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(71) Applicant: ORTHOFIX SRL [IT/IT]; Via delle Nazioni, 9, I-37012 Bussolengo (IT).

(72) Inventors: FAGGIOLI, Giovanni ; Via Europa, 19, I-46040 Monzambano (IT). VENTURINI, Daniele ; Via Di Vittorio, 7, I-37065 Povegliano Veronese (IT).

(74) Agent: THOMSON, Paul, A.; Potts, Kerr & Co., 15 Hamilton Square, Birkenhead, Merseyside L41 6BR (GB).

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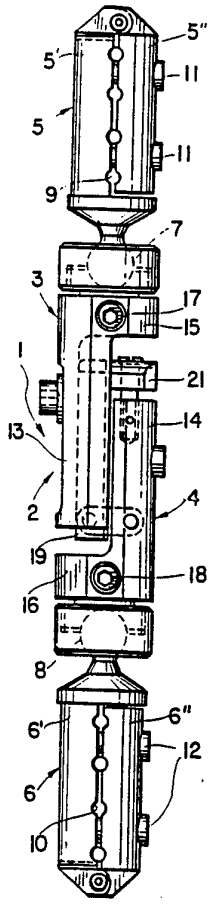
(54) Title: EXTERNAL AXIAL FIXATOR FOR OSTEOSYNTHESIS

(57) Abstract

A dynamic external axial splint for use in rehabilitating a fractured bone comprises a pair of spaced clamps (5, 6) for bone screws or bolts anchored to the respective fragments of the fractured bone. A central body (2) releasably and universally connects and locks these spaced clamps via ball-joints (7, 8) having provision for selective retention of a wide variety of angular relations, between the central body and the central axis of each of the spaced clamps. The central body comprises first (3) and second (4) end members and a third or intermediate member (19), affording on the one hand, longitudinally and adjustably fixed overlap of one end member with the intermediate member, and also affording limited resiliently snubbed and axially guided displaceability as between the intermediate member, and the other end member, thus rendereing the two end members and the respective bone-fragment anchorages clamped to the end members subject to the same axially guided and resiliently snubbed action. The axially displaceable and resilient snubbed action is selectively neutralised by single clamp adjustment (42) which converts the dynamic external splint into a fixed external splint or fixator.



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EXTERNAL AXIAL FIXATOR FOR OSTEOSYNTHESIS

This invention relates to an external axial fixator, in particular for the dynamic repair of bone fractures.

For many years, it has become a practice in bone surgery to employ an external fixation device, essentially comprising a substantially rigid structure provided with bone-anchoring screws or bolts that are inserted in bone fragments on opposite sides of a given fracture, to encourage knitting of the bone by stabilising the relative position of the involved bone fragments.

It has been noted that, with some types of fracture, knitting times can be accelerated and ultimate stability can be increased by exerting axial compression upon the bone fragments.

In the use of rigid external axial fixators, muscular forces and/or external stresses are in general transmitted to the splint and not to the fractured bone. But, to encourage regeneration of hard bone, it is preferred that the patient apply some stress to the bone, to encourage more rapid and reliable knitting at the situs of the fracture. Conventional systems do not permit the application of such forces to the bone, on account of their relative rigidity and lack of deformability.

To overcome the problem of relative rigidity, U.S. Patent No. 5,026,372 discloses a dynamic axial fixators wherein an articulated parallelogram joint is the means of yieldably interconnecting spaced clamps that are respectively anchored to the separate fragments of a

fractured bone. Specifically, the parallelogram joint comprises two spaced longitudinal members pivotally connected at their ends by two pairs of transverse links, thus allowing limited longitudinal displacement of one with respect to the other of the longitudinal members, when the joint is subjected to a compression force or a tension force.

A disadvantage of this known axial fixator lies in the fact that, when the opposing members are subject to longitudinal displacement, they are also caused to move to some extent in a transverse direction, as governed by the accompanying angular displacement of the connecting links. Thus, the clamps which anchor the respective fragments of fractured bone lose their longitudinal alignment and have an adverse effect on the point of fracture. It has in fact been established that bony material which is undergoing consolidation has a very much lesser resistance to transverse (shear) forces than to bending or longitudinal forces. Thus, to contain the transverse movement, provision is made to limit relative longitudinal displacement of the longitudinal members to a few millimetres, but the indicated disadvantage is already appreciable with longitudinal displacements of a few tenths of a millimetre.

A further disadvantage of this known dynamic fixator lies in the fact that, in order to repair or correct the fracture while the bony material is undergoing consolidation, the means for arresting dynamic movement must be released because of the particular configuration of the parallelogram joint and the manner in which it is anchored to opposing members fitted with clamps.

Another advantage of this known axial splint lies

in its appreciable complexity and excessive cost due to the existence within the articulated parallelogram of a number of joints which among other things increase the risk of jamming at pivot connections.

A primary object of the invention is to eliminate or at least substantially reduce the above mentioned disadvantages by providing an external axial fixator which is particularly suited for the dynamic repair of bone fractures and which maintains central-body members fixed to the respective fragments of a fractured bone in a substantially longitudinal alignment throughout a range of dynamic axial displacement.

Another object of the invention is to provide an external axial fixator having high axial mobility within a strictly controlled range of movement so as to reduce to a minimum any risk of jamming during application to the patient.

It is also an object to provide an axial fixator which can induce beneficial non-harmful movements in the bone fragments in order to regenerate hard bone.

A further object is to provide a dynamic axial fixator in which the dynamic function and repair of the fracture are absolutely independent and can be selectively controlled.

Yet another object of the invention is to provide an external axial fixator of relatively simple structure and with a reduced number of component parts.

These objects, together with others which will become more apparent below, are accomplished through an external axial fixator, especially for the dynamic repair

of bone fractures, including a pair of clamps for securing bone pins implanted in respective stumps of a fractured bone, an elongate central body formed by a first end member and a second end member defining a longitudinal axis, a ball-joint for connecting each end member with a respective one of said clamps, means for selectively locking said ball-joints thereby fixing said clamps at selected angular positions relative to said end members, characterised in that it comprises an intermediate member for mutually coupling said first and said second end members, connection means for coupling said intermediate member to said first end member, said connection means including first longitudinal guide means combined with loose-captive coupling means to enable limited and substantially axial displacement of said first end member relative to said intermediate member without any relative rotation about said longitudinal axis.

A loose-link connection between the intermediate member and the other end member provides assurance that the resiliently snubbed axial-displaceability feature cannot be jammed or otherwise impaired.

The primary advantage of the present invention is that the strictly longitudinal nature of the guide means inherently avoids the transverse movement of end members which normally occur in known axial splints having parallelogram-joint action. Excellent axial mobility is assured, without jamming or other misaligning impairment.

Finally, the fixator of the invention is structurally simple, light and reliable, and a degree of selectively variable axially compliant action is afforded, with clear economic and functional advantages.

DETAILED DESCRIPTION

A preferred embodiment of the invention will be described in detail, in connection with the accompanying drawings, in which:

Fig. 1 is a view in side elevation of a dynamic axial splint of the invention, complete with bone-screw clamps at the respective ends of the splint;

Fig. 2 is another view in side elevation of the splint of Fig. 1 but taken from an aspect that is 90° offset from the aspect of Fig. 1, the bone-screw clamps being shown in Fig. 2 to be anchored to the respective fragments of a fractured bone;

Fig. 3 is an enlarged and exploded view of certain parts of the splint of Figs. 1 and 2;

Fig. 4 is a view in side elevation, partly broken away and generally in longitudinal section, for the central body portion of the splint of Figs. 1 and 2;

Fig. 5 is a transverse section taken at 5-5 in Fig. 4;

Fig. 6 is a further enlarged view in side elevation, partly broken away and generally in longitudinal section, to more clearly show the coaction between axially displaceable parts of the central body portion of the split;

Fig. 7 is a fragmentary view in longitudinal section to show a modification; and

Fig. 8 is a view similar to Fig. 6, to show a further modification.

In Figs. 1 and 2, a dynamic external axial fixator or splint of the invention is generally indicated by reference numeral 1 and is seen to comprise a central body 2 having two end members 3, 4 each of which is coupled to an associated clamp 5, 6 via ball-joints 7, 8.

Each clamp 5, 6 may be of generally ellipsoidal section, constructed of two opposing halves 5', 5" and 6', 6" respectively, and having transversely grooved seats 9, 10 and bolts 11, 12 for securely clamping bolts or screws V which will be understood to have been anchored in the cortical tissue of a fractured bone 0. As shown, the outer ends of the halves of each clamp are hinge-connected to each other, and one half (5', 6') of each clamp is fixedly related to the ball (7,8) of its associated ball-joint connection to the central body 2.

The body members 3, 4 are the first and second of three parts constituting the central body 2. Each of these first two parts 3, 4 has an elongate portion 13 (14) of generally semi-cylindrical section and is integrally formed at one end with a generally cylindrical head 15 (16). The semi-cylindrical portions 13, 14 are longitudinally lapped, such that the overall appearance of central body 2 is in generally cylindrical conformance with the two heads 15 (16), adjacent to socket components of the respective ball joints 7 (8). Transverse bolts 17 (18) through the heads 15 (16) will be understood to enable releasable clamping of the respective ball joints 7 (8) for selective setting of particular angular orientation of the longitudinal axis of each bone screw clamp 5 (6) with respect to the longitudinal axis of central body 2, namely, with respect to the axis determined by the geometric line between ball centers at 7, 8. The overall generally cylindrical appearance of the central body applies for the entire range of adjustable overlap of the elongate semi-cylindrical portions 13 (14), as will later become clear.

The third part of the central body is an elongate intermediate member 19 having means determining the longitudinal connection between parts 3, 4 and any

relative longitudinal displacement of parts 3, 4 with respect to each other, while also preventing any relative rotation of parts 3, 4 about the axis of the central body, or any significant axial misalignment of either of parts 3, 4 with respect to the axis of the central body.

As best seen in Fig. 3, the elongate intermediate member 19 extends at 20 with constant generally rectangular section for lap of substantially the longitudinal extent of the generally semi-cylindrical portion 14. At the remote end of member 19, i.e. remote from head 16 of the body part 4 which it substantially laps, member 19 is integrally formed with a transverse head 21.

The intermediate member 19 has a resiliently snubbed and longitudinally guided relation to body part 4, wherein longitudinal guidance derives from the cylindrical shanks of two spaced parallel bolts 26 having relatively deep threaded engagement to tapped threads near the inner ends of deep longitudinal bores in the remote end of the generally semi-cylindrical portion 14 of body part 4. In Fig. 6, longitudinal dimensional notations are helpful in a description of one of the bolts 26 and the bore to which it is fitted, it being understood that both bolts are identical. The dimensional notations a, b, c reflect the full effective depth of the bore, wherein the deeply threaded portion is of limited extent b, and wherein, except for the shall depth c of a counterbore, a major fraction a of the bore is cylindrical, for accurate and substantial determination of correct orientation and support of the cylindrical remainder of the shank of the bolt 26, such that the cylindrical shank portion also projects beyond body portion 14, and through an aligned bore and counterbore in the transverse head portion 21 of

intermediate body member 19. A precision-fitted bushing 30 in each of the bores of head 21 is of hardened material and Teflon-lined, for low-friction guidance on the bolt shank. The bolt shank terminates at an enlarged head 31 having an exposed transverse slot for screwdriver adjustment. First and second sets of dished spring washers 38, 39, sometimes known as Belleville springs, are located in the respective counterbores in body portions 14 and 21, and the threaded advance of each of the bolts will be understood to selectively determine an axially preloaded and longitudinally neutral position of the intermediate body member 19 with respect of body member 4. A transverse slot 36 in each bolt shank will register with a single transverse pin alignment 28 through both bores in body portion 14, twice for each adjusted full turn of bolts 26, and for a range d of several consecutive turns of bolt adjustment, thus enabling pin 28 to lock a given selected spring preload of the neutral position of body members 4, 19, with respect to each other.

At its other end, namely, the end adjacent head 16, the intermediate member may be retained against such transverse displacement as might otherwise jeopardise the fidelity of purely axial displaceability of intermediate member 29 with respect to body member 4. This may be assured by a rod-and-bore engagement similar to what has been described for bolts 26 and their bore-guiding function, but in the form shown it is indicated that a simple transverse link connection at 22 will serve the purpose, in view of the reality that the order of magnitude of maximum displaceability of members 14, 19 is 1.5mm either side of the longitudinally neutral position. As shown, body part 4 is locally recessed at 23, and the corresponding end of intermediate member 19 is locally recessed to define transversely spaced arms for pivotal

connection to the upper end of link 22, via a single pin 24; in similar fashion, another transverse pin 25 pivotally connects the lower end of link 22 to body part 4, between confronting sidewalls of the recess 23 in body part 4. A degree of looseness or play is tolerable in one or the other of the link (22) connections because the function of link 22 is primarily to assure against any jamming or frictional misalignment of the shank of bolt 26 with respect to its truly axial and resiliently snubbed guidance of the head bushing 30.

The connected relation of body part 3 to the intermediate member is one of selected longitudinal adjustment followed by clamping to retain the adjusted position. Specifically, for the longitudinal extent of maximum overlap of body part 3 with intermediate member 19, the interior of part 3 is recessed to define a generally rectangular shell which derives longitudinal guidance from the generally rectangular section of portion 20 of member 19, all as clearly seen in the cross-section of Fig. 5. This guided relation is totally secured by integrally formed longitudinal flanges 31, 32 of body part 3 engaging under bottom edges of portion 20 of intermediate member 19. A given fixed longitudinal adjustment of body part 3 to intermediate member 19 is achieved via a single bolt 33 and its washer 34, with bolt 33 passing through an elongate slot in the portion 13 of part 3, and with bolt 33 tightly engaged to the threads of a tapped bore 37 in intermediate member 19, as seen in Fig. 4 for the most longitudinally compact adjustment of part 3 on member 19.

In the initial phase of applying the described dynamic axial splint to set the segments of a given fracture, it is desirable that the splint shall be a true fixator, i.e. with no provision for dynamic resiliently

snubbed displacement of bone fragments. In such case, a set screw 42, frictionally retained by an elastomeric O-ring in a tapped transverse bore in portion 14 of body part 4 may be selectively driven against the underside of portion 20 of intermediate member 19, thereby completely rigidising the spacing between bone-screw clamps 5, 6. Then later, as healing proceeds, release of set screw 42 from engagement with portion 20 will release the parts for dynamic-splint action.

The fragmentary diagram of Fig. 7 is a detailed showing of a slight modification wherein resiliently snubbed displacements of the described nature can be at least in part implemented via relatively stiff elastomeric bushings 43, 44 which serve the upper and lower pin connections 24, 25 of link 22, it being understood that bushings 43, 44 are bonded both to their respective pins 24, 25 and to their respective bores in link 22, as well as to the pin-mounting bores in portions 14 and 20 respectively, thereby making bushings 43, 44 contribute to the resilient snubbing action via transient torsional stressing of the two elastomeric bushings.

In use of the described dynamic axial splint, it is desirable to select and appropriately adjust the degree of resilient snubbing action, as in accordance with the orthopaedic surgeon's evaluation of each patient's weight and potential for compressive strength in each fractured bone. The described embodiment in connection with Fig. 6 permits a degree of such adjustment, merely by removing the bolt-locking transverse pin 28, so that adjusted preload of both spring sets 38, 39 can be made via a limited number of half-turn screwdriver-adjusted displacements of bolts 26. Alternative, or further, adjustability can follow from selecting individual spring sets at 38, 39 for

substituted assembly, in place of those shown in the drawings. For example, dished-washer stainless-steel springs and spring sets commercially available from Adolf Schnorr GmbH & Co. KG, of Sindelfingen, Federal Republic of Germany, offer a great variety of spring sizes and of spring constants, to suit the surgeon's prescription for the complete range of patient sizes and requirements.

The foregoing description of bolts 26 may be viewed as involving longitudinal guidance via a rod-and-bore engagement, for each of the bolts 26. The threaded deep-bore engagement, coupled with the cylindrical shank and its close-fitting support in the bore of portion 14, and over the relatively great axial span a establishes the projecting remainder of the cylindrical part of the shank as a precision reference for axial guidance of the bushed region 30 of the intermediate member 19. In the circumstances, it is appropriate to refer to this bushing 30 and cylindrical-shank engagement as a rod-and-bore engagement, which by reason of the opposed preloading of spring sets at 38, 39 establishes resiliently snubbed and longitudinally guided displaceability of the intermediate body part 19 with respect to one (4) of the central body parts. For the limited range of such guided displaceability, namely, in the order of 1.5mm either side of the neutral or equilibrium position angular displacement of link 22 involves insignificant axial misalignment of the longitudinal axes of the central body parts 3 and 4, particularly if link pins 24, 25 are in a geometric plane that is normal to the axis of body 2, for the equilibrium condition established by spring sets 38, 39. The insignificance of such axial misalignment flows from the fact that the bone-anchoring bolts or screws (V) respectively clamped to different fragments of the fractured bone (O) are themselves subject to small bending deflection when the fractured bone is under

longitudinal stress, as when transiently weight-bearing or when a longitudinal adjustment of the spacing between clamps 5, 6 is intentionally made by the surgeon in the course of bone healing.

In the alternative construction shown in Fig. 8, the link 22 is replaced by another rod-and-bore engagement, involving coaction between a rod 50 that is fixed to intermediate member 29 and longitudinally oriented in a bore 51, being shown fixed by a transverse pin 52. Rod 50 projects for slidable engagement in an axially aligned bore 53 in the head 16 of body part 4. All other parts may be as described for Fig. 6 and therefore the same reference numbers are used, where applicable. In use, resilient snubbing of limited axially displaceability of body parts 3, 4 is available, under assured conditions of axial displaceability.

CLAIMS

1. External axial fixator, in particular for the dynamic repair of bone fracture, including:

a pair of clamps for securing bone pins implanted in respective stumps of a fractured bone;

an elongate central body formed by a first end member and a second end member defining a longitudinal axis;

a ball-joint for connecting each end member with a respective one of said clamps;

means for selectively locking said ball-joints thereby fixing said clamps at selected angular positions relative to said end members;

characterised in that it comprises an intermediate member for mutually coupling said first and said second end members, connection means for coupling said intermediate member to said first end member, said connection means including first longitudinal guide means combined with loose-captive coupling means to enable limited and substantially axial displacement of said first end member relative to said intermediate member without any relative rotation about said longitudinal axis.

2. External axial fixator as claimed in claim 1, wherein said loose-captive coupling means comprises at least one link connection.

3. Orthopaedic fixator as claimed in claim 2, wherein said link connection comprises at least one transversely oriented link for coupling said intermediate member to said first end member.

4. External axial fixator as claimed in claim 2, wherein said link connection comprises a pair of links

having parallel end pins defining a geometric plane that is substantially normal to said longitudinal axis.

5. External axial fixator as claimed in claim 1, wherein said first and said second end members have opposite expanded heads and adjacent overlapping portions, said third intermediate member being positioned between said overlapping portions.

6. External axial fixator as claimed in claim 1, wherein said intermediate member has a longitudinal main portion and a transversely offset end portion.

7. External axial fixator as claimed in claim 6, wherein said first longitudinal guide means includes at least one rod-and-bore longitudinal coupling.

8. External axial fixator as claimed in claim 7, wherein said longitudinal guide means includes a rod-and-bore engagement extending parallel to said longitudinal axis and being transversely spaced therebetween.

9. External axial fixator as claimed in claim 8, wherein said rod-and-bore engagement comprises a first pair of rods having cylindrical shanks guided in longitudinal through holes formed in said transversely offset end portion of said intermediate member.

10. External axial fixator as claimed in claim 9, wherein said rod-and-bore engagement further comprises a second pair of rods having cylindrical shanks co-acting with the end of said intermediate member remote from said transversely offset end thereof.

11. External axial fixator as claimed in claim 9, wherein the ends of said cylindrical shanks are enlarged

to provide abutment means for said transversely end portion.

12. External axial fixator as claimed in claim 9 or 10, wherein said rods have threaded ends remote from said enlarged ends adapted for adjustable threaded engagement in tapped bores formed in said first end member.

13. External axial fixator as claimed in claim 12, wherein said connection means further comprises resilient means co-acting between said first end member and said intermediate member for resiliently limiting the relative movement thereof upon application of either compressional or tensional forces.

14. External axial fixator as claimed in claim 12, wherein said resilient means comprises a stacked plurality of Belleville spring elements guided by said rods and located between said end member and said offset end portion of said intermediate member.

15. External axial fixator as claimed in claim 12, wherein said resilient means comprises elastomeric bushes inserted between said parallel end pins and their connection point in said first end member.

16. External axial fixator as claimed in claim 1, wherein said intermediate member is adapted for stable connection to said second end member at selected longitudinal fixed positions, by means of second longitudinal guide means and a releasable locking means.

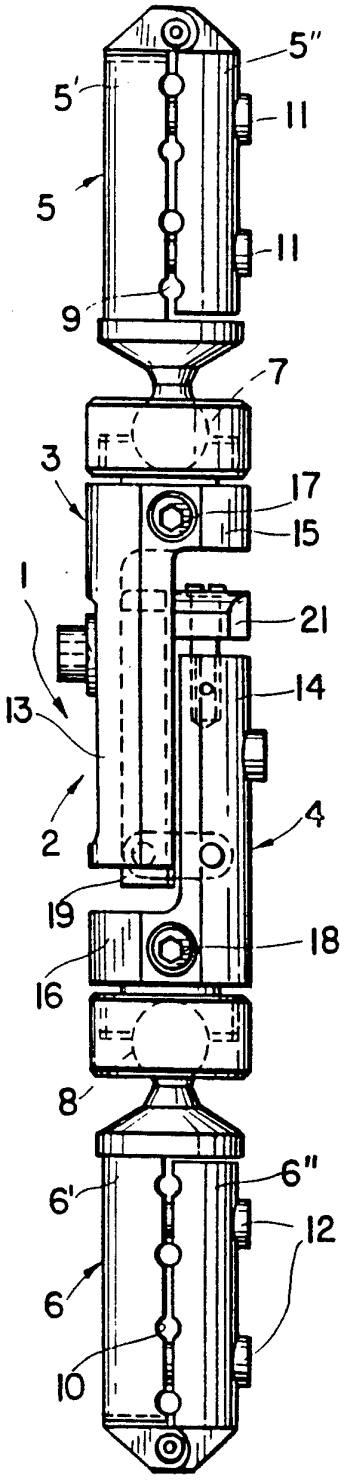
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FIG. 1

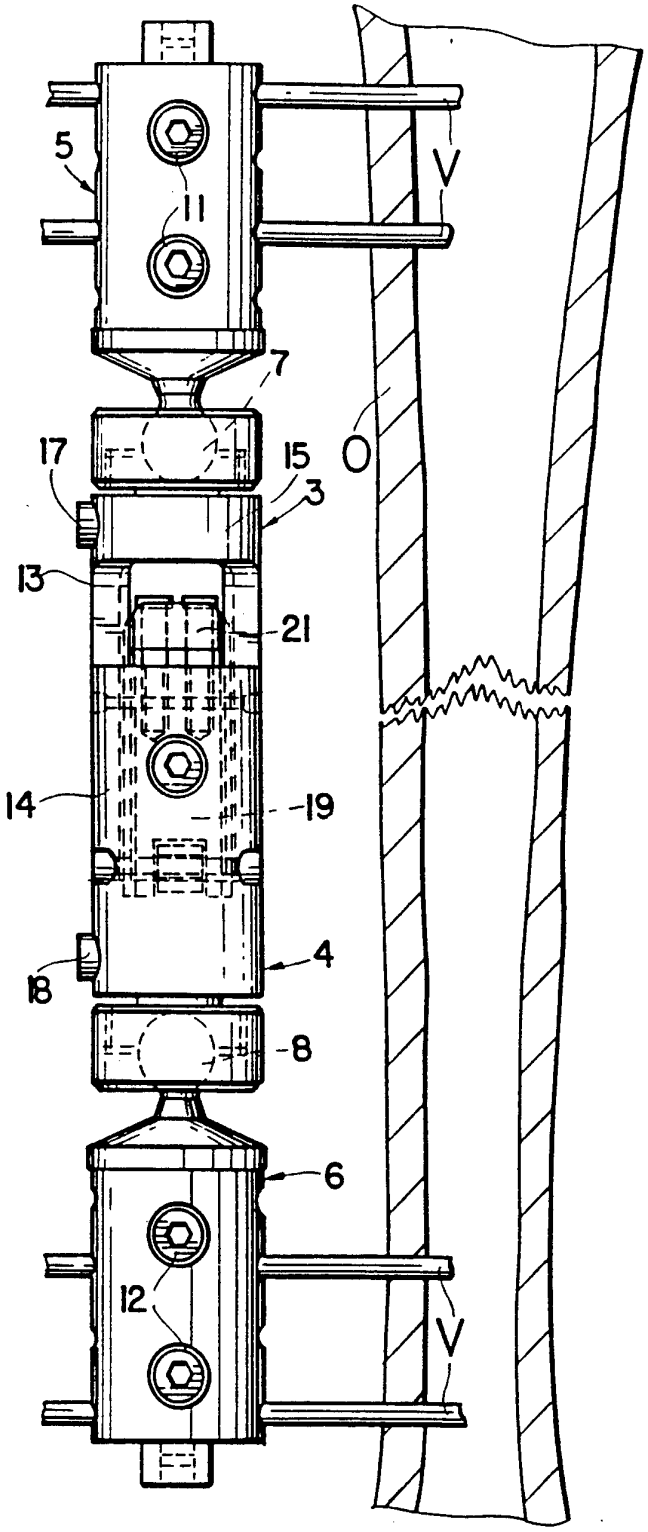
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FIG. 2

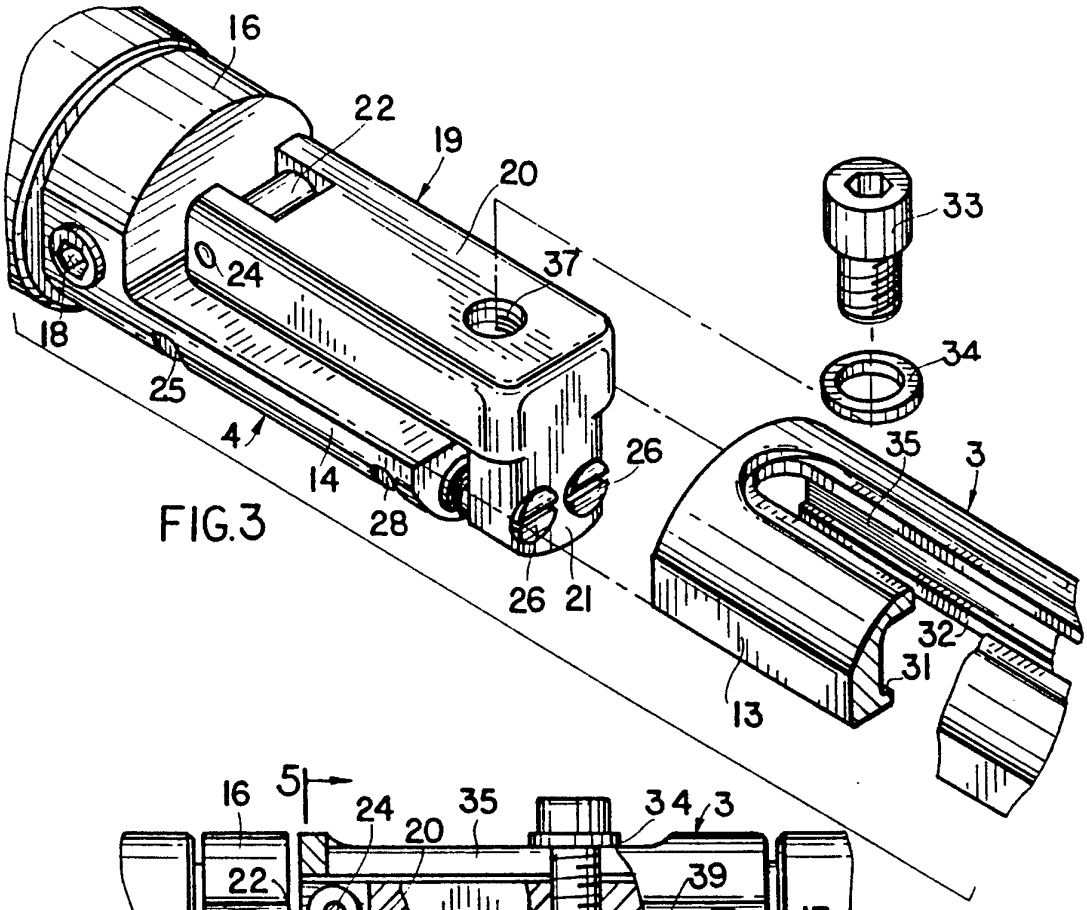

FIG.3

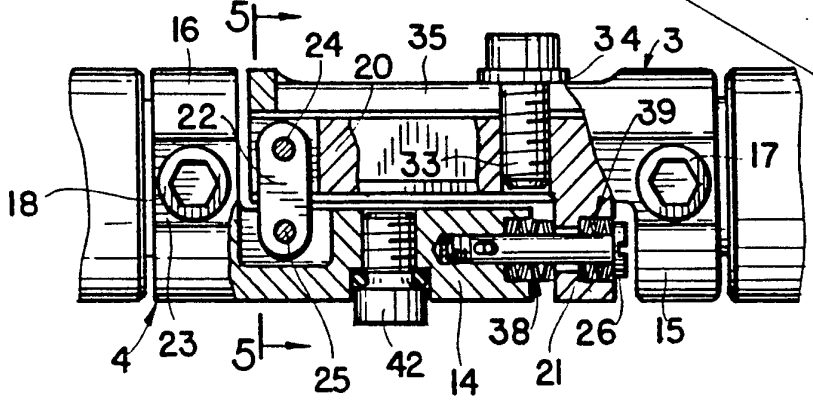

FIG. 4

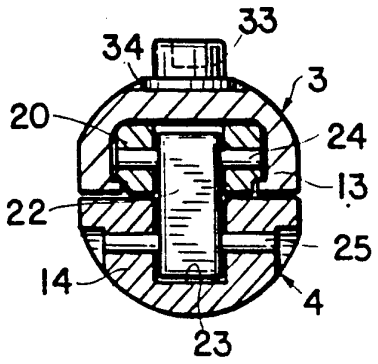

FIG.5

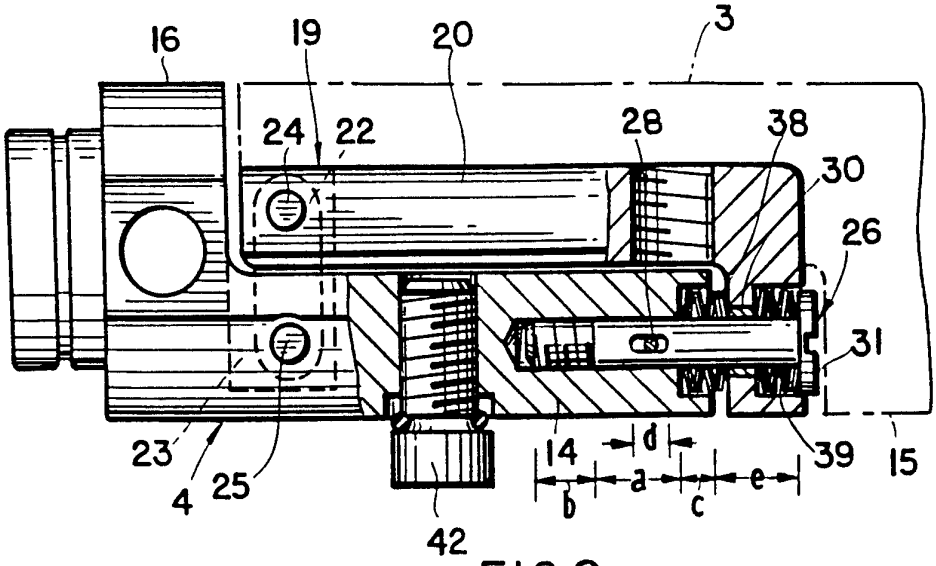

FIG.6

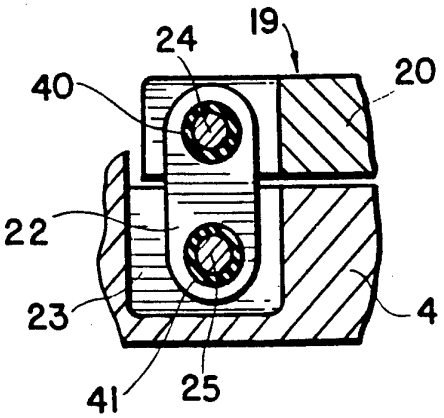

FIG.7

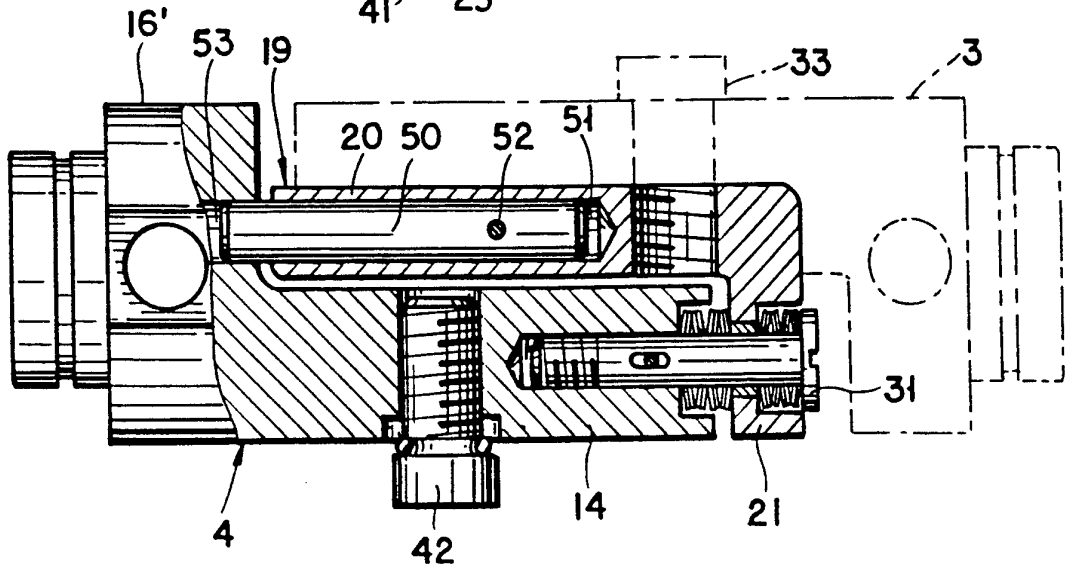

FIG.8

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 93/01825

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

Int.Cl. 5 A61B17/60

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

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 °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP,A,0 315 215 (R.STURTZKOPF AND H.-W.STEDTFELD) 10 May 1989 cited in the application see column 4, line 4 - line 43; figure 1 ---	1-5,16
A	DE,A,3 842 255 (KARL LEIBINGER MEDIZINTECHNIK) 21 June 1990 see column 2, line 36 - line 63 see column 3, line 25 - column 4, line 2; figures 1-2 ---	1,7-8, 13-14,16
A	DE,A,3 936 192 (AESCULAP) 2 May 1991 see column 3, line 59 - column 4, line 6; figures 1-2 ---	7-8

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"&" 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
08 SEPTEMBER 1993	29.09.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	NICE P.

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 93/01825

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
P,X	GB,A,2 258 155 (ORTHOFIX) 3 February 1993 see page 6, line 11 - page 7, line 23; figures 1-3 -----	1-5

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

EP 9301825
SA 77046

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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