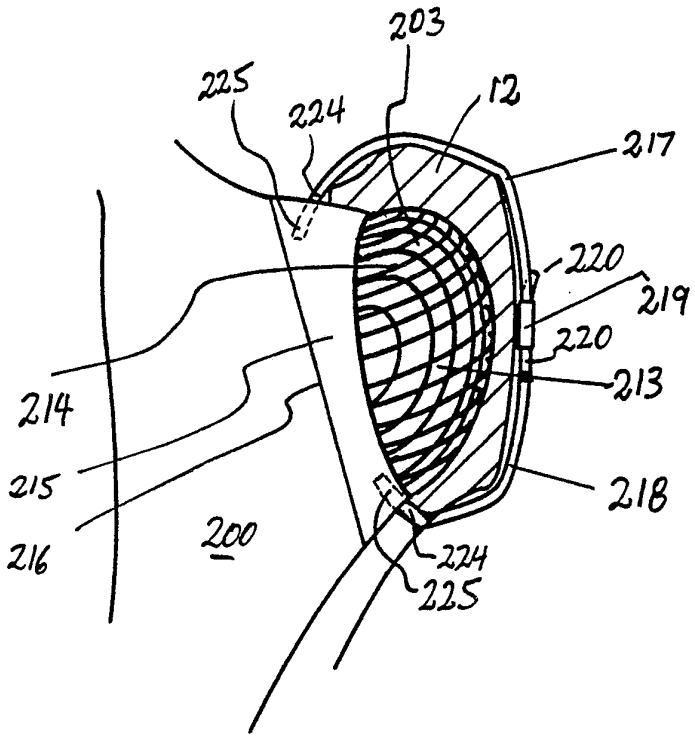

203
225
224
12
217
220
219
220
213
214
215
216
200
218
224
225

Fig. 5

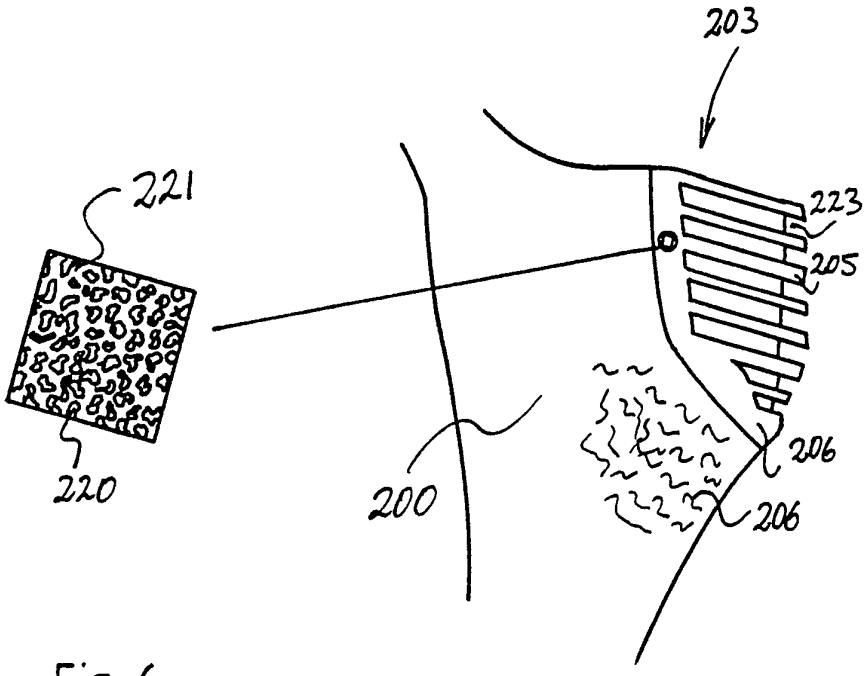

203
221
223
205
220
200
206
206

Fig. 6

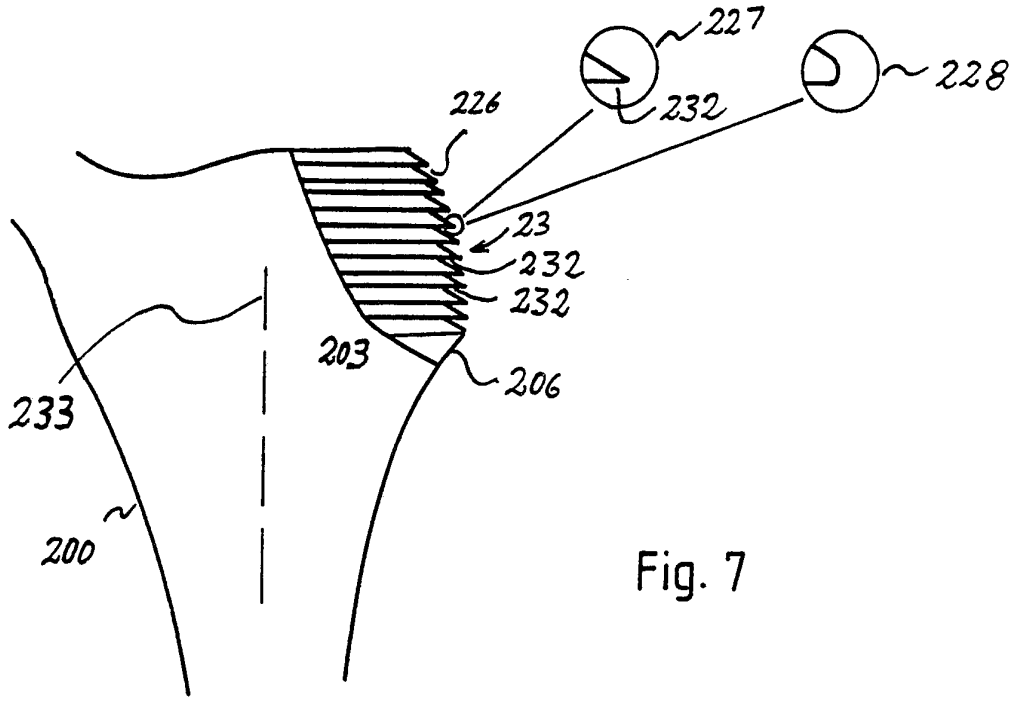

227
228
226
232
23
232
232
203
206
233
200

Fig. 7

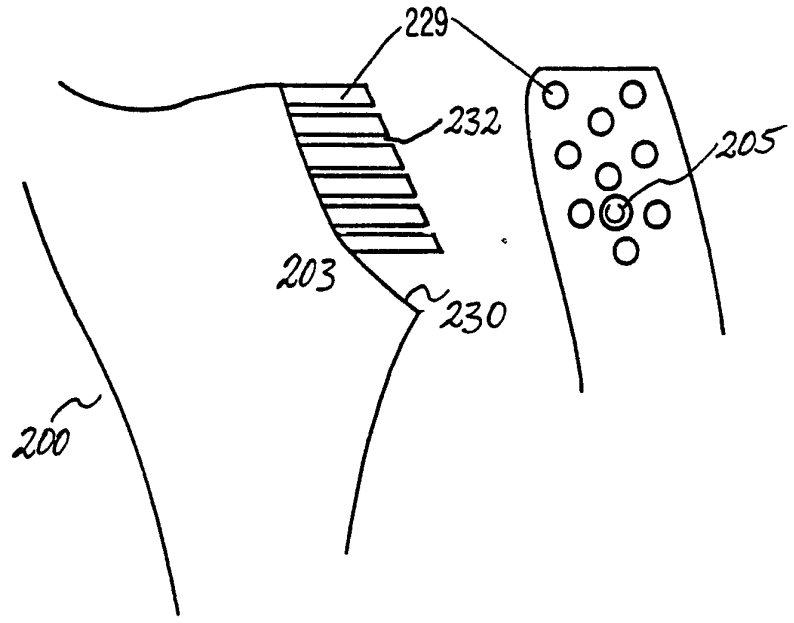

229
232
205
203
230
200

Fig 8

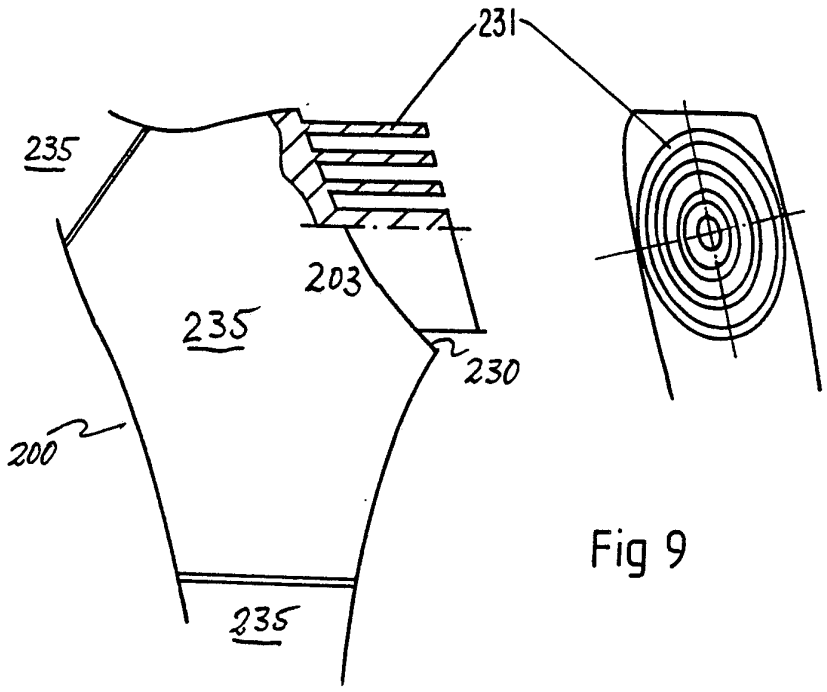


Fig 9

INTERNATIONAL SEARCH REPORT

International Application No PCT/US89/02020

I CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

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

IPC (4): A61F 2/32;
U.S.CL: 623/23

II FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	623/18, 22, 23

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	FR, A, 2,528,307 (TORNIER) 16 December 1983 Figures 1 and 4.	1-4,11,12,17-23,29
Y	DE, A, 2,811,603 (HEIBLER) 20 September 1979 See abstract.	1,8-10,13,24,25
Y	US, A, 4,406,023 (HARRIS) 27 September 1983 See abstract.	14-15
Y	US, A, 4,283,799 (PRATT, JR. ET AL.) 18 August 1981 See abstract.	16

* Special categories of cited documents: [14]

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

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

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

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

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

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

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

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

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 July 1989	27 JUL 1989
International Searching Authority	**Signature of Authorized Officer**
ISA/US	David J. Isabella

Form PCT/ISA/210 (second sheet) (Rev.11-87)