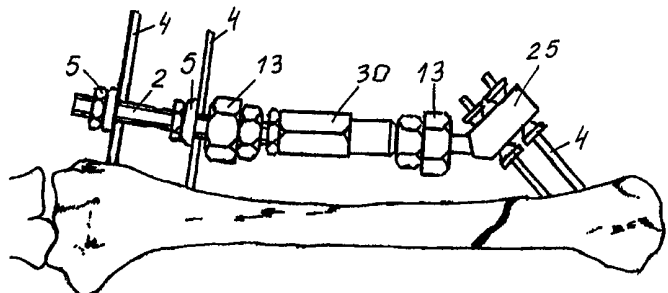




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : <b>A61B 17/66, 17/64</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 99/04714</b></p> <p>(43) International Publication Date: 4 February 1999 (04.02.99)</p>
<p>(21) International Application Number: PCT/BG97/00009</p> <p>(22) International Filing Date: 24 July 1997 (24.07.97)</p> <p>(71)(72) Applicant and Inventor: NESTOROV, Stanislav Georgiev [BG/BG]; Slavyanska Street, 10, 9300 Dobrich (BG).</p> <p>(74) Agent: SHENTOVA, Violeta Varbanova; Gatev &amp; Shentova Patent Bureau, Damyan Gruev Street, 11, 1606 Sofia (BG).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report. With amended claims.</p>
<p>(54) Title: EXTERNAL FIXATOR</p>		
		
<p>(57) Abstract</p>		
<p>An external fixator is comprising threaded carries (2) with the through hole (3) for receiving the bone implants (4) clamping by fixing nuts (5) and the carries (2) being interconnected by compression-destruction mechanisms (30) and/or ball and socket joints (13).</p>		

**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.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## EXTERNAL FIXATOR

### FIELD OF THE INVENTION

5 The invention relates to an external fixator applicable in orthopaedy for treatment of bone fractures by the methods of extrafocal osteosynthesis.

### BACKGROUND OF THE INVENTION

The extrafocal osteosynthesis is applied in tube bone fractures of various types and  
10 localizations: fragmentations, oblique, heliciform, transverse, periarticular and articular fractures, regardless of the form and curve of the bone canal. External fixators are used for reposition and fixation of the bone fragments in an increasing number of cases. Typically, the fixator comprises an extended carrier, a great number of transosteal pins being fixed thereto using a variety of fixtures, as holders,  
15 clumps, etc. The clinical applications of the fixator increase in variety when elements allowing fixation at various angles and at different fracture localizations are used. These are a variety of adjustable couplings between a minimum of two elements of the fixator.

A ball-and-socket joint between two elements of an external fixator is known  
20 from DE 3837228 - Fig. 4, DE 3543042 - Fig. 1 and 2, and SU 1739984, where one of the elements has a ball-shaped end coming in contact with a socket which is connected with one end of the second element, the ball being fixed in the intended position into a socket using an enveloping nut tightened on an external thread of the socket. This coupling allows the two coupled elements to be positioned in  
25 space at various angles but it is not secured against sliding of the spherical surfaces resulting from a loosened screwed joint. To provide a reliable coupling, a considerable effort should be applied when tightening the enveloping nut in order to obtain final stabilization upon assembling the fixator, which results in additional dislocation of fractured bones reposition.

30 An external fixator for osteosynthesis is known from EP 0140786, said fixator comprising bone implants, bone screws for example connected with one another by at least one carrier and fixed by clamps by using clamping screws. The carrier is a tube in which holes for the bone screws are made perpendicularly to the carrier's axis, along with the screw holes for the clamping screws. The carriers can be  
35 directly interconnected using a compression-distraction mechanism and/or a ball-and-socket joint. The ball-and-socket joint is a sphere consisting of two or three interconnected parts. Each part is provided with a tip which enters the carrier's tube and is fixed with a screw. A disadvantage of this external fixator is that the clamping

screws do not guarantee reliable fixation. Consequently, a load on the damaged bone, e.g. in the course of rehabilitation treatment, may cause the clamping screws to loosen or fall out since the screw holes are of small length, which may result in lower reliability and effectiveness during the treatment.

5 Another external fixator is known from PCT WO97/16/28, said fixator comprising bone implants which are to be introduced into the bone fragments and are indirectly interconnected using at least one carrier with circular cross-section and riffled surface. The bone implants are positioned by at least one holder and/or clamp mounted so as to allow further adjustment of the carrier. The carriers are  
10 interconnected by a compression-distraction mechanism and/or by a coupling mechanism provided with a screw-type retainer to stop them in the intended position. The coupling mechanism may be a ball-and-socket joint, which comprises a ball connected with a carrier and a socket where the ball is fixed using an enveloping nut tightened to a socket's thread. The working surface of the ball is  
15 made of a material which differs in hardness from the one used to make the working surface of the socket, the spherical surface being of greater hardness and has sharp edges or tips. In this external fixator the couplings guaranteeing the carriers' positioning to one another and the positioning of the bone implants into the carriers are more secure and reliable, since under the effect of the pressing force the riffled  
20 surfaces of the element of greater solidly penetrate into the softer material of the other element connected, thus preventing their relative sliding. However, if a greater effort is applied to tighten the screwed joint at the ball, the reposition of the fractured bones is displaced and, on the other hand, the need to make sharp edges or tips on one spherical surface requires a complicated manufacturing technology.

25

## **SUMMARY OF THE INVENTION**

A major object of the present invention is to provide a reliable external fixator guaranteeing secure fixation of each transosteal pin or screw mounted.

Another object of the present invention is to provide a reliable adjustable  
30 coupling between at least two elements for external fixation, said coupling allowing these elements to be positioned at various angles and in various spatial directions.

A further object of the present invention is to provide an adjustable coupling which, when tightened after putting the fixator in place, does not allow displacement of repositioned bones.

35 Yet another object of the present invention is to provide an external fixator securing a flexible fixation.

A further object of the present invention is to provide an external fixator which is technologically feasible.

A further object of this invention is to provide a fixator which allows the application of low distraction and compression when used as a monofixator.

An object of the invention is to provide a fixator which allows simple and safe positioning, non-dependent on the experience and bodily strength of the operating  
5 orthopaedist.

This invention provides an external fixator for osteosynthesis comprising solid bone implants to be introduced into the bone fragments, said implants being indirectly interconnected by at least one carrier with circular cross-section and threaded outer surface and/or by at least one holder. On each carrier has at least  
10 one through-hole for transosteal implant, which is perpendicular to the carrier's axis. On each carrier, at least one clamp is mounted to fix the transosteal pin into the through-hole. The clamp consists in a fixing nut tightened on the carrier. The carriers can be interconnected by a compression-distraction mechanism and/or by a hinged coupling mechanism having a screw-type retainer to stop them in the  
15 intended position. The hinge can be ball-and-socket jointed comprising at least one ball element connected with a carrier or a holder on which an enveloping nut is placed, and an element with at least one socket, where the ball could be fixed using the enveloping nut, which can be connected with a carrier. The working surface of the ball is made of a material inferior in hardness to the material of the socket's  
20 working surface. The socket element has at least one opening towards the working spherical surface of each socket. In each opening a retainer is placed to allow change of position, the end of the retainer having a sharp tip which can penetrate into the ball's material. The implants can be interconnected also by means of hinged holders. Each holder includes one element of the ball-and-socket joint firmly  
25 connected with a screw-mount. The compression-distraction mechanism comprises a guide with one end connected with a carrier or holder and having a thread at its outer end, an operating element tightened so as to allow displacement on the guide. Said mechanism further comprises a follower with one end connected with a carrier or holder flexibly connected with the guide by a finger moving along  
30 rectilinear groove on the threaded stem of the guide. The follower is coming in a flexible contact with the operating element, so as to effectuate only an axial displacement through the guide.

In one embodiment of the invention, the through-holes on the carrier are oblongue.

35 In another embodiment the socket element further comprises at least one pusher permitting at least one retainer to be pushed. The pusher can be an adjusting screw to be tightened into a screwed hole connected with at least one

retainer hole, said screw being able to come in contact with each retainer in order to push it away.

In yet another embodiment the fixing nut comprises a sliding screw nut with a freely rotating unreleasable compression washer mounted at one of its ends. The  
5 outer face of the washer has at least one diametrical groove for the transosteal screw or pin to be fixed thereinto.

In one embodiment the screw-mount has at least one through-hole for receiving the bone screw which screw shank is threaded. From both sides of the hole fixing nuts for tightening the bone screw are provided.

10 In other embodiment the through-hole has bevelled edges and each fixing nut has a bevelled split end fitting to the bevelled edge of the hole.

This fixator is simple and technologically feasible. Its use does not require strict choice of bone screws or special skills from the operating orthopaedist. The fixator allows spatial change of reposition of the bone fragments.

15 An advantage of the fixator proposed herein is that each bone screw or pin is independently fixed using an appropriately shaped nut tightened to the carrier, which guarantees greater reliability of osteosynthesis since both the supporting threaded surface and the clamping surface of the bone screw are increased.

Another advantage is that a variety of bone screw diameters can be used  
20 along the carrier, in accordance with the therapeutical logic. For instance, screws with greater diameters can be placed farthest from the fracture to guarantee a firm support, while near to the fracture the screws may be of smaller diameter. This allows the part of the thinner screw, which is fixed into the fracture zone, to produce microvibrations as a result of external load, e.g. rehabilitation treatment. A flexible  
25 fixation is thus secured which stimulates the fracture healing process.

A very important advantage of the fixator is that by choosing the direction of clamping each screw to the hole's wall, the carrier itself can be used to obtain compression or distraction whose magnitude depends on the size of the holes.

When tightening the enveloping nut, the ball-and-socket joint allows initial  
30 fastening of the hinge. The retainer being inactivated, its solid tip penetrates into the softer metal of the ball, thus serving as additional prevention against sliding between the parts of the ball-and-socket joint in case of unwanted external influences. Thus, a reliable coupling between at least two external fixator elements is secured, with the possibility to place these elements at various angles and in  
35 various directions in space. Moreover, the initial fastening of the enveloping nut does not require much effort which otherwise could displace the repositioned bone fragments. Final fixation of the hinge is obtained by exerting additional effort on the retainer, the direction and magnitude of this effort not leading to unwanted

displacement. This is another way to secure a simple and safe positioning of the fixator, independently from the experience and bodily strength of the orthopaedist, the reposition being guaranteed. Since no sharp edges or tips have to be made on a spherical surface, the manufacturing technology is simplified.

5 The special make of the fixing nuts of the hinge holder ensures a reliable tightening of the bone screw into the screw-mount's hole.

The proposed compression-distraction mechanism guarantees preserving the bone reposition during the treatment. It is handy to operate and reliable for exploitation.

10

### BRIEF DESCRIPTION OF THE DRAWINGS

**Fig. 1** shows a general view of a fixator mounted in a patient with humeral fracture.

**Fig. 2** shows part of the fixator using transosteal pins.

15

**Fig. 3** shows a magnified section of a fixing nut.

**Fig. 4** shows a carrier with oblongue through-holes.

**Fig. 5** shows a section of a ball-and-socket joint.

**Fig. 6** shows a section of an embodiment of a two-socket element.

20

**Fig. 7** shows a section of a ball-and-socket joint comprising the element from Fig. 6.

**Fig. 8** shows a section embodiment of a ball element.

**Figs. 9 and 10** show different embodiments of the holder.

**Fig. 11** shows a section of a compression distraction mechanism.

25

**Fig. 12** shows a general view of another fixator assembly mounted to the fractured bone.

### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Fig. 1 shows the fixator 1 which, in accordance with the invention, is mounted on a right humerus viewed from the face. The fixator (Fig. 2) comprises a straight compact threaded carrier 2. Through-holes 3 are made into the carrier 2 at a distance from one another and bone screws 4 are introduced thereinto. The screw 4 are clamped with fixing nuts 5. The holes 3 have diameters at least equal to the diameter of the thickest screw applicable to the humerus case. Fig. 3 shows an embodiment of the fixing nut 5. It comprises a sliding screw nut 6 and a compression washer 7. The sliding screw nut 6 could be for instance a hex nut whose threaded part is prolonged by a thin-walled arm 8 with an outer diameter smaller than the hex head 9 of the smallest size. The unreleasable compression washer 7 in the form of a chock with a stepped inner orifice is mounted on the freely

30

35

rotating thin-walled arm **8**. In the smaller orifice the thin-walled arm **8** of the sliding screw nut **6** is mounted, the ends **10** of said sliding screw nut **6** being stretched, so that an unreleasable coupling is secured between the elements **6** and **7** of the fixing nut **5**. On the outer face **11** of the compression washer **7** there are two diametrical  
5 grooves **12**. In this case, the grooves **12** are trapezium-shaped, but could be circular, triangular or otherwise shaped.

In the embodiment shown in Fig. 4, the through holes in the carrier are oblongue.

The fixator further comprises a ball-and-socket joint **13** (Figs 1 and 5).

10 Fig. 5 shows a ball-and-socket joint **13** between two external fixator carriers **2** which consists of a ball **14** and a socket **15**. The ball **14** is made of a soft material, i.e. aluminium, while the socket **15** is made of a more solid material than the ball **14**, i.e. stainless steel. A enveloping nut **16**, which is made as a cover nut with an opening greater than of the carrier's diameter and smaller than the ball's **14**  
15 diameter and has a spherical hollow to hold the ball **14**, is put on the carrier with a ball **14**. The socket element **15** has an outer thread on which the nut **16** having a stop **17** is tightened. The outer surfaces of the nut **16** and the stop **17** are provided with means for manual tightening. In this case, these are hexahedrons, but can be otherwise shaped, e.g. rolled or openings with spanners penetrating thereinto. In  
20 the socket element **15**, there is at least one through-hole **18** bored obliquely to the socket element's **15** axis and in this case having a thread and beginning from the stop **17**, this through-hole **18** being opened towards the spherical surface of the socket **15**. A retainer **19**, in this case an adjusting screw with a hidden head ending in a sharp tip, is located in the hole **18**. The material of the screw **19** is of greater  
25 hardness than the material of the ball **14**. When the coupling is mounted and the nut **16** is tightened, after fastening the screw **19** its tip penetrates into the soft material of the ball **14**.

Fig. 6 shows an embodiment of an independent element **15** which is symmetrically made and further comprises a pusher **20**, in this case an adjusting  
30 screw which is screwed into the hole **21** bored in the stop **17** and located perpendicularly of the axis of the element **15**. One end of the hole **21** comes in contact with a central through-hole **18**, which in this case is cylindrical. The retainers **19**, round pins in this case, freely sliding, are set in said through hole **18**. The retainers **19** have at their adjacent ends bevels which form an angle on  
35 touching each other. The total length of the retainers **19** in this case is equal to the length of the hole **18** but they could also protrude slightly, e.g. 0.5 mm. The pusher **20** has an angle at the top corresponding to the angle between the adjacent ends of the retainers **19**. Thus the retainers **19** are pulled apart when tightening the



pusher **20** and their external sharp tips penetrate into the soft material of the ball **14**.

Fig. 7 shows ball-and-socket joint having the element **15** from fig.6. The carriers **2** are positioned in a desired direction.

5 Fig. 8 shows the ball **14** made of two parts: an upper one **22** made of a soft material, e.g. aluminium, and a lower one **23** made of a material of greater hardness, e.g. stainless steel. The two parts are coupled by two supporting pegs **24** rammed into the lower part **23** and tightly entering the corresponding openings made in the upper part **22**.

10 Fig. 9 and fig. 10 show different embodiments of hinged holder **25** comprising a ball element **14** with an enveloping nut **16** or a socketed element **15** firmly connected with a screw mount **26**. The screw mount **26** is a flat body having through holes **27** for receiving the bone screw **4**. This screw mount operates with bone screws having a threaded shank on which two fixing nuts **28** are screwed on  
15 both sides of the flat body **26**. Each through hole **27** has bevelled edges. One end of the fixing nut **28** is bevelled and splitted for fitting to the bevelled edge of the hole **27**.

Fig. 11 shows a compression-distraction mechanism **30** according to the invention. The mechanism **30** comprises a threaded guide **31** ending with an  
20 element **14** and **16**, or **15** of the ball-and-socket joint **13** and having a rectilinear groove **32** along the threaded stem. An operating element **33** is screwed on the guide **31** by a threaded bushing **34** fixedly connected to an envelope **35**. The envelope **35** wraps a follower **36** compressed to the inner face of the threaded bushing **34** and limited by a restrictor **37**. The follower **36** has a blind hole **38**  
25 receiving the threaded stem of the guide **31** and has a spring finger **39** moving along the rectilinear groove **32**. Said follower **36** is being fixedly connected with an element **15** of the ball-and-socket joint **13**. A clamping nut **40** mounted on the threaded stem of the guide **31** serves for blocking the operating element **33**. Thus  
30 when screwing the operating element **33** on the guide **31**, the restrictor **37** or the inner face of the threaded bushing **34** pushes the follower **36** which is moved rectilinearly owing to the presence of the finger **39** and the groove **32**.

Fig. 12 shows a general view of another fixator assembly mounted to the fractured bone comprising one carrier **2**, one distractor **30** and one hinged holder **25**.

35 It should be understood that the invention is not to be limited to the precise forms disclosed but may be modified within the keeping of the appended claims.

**CLAIMS**

1. An external fixator for osteosynthesis comprising bone implants to be introduced into the bone fragments, said implants being indirectly interconnected by at least one carrier with circular cross-section and independently positioned by at least one holder and/or clamp mounted so as to allow angular or linear change of position on the carrier, said carriers being interconnected by a compression-distractive mechanism and/or a hinge provided with a screw-type stopping and made in the form of a ball-and-socket joint comprising at least one ball element connected with the carrier or holder on which an enveloping nut is located and an element with at least one socket into which the ball can be fixed using the enveloping nut, the working surface of the ball being made of a softer material than the material of the spherical working surface of the socket, characterized by the fact that at least one opening (18) is made in the element with the socket (15) towards the working surface of each socket (15), and in each of said openings (18) there is a retainer (19) allowing displacement and having a sharp-tipped end which can penetrate into the ball's material, while each carrier (2) has a thread on its outer surface and at least one through-hole (3) for a transosteal implant (4), said through-hole (3) being perpendicular to the carrier's axis, the clamp being made as a fixing nut (5) and each holder (25) being connected with a carrier (2) by a ball-and-socket joint (13), said holder (25) being provided with an element (14 or 15) of the ball-and-socket joint (13) firmly connected with a screw mount (26) designed to fix at least one bone screw (4), while the compression-distractive mechanism (30) comprises a guide (31) with one end connected with a carrier (2) or holder (25) and having a thread at its other end, an operating element (33) tightened so as to allow displacement on the guide (31), and a follower (36) with one end connected with a carrier (2) or holder (25) and is flexibly connected with the guide (31) by a finger (39) moving along a rectilinear groove (32) on the threaded stem of the guide (31), said follower (36) coming in a flexible contact with the operating element (33) too, so as to effectuate only an axial displacement through the guide (31).
2. An external fixator according to Claim 1, characterized by the fact that the element with a socket (15) is rigidly connected to a carrier (2).
3. An external fixator according to Claims 1 and 3, characterized by the fact that the retainer (19) is an adjusting screw tightened into a thread of the opening (18).
4. An external fixator according to Claim 1, characterized by the fact that the socket element (15) further comprises at least one pusher (20) allowing stopping and designed to push at least one retainer (19).
5. An external fixator according to Claim 4, characterized by the fact that the pusher (20) is an adjusting screw to be tightened into a threaded opening (21) connected with at least one retainer opening (18), said pusher (20) susceptible to come in contact with the retainer (19) and to push it away.

6. An element for a ball-and-socket-joint from an external fixator with at least one socket wherein a ball can be fixed, characterized by the fact that at least one opening (18) is made towards the working spherical surface of each socket (15) and in each of said openings (18) a movable retainer (19) is placed whose end  
5 has a sharp tip that can penetrate into the ball's material.
7. An element for a ball-and-socket joint from an external fixator with at least one socket wherein a ball can be fixed, characterized by the fact that at least one opening (18) is made towards the working spherical surface of each socket (15) and in each of said openings (18) a movable retainer (19) is placed whose end  
10 has a sharp tip that can penetrate into the ball's material, and further comprises at least one pusher (20) which can be stopped and which is to push at least one retainer (19).
8. An element for a ball-and-socket joint according to Claim 7, characterized by the fact that the pusher (20) is an adjusting screw to be tightened into an opening  
15 (21) connected with at least one retainer-containing opening (18), said PUSHER (20) being able to come in contact with the retainer (19) and to push it away.
9. An element for a ball-and-socket joint according to Claims 6, 7 and 8, characterized by the fact that it is rigidly connected with a carrier for external fixator.
- 20 10. An external fixator according to Claim 1, characterized by the fact that at least one end of the carrier (2) is made as a part of a distractor (30) or as a part of a ball-and-socket joint (13).
11. An external fixator according to Claim 1, characterized by the fact that the fixing nut (5) comprises a sliding screw nut (6) with a compression washer (7)  
25 unreleasably mounted on one of its ends thus allowing free rotation, the outer face (11) of the washer (7) having at least one diametrical groove (12) to fix the transosteal implant (4).
12. A clamp to be mounted on a carrier for external fixator, characterized by the fact that it is made as a fixing nut (5) comprising a sliding screw nut (6) with a  
30 compression washer (7) unreleasably mounted on one of its ends thus allowing free rotation, the outer face (11) of the washer (7) having at least one diametrical groove (12) to fix the transosteal implant (4).
13. A carrier for external fixator with circular cross-section, characterized by the fact that it has a thread on its outer surface and at least one through-hole (3) for  
35 transosteal implant (4) perpendicular to its axis, and all holes (3) are at a distance from one another.
14. A carrier according to Claim 13, characterized by the fact that the holes (3) are made oblongue.
15. A carrier for external fixator with circular cross-section, characterized by the fact  
40 that it has a thread on its outer surface and at least one through-hole (3) for transosteal implant (4) perpendicular to its axis, and all holes (3) are at a

distance from one another, at least one of the carrier's ends being shaped so as to be part of a ball-and-socket joint (13).

16. An external fixator according to Claim 1, characterized by the fact that the screw mount (26) is made as a flat body with at least one through hole (27) with  
5 bevelled ends, the through hole (27) receiving a bone implant (4) which is a bone screw with a threaded shank, said implant (4) is fixed to the screw mount (26) by two fixing nuts (28) with bevelled split ends (29), tightened at the two sides of the flat body, the bevelled split end of each fixing nut (28) entering the bevelled end of the hole (27).
- 10 17. A hinged holder having at least one hole for a bone screw, characterized by the fact that it comprises a ball (14) and an enveloping nut (16) loosely slipped on at one end, the other end being shaped as a screw mount (26) which is made as a flat body with at least one through hole (27) with bevelled ends, the through hole (27) receiving a bone implant (4) which is a bone screw with a threaded shank,  
15 said implant (4) is fixed to the screw mount (26) by two fixing nuts (28) with bevelled split ends (29), tightened at the two sides of the flat body, the bevelled split end (29) of each fixing nut (28) entering the bevelled end of the hole (27).
18. An external fixator according to Claim 1, characterized by the fact that the guide (31) from the compression-distraction mechanism (30) comprises a  
20 rectilinear groove (32) on the thread, parallel to the axis and spring finger (39) that can move along the rectilinear groove (32), while an operating element (33) freely covers a follower (36) and has two face restrictors (37) to limit the axial movement of the follower (36).
19. A compression-distraction mechanism for external fixator, characterized by the  
25 fact that it comprises a guide (31) with one end connected with a carrier (2) or holder (25) and having a thread at its other end, an operating element (33) tightened so as to allow displacement on the guide (31), and a follower (36) with one end connected with a carrier (2) or holder (25) and is flexibly connected with the guide (31) by a finger (39) moving along a rectilinear groove (32) on the  
30 threaded stem of the guide (31), said follower (36) coming in a flexible contact with the operating element (33) too, so as to effectuate only an axial displacement through the guide (31) and the guide (31) comprises a rectilinear groove (32) on the thread, parallel to the axis and spring finger (39) that can move along the rectilinear groove (32), while an operating element (33) freely  
35 covers a follower (36) and has two face restrictors (37) to limit the axial movement of the follower (36).

## AMENDED CLAIMS

[received by the International Bureau on 24 November 1998 (24.11.98);  
original claims 1-19 replaced by amended claims 1-10 (2 pages)]

1. An external fixator for osteosynthesis comprising bone implants to be introduced into the bone fragments, at least one carrier with circular cross-section for indirect interconnection of said bone implants, at least one holder  
5 and/or a clamp for independent positioning of said bone implants and allowing angular or linear change of its position on the carrier, a compression-distraction mechanism and/or a hinge for interconnection of said carriers, said hinge is provided with a screw-type stopping and made in the form of a ball-and-socket  
10 joint with at least one ball element connected with the carrier or holder on which an enveloping nut is located and an element with at least one socket into which the ball can be fixed using the enveloping nut, the working surface of the ball being made of a softer material than the material of the spherical working surface of the socket, characterized by the fact that:

a) the element with the sockets (15) have openings (18) towards the  
15 working surface of each socket (15), and in each of said openings (18) there is a retainer (19) allowing displacement and having a sharp-tipped end which can penetrate into the ball's material, and further comprises at least one pusher (20) allowing stopping and designed to push at least one retainer (19);

b) each carrier (2) has a thread on its outer surface and at least one  
20 through-hole (3) for a transosteal implant (4), said through-holes (3) being perpendicular to the carrier's axis, said clamp being made as a fixing nut (5) comprises a sliding screw nut (6) with a compression washer (7) unreleasable mounted on one of its ends thus allowing free rotation, the outer face (11) of the washer (7) having at least one diametrical groove (12) to fix the transosteal  
25 implant (4);

c) each holder (25) allowing connection with a carrier by a ball-and-socket joint (13), said holder (25) being provided with an element (14 or 15) of the ball-and socket joint (13) firmly connected with a screw mount (26) designed to fix at least one bone screw (4);

30 d) said compression-distraction mechanism (30) comprises a guide (31) for connecting with a carrier (2) or holder (25) and having a thread at its other end where a rectilinear groove (32) is provided axially, further comprises an operating element (33) tightened so as to allow displacement on the guide (31), and further comprises a follower (36) for connecting with a carrier (2) or holder  
35 (25), said follower (36) is flexibly connected with the guide (31) by a spring finger (39) for axial guiding on said groove (32), said operating element (33) freely covers said follower (36) and having two face restrictors (37) for limiting the axial movement of said follower (36).

2. An external fixator according to Claim 1, characterized by the fact that  
40 the pusher (20) is an adjusting screw to be tightened into a threaded opening (21) on the socket element (15), said opening (21) is connected with at least one retainer opening (18) , said pusher (20) susceptible to come in contact with the retainer (19) and to push it away.

3. An external fixator according to Claim 1, characterized by the fact that at least one end of the carrier (2) is made as a part of distractor (30) or as a part of ball-and-socket joint (13).

5 4. An external fixator according to Claim 1, characterized by the fact that the screw mount (26) is made as a flat body with at least one through hole (27) with bevelled ends for receiving a bone implant (4) which is a bone screw with a threaded shank, and said screw mount (26) having two fixing nuts (28) for tightening at the two sides of the flat body for fixing said bone implant (4), each fixing nut (28) having bevelled split end (29) for entering the bevelled end of the hole (27).  
10

5. An external fixator according to Claim 1, characterized by the fact that said guide (31) and said follower (36) of the compression-distraction mechanism (30) end as a part of ball-and-socket joint (13).

15 6. An element for a ball-and-socket joint from an external fixator with at least one socket wherein a ball can be fixed, characterized by the fact that at least one opening (18) is made towards the working spherical surface of each socket (15) and in each of said openings (18) a movable retainer (19) is placed whose end has a sharp tip that can penetrate into the ball's material, and further comprises at least one pusher (20) which can be stopped and which is provided to push at least one retainer (19), said pusher (20) is an adjusting screw to be tightened into an opening (21) of the socket (15) connected with at least one retainer-containing opening (18).  
20

7. An element for a ball-and-socket joint according to Claim 6, characterized by the fact that it is rigidly connected with a carrier (2) for external fixator.

25 8. A carrier for external fixator having a thread on its outer surface and at least one through-hole for transosteal implant perpendicular to its axis, and at least one fixing nut is screwed on the carrier, characterized by the fact that said fixing nut (5) comprises a sliding screw nut (6) with a compression washer (7) unreleasably mounted on one of its ends thus allowing free rotation, the outer face (11) of the washer (7) having at least one diametrical groove (12) to fix the transosteal implant (4), and at least one of the carrier's ends being shaped so as to be part of a ball-and-socket joint (13).  
30

9. A carrier according to Claim 8, characterized by the fact that the holes (3) are made oblongue.

35 10. A hinged holder having at least one hole for a bone screw, characterized by the fact that it comprises a part of a ball-and-socket joint (13) at one end, the other end being shaped as a screw mount (26) which is made as a flat body with at least one through hole (27) with bevelled ends for receiving a bone screw with a threaded shank to be fixed to the screw mount (26), further comprises two fixing nuts (28) with bevelled split ends (29) for tightening at the two sides of the flat body, the bevelled split end (29) of each fixing nut (28) entering the bevelled end of the hole (27).  
40

Fig. 4

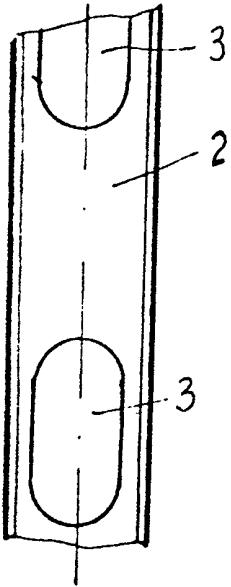


Fig. 3

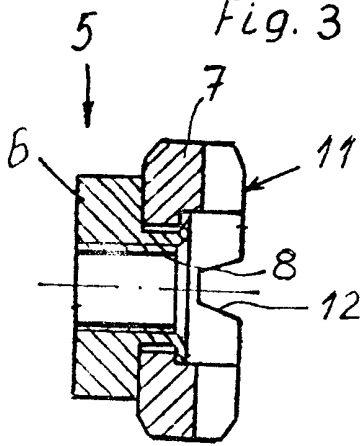


Fig. 1

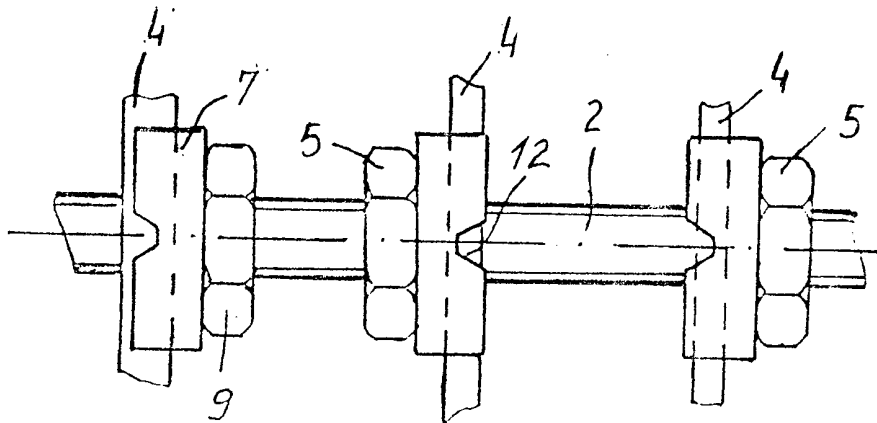
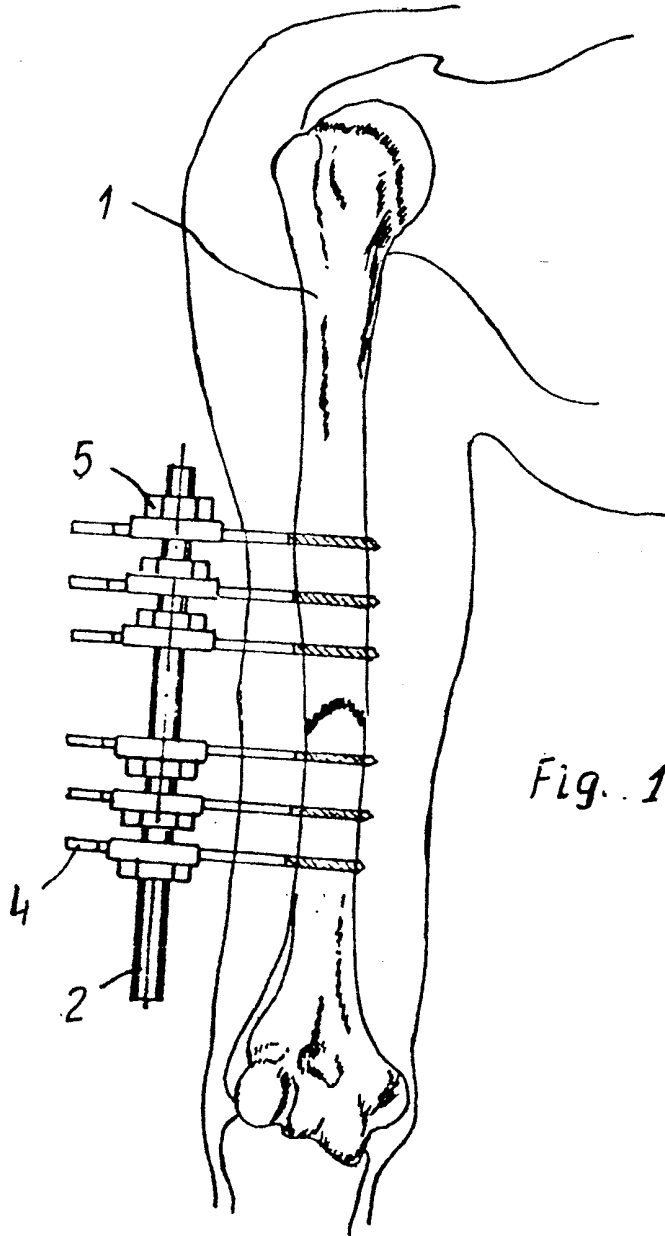


Fig. 2

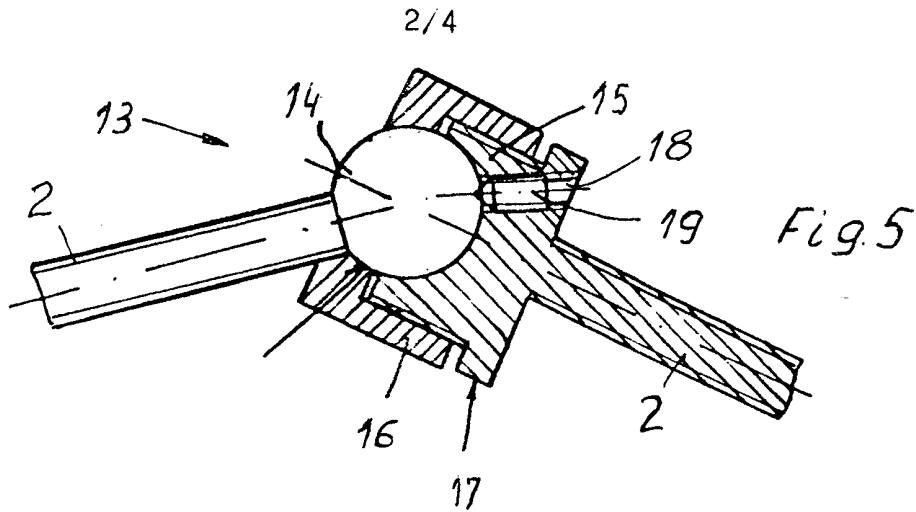


Fig. 6

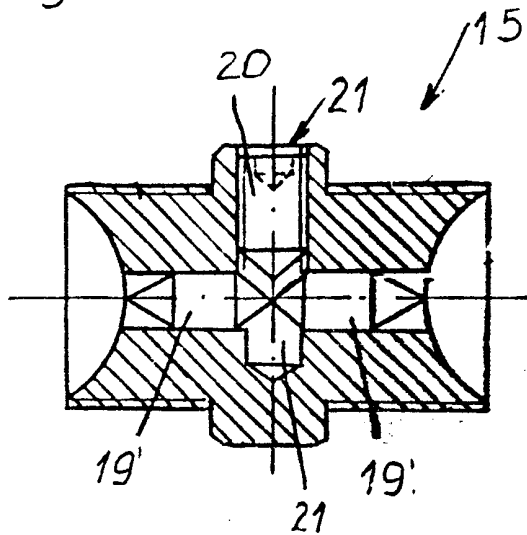


Fig. 8

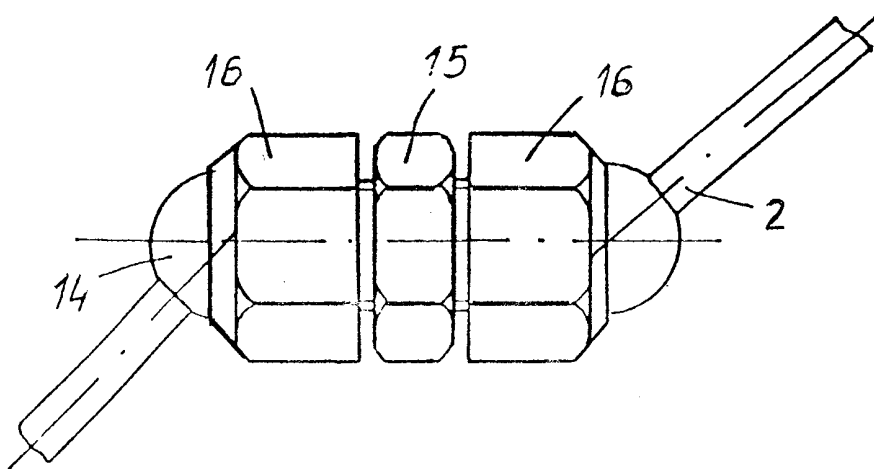
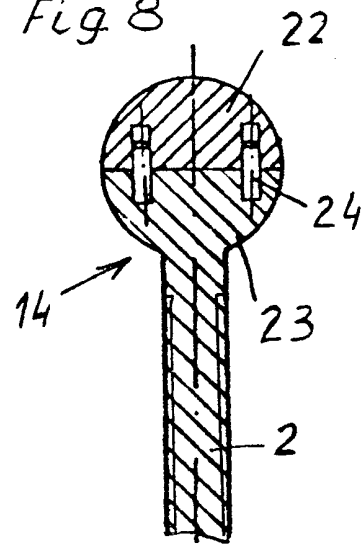


Fig. 7



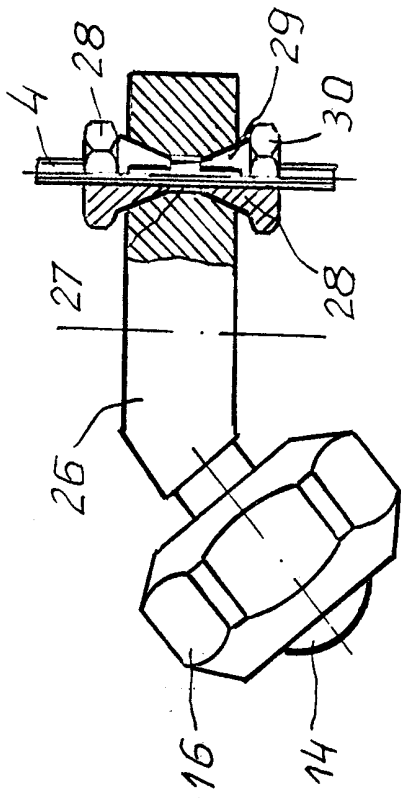


Fig. 9

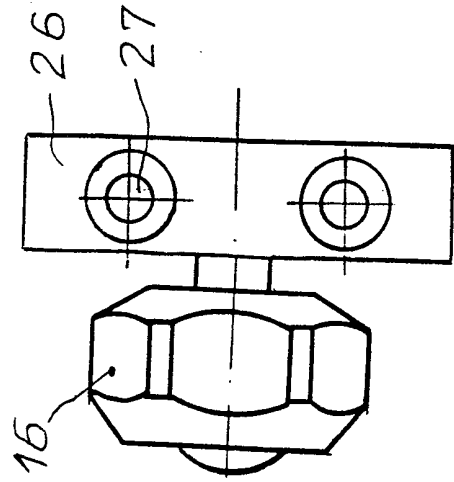


Fig. 10

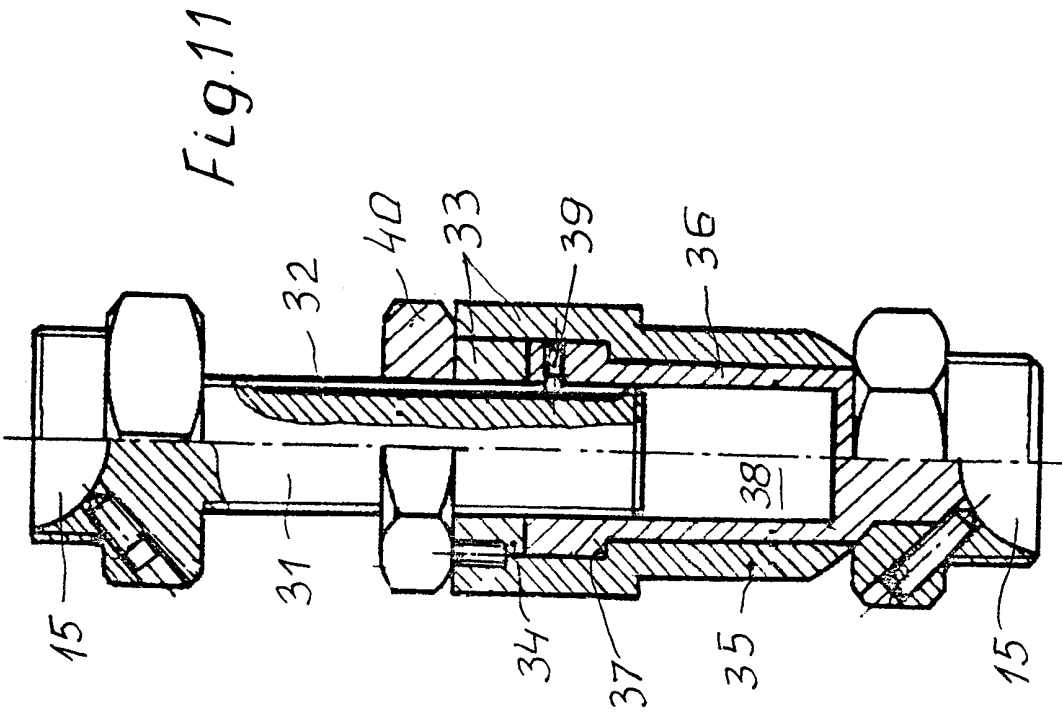


Fig. 11

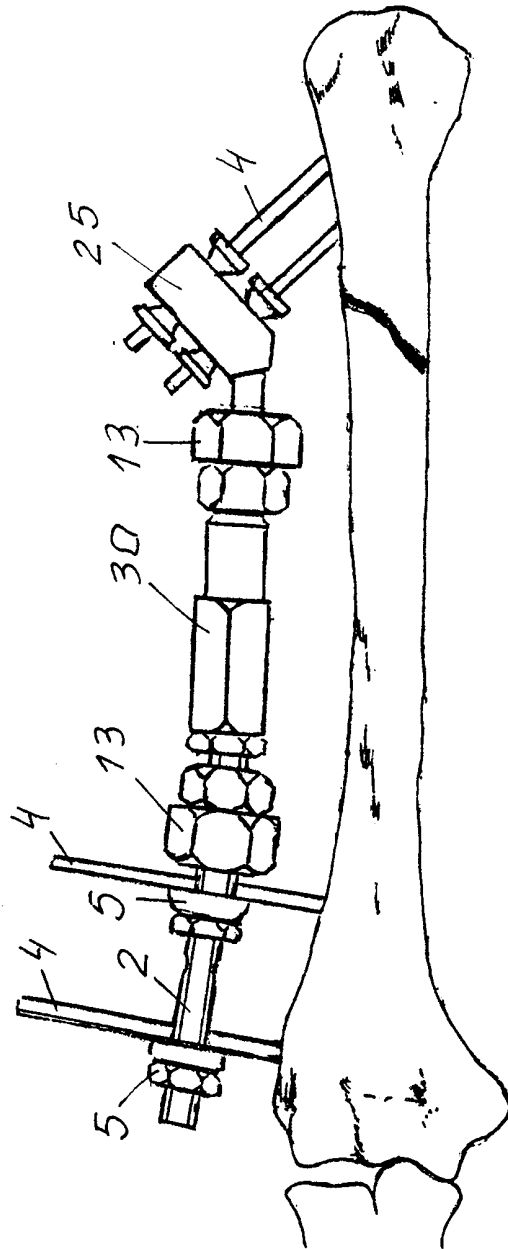


Fig. 12

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/BG 97/00009

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B17/66 A61B17/64

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 6 A61B

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

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

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91 11151 A (SHEFFIELD CITY COUNCIL) 8 August 1991	6,9
Y	see abstract; figures ---	7,8
Y	DE 93 20 834 U (D.PENNIG) 16 March 1995 see figure 2 ---	7,8
X	DE 94 08 668 U (WALDEMAR LINK) 28 September 1995 see claims 1-3; figures 4,6-9 see page 1, line 13 - page 2, line 10 see page 4, line 29 see page 5, line 3 - line 6 see page 5, line 18 - line 21 --- -/--	13,14

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

Date of the actual completion of the international search

15 June 1998

Date of mailing of the international search report

25.06.98

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

Nice, P

## INTERNATIONAL SEARCH REPORT

Internat. Application No

PCT/BG 97/00009

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

Category <sup>o</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 377 744 A (VSESOJUZNY KURGANSKY NUCHNY TSENTR VOSSTANOVITELNAYA TRAVMATOLOGIYA ) 18 July 1990 see figures 1,2 ---	12
A	EP 0 140 786 A (SOCIETE DE REALISATIONS ELECTROMECHANIQUES) 8 May 1985 cited in the application see figures 1-4 ---	13,15
A	US 4 621 627 A (G.DEBASTIANI ET AL.) 11 November 1986 see figures 1,2 ---	15,17
A	FR 2 520 607 A (E.BOSSI ET AL.) 5 August 1983 see page 6, line 1 - line 30 see page 8, line 15 - line 22 see figures 1,3 ---	17
X	EP 0 386 308 A (J.PFEIL AND W.VEITH) 12 September 1990 see column 4, line 18 - column 5, line 17 see column 8, line 10 - line 52 see column 9, line 26 - column 10, line 2 see figures 1,2,6-10 ---	19
X	EP 0 424 292 A (FIXANO PRODUCTION) 24 April 1991 see column 4, line 39 - line 48 see column 4, line 54 - column 5, line 2 see figures 2,3 ---	19
X	FR 2 457 676 A (V.INGRASSIA) 26 December 1980 see page 5, line 6 - line 17; figure 4 ---	19
E	BG 100 328 A (S.G.NESTOROV) 31 July 1997 see figures ---	6-9
E	BG 100 327 A (S.G.NESTOROV) 31 July 1997 see figures -----	12-14

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/BG 97/00009

## 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.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 1-5, 10-11, 16, 18  
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:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
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:

see additional sheet

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.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 6-9

External fixator ball-and-socket joint

2. Claims: 12-15

Clamp for external fixator, in the form of a fixing nut

3. Claim : 17

Holder for bone screw

4. Claim : 19

Compression-distraction mechanism

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Claims Nos.: 1-5,10-11,16,18

Claim 1 (on which claims 2-5,10-11,16 and 18 are dependent) mentions features which are also specified in the other independent claims. The manner in which claim 1 is drafted does not make it clear which alternative combinations of these features are intended to be included within the scope of this claim.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/BG 97/00009

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9111151    A	08-08-1991	AU 7305391 A	21-08-1991
DE 9320834    U	16-03-1995	DE 4220936 C	16-09-1993
		DE 9320849 U	20-04-1995
		AT 149813 T	15-03-1997
		AU 659022 B	04-05-1995
		AU 4307493 A	24-01-1994
		CA 2099240 A,C	27-12-1993
		WO 9400067 A	06-01-1994
		DE 59305741 D	17-04-1997
		DK 601152 T	01-09-1997
		EP 0601152 A	15-06-1994
		ES 2099443 T	16-05-1997
		JP 6509970 T	10-11-1994
		MX 9303763 A	31-01-1994
		NO 940651 A	25-02-1994
		US 5304177 A	19-04-1994
		ZA 9304580 A	29-06-1994
DE 9408668    U	28-09-1995	EP 0685206 A	06-12-1995
EP 0377744    A	18-07-1990	WO 8911254 A	30-11-1989
		DK 19690 A	26-01-1990
		JP 3501092 T	14-03-1991
		US 4978348 A	18-12-1990
EP 0140786    A	08-05-1985	FR 2553994 A	03-05-1985
		DE 3472753 A	25-08-1988
US 4621627    A	11-11-1986	AT 394940 B	27-07-1992
		AU 564568 B	13-08-1987
		AU 5071685 A	26-06-1986
		BE 903869 A	16-04-1986
		CA 1235972 A	03-05-1988
		CH 666177 A	15-07-1988
		DE 3543042 A	19-06-1986
		DK 586485 A,B,	19-06-1986
		FR 2574654 A	20-06-1986
		GB 2168255 A,B	18-06-1986
		JP 61146254 A	03-07-1986



# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati	Application No
PCT/BG 97/00009	

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4621627    A		LU     86216 A NL     8503453 A,B, PT     81664 B SE     463073 B SE     8505962 A	14-04-1986 16-07-1986 18-09-1987 08-10-1990 19-06-1986
-----			
FR 2520607    A	05-08-1983	CH     651744 A	15-10-1985
-----			
EP 0386308    A	12-09-1990	DE     8902691 U AT     133847 T CA     2027856 A DE     58909600 D WO     9010421 A JP     3504456 T US     5451226 A	19-07-1990 15-02-1996 07-09-1990 21-03-1996 20-09-1990 03-10-1991 19-09-1995
-----			
EP 0424292    A	24-04-1991	FR     2653007 A DE     69021004 D	19-04-1991 24-08-1995
-----			
FR 2457676    A	26-12-1980	NONE	
-----			
BG 100328     A	31-07-1997	NONE	
-----			
BG 100327     A	31-07-1997	NONE	
-----			