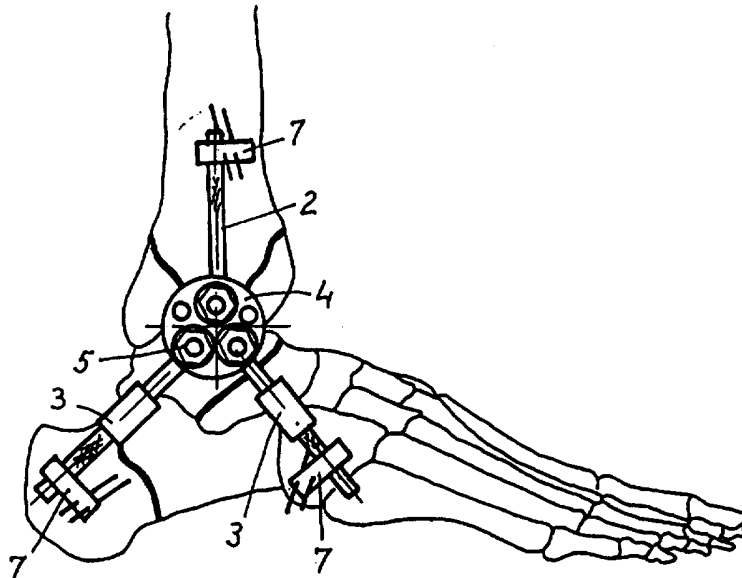




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(54) Title: MODULAR EXTERNAL FIXATION SYSTEM



(57) Abstract

The modular external fixation system can be used in orthopedics and traumatology in the treatment of traumas and deformations of various parts of the locomotory system for the building of external fixation devices used in reposition, fixation and traction. The system consists of supporting elements - one piece and adjustable, with circular section and a rifled external surface, jet comprising modular coupling elements for coupling supporting elements or coupling a supporting element to implants, in addition to that comprising a flat coupling element with holes in which can be mounted modular coupling elements for building ties with flat reciprocally arrangement of the supporting elements. Each modular coupling element has a stepped body with holes and ring bodies with slits, both manufactured from materials with different rigidity.

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MODULAR EXTERNAL FIXATION SYSTEM

FIELD OF THE INVENTION

The invention relates to human and veterinary medicine and can be used in orthopedics and traumatology in the treatment of traumas and deformations of various parts of the locomotory system for the building of external fixation devices used in reposition, fixation and traction.

BACKGROUND OF THE INVENTION

Since the end of the 19th century two major trends have been established in the development of external fixation systems, according to the type of the implants used, namely the use of radial and axial external fixtures.

The former comprise mainly pairs of intersecting flexible transfixing pins fixed to flat distance rings, which engird the bone and have holes on their periphery, and hard rectilinear carriers - adjustable and one-piece rods keeping two rings at a distance from one another, while in the latter hard implants are used, such as transfixing pins and half-pins, fastened and fixed to a framework of special holders.

There are systems where the two concepts coexist, their mutual advantages being thus combined, for example the radial-axial system of Superfixation. The latter is based mainly upon radial fixation with additional use of hard half-pins, fixed by means of coupling elements to straight carriers mounted on said distance rings. Here, however, the disadvantages of the radial fixation devices have not been avoided, i.e. the heavy, bulky and inconvenient preconfigured construction.

Another modular external fixation system known is the axial-radial system of Orthofix using mainly hard implants. It is build of cylindrical coupling elements and compression-distraction mechanisms directly connected by hinges, the coupling elements being simultaneously implant holders. Flat distance rings for radial fixation with flexible transfixing pins are also used. This modular system is very flexible, but the supporting distance between the implant series is preset and depends upon the length of the distractor. Besides, the use of multiple hinge joints for long distances ensures the system's convenience and safety only when applied in local fractures. The modular elements used are relatively wide in diameter which renders the construction of the device heavier and causes discomfort to the patient.

An extra-focal fixing device for transosteal syndesis in traction and compression is also known to exist for use in orthopedics and traumatology (US 5021054) and it includes rectilinear and curved supporting elements which may be coupled by modular coupling elements that can fix the implants to the framework by means of additional plates with straight knurled clamping surfaces. Regardless to its versatility, the coupling element does not grant stability of the connection but when

the supporting elements have a polyhedral section, without additional protection against slippage, the positioning capacities being thereby reduced. The coupling element is bulky and with a complex and non-technological construction which does not allow the building of simplified versatile devices.

Another system known is the Hoffmann external fixation system created in 1934 and improved in 1968 (4), which in essence is an axial modular system for building of frameworks consisting of supporting and coupling elements. The supporting elements are smooth cylindrical rectilinear and curved rods - one-piece or adjustable. The adjustable supporting elements are compression-distraction mechanisms which may be also monoaxial. A one-piece supporting element curved at angle can be used as well. The construction of the one-piece parts of the supporting elements is not secured against deformability. The coupling elements are two types: 1) for fixing the supporting elements to the frame and 2) universal ball joints to fix the implants to the frame. The coupling elements for fixing the supporting elements consist of two hinged parts having holes whose radius is at least equal to the radius of the supporting element's cross-section. Each part is slitted on one of its ends along the hole, perpendicularly to the hinge's axis, the slitted parts being clamped up by a screw joint at the side of the slitted end, thus fixing the supporting element. This construction allows the coupling, at different angles, of two supporting elements lying in two parallel or perpendicular planes, the two parts being retained by clamping along the axis of the hinge of the osculating surfaces which are riffled. The element is bulky and can couple only two supporting elements. The universal ball joints are prismatic junctions connected by a hinge and at least one junction consists of two parts forming an opening for the supporting elements and having opposite clamping arched areas, the radius of the arc being at least equal to the radius of the supporting elements' section. The fixing of the supporting element into the opening is obtained by using a unilaterally located screw joint, consisting of a screw passing subsequently through threaded holes made into two flat elements in which the parts comprising the clamping opposite arched areas are fixed by a hinge, this screw being fastened with a nut. The axes of the screw joint and the supporting element are situated in two parallel planes, the screw joint's axis being immobile. The implants are fixed by means of another junction of the universal ball joint similarly comprising two clamping surfaces with oppositely disposed arched areas. Here the fixing is obtained by using at least two screw joints whose axes are perpendicular to the plane formed by the axes of the implants. This type universal ball joint allows the building of external fixation devices of various constructions, but regardless to its high flexibility and versatility, this ball joint is too bulky and complicates the frame's construction. Besides, the unilateral clamping of the supporting element leads to the creation of uneven contact forces

which lowers the quality of fixation. The reliability of the joints thus obtained is based uniquely upon the clamping force resulting from the fastening of the screw joint.

Using these elements of the Hoffmann system, frameworks and monofixtures involving the exclusive use of hard implants can be built. On the other hand, the coupling elements secure the joining of two elements whose axes do not lie in the same plane, which in turn reduces the capacities of the system. The absence of a direct link between the supporting elements allowing to fix steadily their disposition at angle to one another so that the axes of two directly connected neighboring elements define one and the same plane also results in lowered flexibility and increased voluminosity of the devices thus built. Moreover, there is no additional protection against slippage.

SUMMARY OF THE INVENTION

A problem of the present invention is to create a modular external fixation system allowing to connect two and more supporting elements of the system so that the axes of all supporting elements in a joint could define one and the same plane.

Another problem which finds a solution is the reduction of the supporting elements in volume and weight by increasing their rigidity.

A problem finding its solution is the improvement of the coupling in terms of reliability by preventing the relative shift between the coupled elements upon fixation, simultaneously obtaining a more regular clamping and an increase of the supporting elements in rigidity.

According to the invention, the problems have been solved by the creation of a modular external fixation system comprising supporting elements with a circular section of $2r$ in diameter - one-piece and adjustable ones, and modular coupling elements with at least one hole into which the end of another coupling element or an implant fixable to the bone is inserted, said system comprising at least one more coupling element which is a flat body with thickness h , and which has holes with a diameter D , greater than the diameter $2r$ of supporting elements.

The supporting elements are one-piece and adjustable. The adjustable supporting elements are monoaxial compression-distraction mechanisms, their ends having a diameter equal to the diameter of the whole supporting elements. The whole parts of the supporting elements can be can be arched. The external surface of the supporting elements is either grooved or riffled or is made of a material with better friction properties. The supporting elements can be pre-strained compound bodies consisting of a tube whose outer surface is grooved and in which a core of an elastic material, softer than the material of the tube, is placed and at least one of the tube's ends is unrolled towards the core. The pre-straining of the supporting elements aimed at increasing their rigidity is obtained by stuffing said core made of a softer

elastic material into the tube by means of pressing, after which the core is submitted to additional radial straining by knurling the external surface of the tube in order to groove it, while the linear straining is obtained by unrolling the tube's ends towards the core of the construction. Thus, the increase of the supporting element in rigidity allows the reduction of its diameter.

The modular external fixation system may comprise at least two supporting elements, whose ends are connected directly by a ball joint, where the radius of the spherical surfaces is R_{sph} , the first spheric part having sharp edges or tips on its surface, while the other spheric surface is smooth and made of a material softer than the material of the first spherical part. The ball joint is fixed with a cover nut mounted on the supporting element with a spherical head, this nut being tightened up on a thread M made on the outer cylindrical surface of the spherical seat. The end of the nut's internal hole opposite to the thread is shaped like a spherical seat with a radius R_{sph} and a centered hole in which an end of a supporting element enters and whose diameter is greater than $2r$ and smaller than the diameter $2R_{sph}$ of the spherical head. On tightening up the cover nut the two spherical parts are pressed to each other, the sharp edges or tips of the first spherical part penetrating into the softer material of the second spherical part, thus providing additional protection against the relative shifting between the parts of the ball joint in case of undesirable external influence.

The modular external fixation system may comprise at least two supporting elements whose ends form a threaded coupling, the first supporting element having one end topped by a thread and the second supporting element having one end topped by a grooved seat.

The modular coupling elements are compound monoaxial bodies, each of them comprising a stepped body, whose axis defines the axis of the modular coupling element, this stepped body having one step with a maximum diameter $d1$ and a length greater than the supporting element's radius r , next to which step, on one side at least, there is a step with a diameter d equal to the diameter d of the flat coupling element's holes at the most and greater than the diameter $2r$ of the supporting elements' cross-section. The length l of the step with a diameter d is smaller than the thickness h of the flat coupling element and is at least equal to the radius r of the supporting elements' cross-section. This step ends with an extremity with a thread $M1$, whose outer diameter is equal to the diameter d at the most. Perpendicularly to the stepped body's axis, there is a hole, whose axis form one and the same plane with the axis of the stepped body, the diameter of this hole being at least equal to the diameter $2r$ of the supporting elements, so that the surface perpendicular to the stepped body's axis and forming the fore-part of the step with the greatest diameter $d1$ passes through the hole. A ring-shaped body made of a material softer than that

of the stepped body is mounted on the step with a diameter d , the height of the ring being greater than the length l of the step with a diameter d . On one of the front surfaces at least, there are two opposite arched co-axial cuts in the form of segments on the outer surface of the ring, the radius of the arc being at least equal to the radius of the hole cut into the stepped body and the height of the segment being smaller than the radius of the arc. The stepped and the ring-shaped bodies are fixed to each other with a clamping nut, tightened up on the extremity with a thread $M1$ of the stepped body, so that if there is a supporting element mounted in the hole of the stepped body, the arched cuts on the ring-shaped body press this supporting element to the wall of the stepped body's hole. Besides, the ring-shaped body's soft material penetrates into the ripples on the supporting element's surface, contributing thus additionally to avoid the relative shifting of the supporting element to the coupling element.

It is possible to divide the step with the greatest diameter $d1$ into two parts, connected by a piece with a smaller diameter.

By the modular coupling element intended to connect supporting elements, on the other side of the step with a greatest diameter $d1$ of the stepped body, there is a symmetric step with a diameter d and a length l having an extremity ending with a thread $M1$, a hole being pierced therein whose diameter is equal to $2r$ at least and whose axis is parallel, perpendicular or at angle to the axis of the first hole and perpendicular to the stepped body's axis. Another ring-shaped body with arched slits is mounted on the second step with a diameter d and is fixed with a clamping nut.

By the modular element pin strainer intended to fix and strain flexible transfixing pins, on the other side of the stepped body's step with a greatest diameter $d1$, a step is made, with a diameter at least equal to the diameter d and a length l , having along its periphery a slot whose width is at least equal to the implanted pin's diameter, this slot being perpendicular to the stepped body's axis, its own axis being at a distance a from the forepart of the step with a greatest diameter $d1$. This step in turn has an extremity ending with a thread $M1$. A pin guide, which is a body with central axial symmetry and a hole whose diameter is at least equal to the diameter of the peripherally slotted step and whose length is at least equal to the length of the peripherally slotted step, is mounted on it. The hole with a smaller diameter has a diameter equal or greater than the outer diameter of the stepped body's thread $M1$. The periphery of a fixation pin guide is cut by a slit forming a plane perpendicular to the central axis. The slit's width is equal or greater than the width of the stepped body's peripheral slot and the plane passing through its middle is at a distance from the forepart of the end with the wider hole, which distance is at the most equal to the distance a from the stepped body. Two holes with a diameter at least equal to the implanted pin's diameter and with axes lying on the plane which passes through the

middle of the slit are pierced into the thick part of the periphery. The fixation pin guide is retained by a nut tightened on the thread $M1$ of the stepped body

By the modular coupling element intended to connect the device to hard implants, on the other side of the stepped body's step with a greatest diameter $d1$, a step is made whose diameter is equal to the outer diameter of the thread $M1$ and on which the implants' holders are mounted. This step has a length that the most equal to the thickness of the implants' holders. These are two flat collars with a central hole whose diameter is at least equal to the outer diameter of the thread $M1$, one front of each collar bearing arched slots by the sides of the central hole into which slots the implants are inserted. The position of the flat collars is fixed by a nut tightened on a thread $M1$ cut on the end of the step on which the collars are mounted. This make of the hard implants' holders allows to adjust the construction thus built to the implants by revolving the flat collars around the element's axis and, in particular, to the hole intended for a supporting element to pass through.

According to the invention, the modular external fixation system allows the building of a variety of external fixation devices and grants the applicability of the traumatologic ophthopaedist's approach in all types of local and general traumae of the locomotory system by using coupling elements and elements securing both the spatial and plane disposition of the system's component elements with no limitations as far as repositioning of the device is concerned. The system allows to construct lighter and more reliable modular external fixation devices using all types of implants by increasing the moment of friction where the supporting elements are fixed and by improving the way to fasten and fix the implants to the coupling elements. The use of a set of standardized modular coupling elements increases the system's universality and reduces its price.

The reduced volume of the modular coupling elements renders the system more compact and the devices built therewith are lighter and more convenient to the patient. Making the coupling elements of materials of various rigidity leads to manifold higher reliability providing additional protection against slippage.

DESCRIPTION OF THE DRAWINGS

Examples are given in the description below to illustrate the drawings enclosed herein where:

Figure 1 represents a longitudinal section of a supporting element's one-piece part;

Figure 2 represents a view of different embodiments of one-piece supporting elements;

Figure 3 shows an adjustable supporting element representing a compression-distraction mechanism;

Figure 4 represents a plan view and a side section of a flat coupling element;

Figure 5 shows a supporting element with a grooved spherical head;

Figure 6 represents a magnified partial view of a grooved spherical head.

Figure 7 shows a supporting element with a spherical seat;

Figure 8 represents a section of a supporting element with a two-piece smooth spherical head;

Figure 9 represents a section of a supporting element with a grooved spherical seat;

Figure 10 represents a section of a ball joint between two supporting elements;

Figure 11 represents a section of a threaded coupling between two supporting elements;

Figure 12 represents a disassembled modular coupling element for supporting elements;

Figure 13 represents a section of a variation of a ring-shaped body with stepped central hole;

Figure 14 represents a section of a modular coupling element for supporting elements with parallel holes;

Figure 15 represents a section of a modular coupling element for supporting elements with perpendicular holes;

Figure 16 shows an embodiment of a modular coupling element for supporting elements with a two-part step with a greatest diameter $d1$;

Figure 17 represent a half-section/half-view of an embodiment of a modular coupling element - pin strainer;

Figure 18 shows a pin strainer's stepped body; Figure 19 represents a longitudinal section of affixation pin guide;

Figure 20 represents a cross-section through the fixation pin guide's slit and holes;

Figure 21 represents a longitudinal section of a modular of a modular coupling element - pin holder;

Figure 22 represents half-section/half-view of an embodiment of a modular coupling element-screw holder;

Figure 23 represents a plan view of a flat coupling element with coupling and supporting elements mounted;

Figure 24 represents a side view of a flat coupling element with modular coupling elements mounted;

Figure 25 shows parallel coupling of supporting elements using a modular coupling element;

Figure 26 represents a cross-section of a modular coupling element - pin strainer with a transfixing pin mounted;

Figure 27 represents a modular coupling element pin holder with pins mounted and axonometry of a supporting element;

Figure 28 shows a model device applied in a treatment for fracture in the area of the ankle-joint and the foot;

Figure 29 shows the device from Figure 28 used as a dynamic ligamentotaxis.

PREFERRED EMBODIMENTS

As seen in Figures 1-22, the modular external fixation system according to the invention comprises the following basic component elements: supporting elements 1 with one-piece parts 2 and adjustable supporting elements 3, a flat coupling element 4, a modular coupling element for supporting elements 5, a modular coupling element - a pin strainer 6, a modular coupling element for hard implants 7, a ball joint 8, and a threaded coupling 9 for supporting elements 1.

The adjustable supporting elements 3 in Figure 3 are monoaxial compression-distraction mechanisms which can be implemented as a dynamic construction. The one-piece parts 2 of the supporting elements 1 can be (see Figure 3): rectilinear, curved at angle, in particular L-shaped 10 or arched 11. They consist of (see Figure 1): a cylindrical tube 12 with an outer diameter $2r$ and with riffls 13 on its surface, a core 14 made of a soft elastic material, for example duralumin being stuck into said tube 12 made of a hard material, for example chrome-nickel steel and at least one end 15 of said tube 12 is unrolled towards said core 14.

Figures 5-10 show the ball joint 8 and its different parts. The one-piece part 2 of the supporting element 1 in Figure 5 has on one of its ends a spherical head 16 with a radius R_{sph} and at least 1/3 of the spheric surface has grooves 17 with sharp edges 18 (Figure 6). The spherical head 16 is made of a hard material, for example chrome-nickel steel. In an embodiment not shown on the drawings, diamond crystals forming sharp tips can be stuck into the spheric head's material. In Figure 7, the one-piece part 2 of the supporting element 1 ends by a spherical seat 19 with a radius R_{sph} , said seat being made of a soft material, for example duralumin. A thread M is cut on the outer cylindrical surface of said spherical seat. In one possible embodiment, unshown in the Figures, the spheric seat is a grip.

Another embodiment of the ball joint's 8 components is shown in Figures 8 and 9. Here, the spherical head is made of two parts: a base 20 made of a hard material, for example steel, said base being a hemisphere with a centered hole 21 into which an end 20 of a supporting element 1 is fastened. The end 2 is topped with a thread 22 which protrudes out of the plane separating surface 23 of said base 20 and is fastened into a blind hole 24 of the upper hemisphere 25 made of a soft material, for

example plastic. A slot 27, concentric to the spherical head's axis 26, is cut into said flat separating surface 23 of said base 20 and a ledge 28 of the hemisphere 25 having the shape and dimensions of the slot 27 is inserted into said slot. The spherical seat 29, made of a hard material, for example steel, has grooves 17 with sharp edges 18 and a thread M is cut into its outer cylindrical surface. A releasing slit 30 is cut into the spherical seat bottom. A pin 31 may be additionally inserted to prevent an undesirable rotation round the axis 26. In another embodiment, unshown on the drawings, the separating surface 23 of the base 20 is part of another sphere whose radius is greater than R_{sph} , the corresponding surface of the upper hemisphere 25 being a negative image of said separating surface 23 of said base 20. Reduction of the devices in weight and cost is achieved in the embodiments shown in Figures 8 and 9. Moreover, the spherical head's making of a soft material results in a manifold increase of the spherical seat in durability, said spherical seat being made here of a harder material. i.e. a possibility of a multiple use of the metal part is thus created. The fixing of the ball joint 8 is shown in Figure 10, a grooved spherical head and a smooth spherical seat being given as an example thereof. Similarly, there is a fixing involving a smooth compound spherical head and a grooved spherical seat. The spherical head 16 is mounted into the spherical seat 19 and is tightened to the supporting element 1 by a cover nut 33 passing through the one-piece part 2 of said supporting element 1. The cover nut 33 has an inner thread M on one of its ends while the other end is shaped as a spherical seat 34 with a radius R_{sph} and having a centered hole 35, whose radius is greater than the radius r of the section of the one-piece parts 2 of the supporting elements 1 and smaller than the radius R_{sph} of the spheric head 16. The length of the thread M is at the most equal to $1/2$ of the height of said cover nut 33.

In the threaded coupling 9, one end 2 of a supporting element 1 is topped by a thread $M2$, while one end 2 of another supporting element 1 is topped with a threaded seat 36. In another embodiment, the outer diameter of the thread $M2$ may be equal to the diameter $2r$ of the one-piece parts 2 and the supporting elements 1.

The flat coupling element 4 has a thickness h and holes with a diameter D , greater than the diameter $2r$ of supporting elements 1, located on concentric circumferences with diameters D_i , which centre with said flat coupling element 4. A preferred embodiment is shown in Figure 4 where the flat coupling element 4 is a flat ring having holes 37 with a diameter D , located on a circumference whose diameter D_i is the mean diameter of the ring's hole inner diameter and its outer diameter.

Each modular coupling element 5 for supporting elements shown in Figures 12-16 is a cylindrical junction and includes a stepped cylindrical body 38 which has at least one step 39 with a greatest diameter $d1$ and a length greater than $2r$, said step having bilateral symmetric steps 40 with a diameter d and a length l . The diameter d

is selected to secure free slipping upon mounting the step 40 into the hole 37 of the flat coupling element 4. The length l of said step 40 is smaller than the thickness h of the flat coupling element 4 and is at least equal to the radius r of the cross-section of the supporting elements 1. Each step 40 ends by a thread M whose outer diameter is at the most equal to the diameter d . Perpendicularly to the axis of the stepped body 38, holes 41 are pierced having a diameter selected to allow free movement of the one-piece parts 2 with a diameter $2r$ of the supporting elements 1. The surfaces perpendicular to the axis 42 of the stepped body 38 and shaping the fronts of the step 39 with a greatest diameter pass through one of the diameters of each hole 41. The axes of the two holes 41 may be parallel (Figure 14), perpendicular (Figure 15), or at angle to each other. The diameter of the step 40 is greater than the diameter of the hole 41 so that supporting walls 43 are formed on the step 40. The stepped body is made of a hard material, for example chrome-nickel steel. Figure 16 shows a variation of a modular coupling element 5 for supporting elements where the step 39 with a diameter d is divided into two parts fixed together by a cylindrical piece 44 with a smaller diameter which for example may be equal to the diameter $2r$ of the one-piece parts 2 of the supporting elements 1. Ring-shaped bodies 45 are mounted on both steps 40 of the stepped body 38, the height of the ring being greater than the length l of the step 40 with a diameter d and their outer diameter being equal to the diameter $d1$ of the step 39, while their inner diameter is at least equal to the diameter d of the step 40. At least one of the front surfaces of each ring-shaped body bears two opposite arched co-axial slits 46 in the form of segments of the ring's cylindrical surface, the diameter of the arc being at least equal to the radius r of the cross-section of the one-piece parts 2 of the supporting elements 1 and the segment's height being smaller than the arc's radius. The ring-shaped body is made of a soft material, for example duralumin. Figure 13 shows a variation of a ring-shaped body where the inner hole is stepped and the hole with a smaller diameter has a diameter smaller than the diameter d of the step 40, while the hole with a greater diameter has a diameter at least equal to the diameter d of the step 40 and a length greater of equal to the length of said step 40. The ring-shaped body 45 is fixed to the stepped body 38 by a nut 49, tightened on the end with a thread M .

The modular coupling element - pin strainer 6 shown in Figure 17 is a compound body comprising a stepped body 50, a ring-shaped body 45, a fixation pin guide 51, and two clamping nuts 49. The stepped body 50 made of a hard material, for example chrome-nickel steel, has one step 39 with a greatest diameter also $d1$. One of the ends by the step 39 with a diameter $d1$ is shaped for a supporting element with a step 40 having a diameter d and a hole 41 to be fixed therein. The other end after the step with a diameter $d1$ has a step 52 with a diameter at least equal to the diameter d into whose periphery a slot 53 is cut, its width being at least equal to the

diameter of the flexible transfixing pin, said slot being perpendicular to the axis of the stepped body 50 and at a distance a from the front of the step 39 with a greatest diameter. The step 39 with a greatest diameter $d1$ has here a length greater than the radius of the hole 41. The stepped body 50 has a thread $M1$ at each of its two ends. The step 39 may be divided into two parts fixed together by a cylindrical piece with a smaller diameter. On the step 52, a fixation pin guide 51 is mounted, said fixation pin guide being a prismatic body with a stepped centered hole 54, whose greater diameter is equal or greater than the diameter of the step 52, while the length of the hole with a greater diameter is at least equal to the length of the step 52. The hole with a smaller diameter has a diameter equal to or greater than the outer diameter of the thread $M1$. The periphery of the fixation guide pin 52 is slitted up to the central axis at the most, this slit 55 having a width equal to or greater than the width of the slot 53 on the stepped body 50. The separating surface of the slit 55 is perpendicular to the axis 56 of the fixation pin guide 51 and is at a distance equal to or shorter than the distance a . In the thick area of the periphery of the fixation pin guide 51, symmetrically to the plane dividing the slit and the thick area, two parallel holes 57 are pierced, their diameter corresponding to the diameter of the implanted pin and their axes lying in the separating surface of the slit 55, the distance between said holes 57 being at least equal to the greater radius of the stepped hole 54. The fixation pin guide 51 is fixed with a nut 49 to the stepped body 50. Said pin guide is made of a hard material, for example chrome-nickel steel.

The modular coupling element 7 for hard implants (Figures 21 and 22) also comprises a stepped body 58, a ring-shaped body 45 and clamping nuts 49 in addition to two clamping collars 59. The stepped body 58 is also made of a hard material, steel for example, and has a step 39 with a greatest diameter $d1$. One of the ends is shaped as an end for a supporting element to be fixed thereinto through a step 40 on which a ring-shaped body 45 is mounted ending with another step with a thread $M1$ on which a clamping nut 49 is tightened and whose hole is perpendicular to the axis and has a diameter at least equal to the diameter $2r$ of the cross-section of the one piece parts 2 of the supporting elements. Here again the step 39 with a greatest diameter $d1$ has a length greater than the radius of the hole 41. The other end, posterior to the step, is shaped as a step 60 with a diameter at least equal to the outer diameter of the thread $M1$, which has a smooth cylindrical section whose length is equal to or smaller than the thickness of two clamping collars 59, and ends with a thread $M1$. The clamping collars 59 are made of an insulator and represent flat round bodies with a centered hole into which the step 60 is inserted, the opposite fronts of each clamping collar 59 bearing arched slots 61, symmetric to the centered hole's axis and at a distance b from each other, the arc's radius being equal to the radius of the implants and said clamping collars' height being smaller than the arc's

radius. The clamping collars are fixed with a clamping nut 49, tightened on the thread **M1**. Here again a variation is possible where the step 39 is divided into two parts. Figure 22 shows a variation of a modular coupling element 7 for hard implants with a prolonged step 39, where the end intended for the fixing of the clamping collars 59 of said prolonged step 39 and one of the clamping nut's 49 ends are shaped as supporting steps 62 with an outer diameter equal to the outer diameter of the clamping collars 59.

The embodiments thus suggested according to the invention are not limited as to the scope of the inventive concept. For instance, the system's component elements may be made of material other than metals, e.g. material permeable to X-rays and other kinds of rays. Also the component elements of the modular coupling elements may be shaped as a polyhedral prism whose circumscribed cylinder has a cross-section diameter **d1**.

USING OF THE INVENTION

Figures 23 and 24 show couplings of the system's elements where the axes of two or more elements 1 lay in one or more parallel planes. Modular coupling elements 5 for supporting elements are mounted to the flat coupling element 4 by inserting the steps 40 of the modular coupling elements 55 into the holes 37 of the flat coupling element 4 and fixing them with a nut 49. The one-piece parts 2 of supporting elements 1 are fixed into holes 41 on the other end of the elements 5 by means of nuts 49. In this fixing, the ruffles 13 of the supporting element 1 penetrate into the material of the ring-shaped bodies 45 and thus provide additional protection of the system against slippage. The position of the supporting elements 1 is adjusted by loosening nuts 49, orientation in the desired direction, and subsequent tightening of nuts 49.

The spatial position of the axes of the supporting elements 2 and 3 in Figure 10 is adjusted by tightening the cover nut 33 after orientation in the desired direction. The grooves or tips on the spherical part made of a hard material penetrate into the soft material of the other spherical part, the contact surface being thus increased and hence additional protection against slippage being secured.

The supporting elements shown in Figure 25 are fixed by tightening of nuts 49 and clamping the ring-chapped bodies 45 to the supporting elements 1. Thereby, the ruffles 13 of the supporting elements 1 penetrate into the material of the ring shaped bodies 45 to prevent slippage.

Figure 26 shows a modular coupling element - pin strainer 6 on which a modular pin 63 is mounted, the end 64 of the transfixing pin 63 being passed through the inner end of the first hole 57 so that it passes through the slit 55 of the fixation pin guide 51 and enters the second hole 57 through its outer end. The straining of the

transfixing pin 63 is adjustable by turning the fixation pin guide 51 in a counter-clockwise direction, in this instance, and fixing it subsequently by means of a nut 49.

The hard implant 65 in Figure 27 are mounted to the module 7 by clamping into the arched slots 61 of the clamping collars 59 by tightening a nut 49. The position of the hard implants 65 to the axis of said module 7 can be adjusted by rotation of the clamping collars 59 round this axis. the supporting element 1 is mounted into the hole 41 of the stepped body 58 and is fixed with a nut 49, so that the supporting element's riffles penetrate the material of the ring-shaped body 45 and secure the elements against mutual slippage.

The modular external fixation system proposed can be used in a flexible building of various devices for osteosynthesis, the three-support device shown in Figures 28 and 29 for treating ankle and foot fractures being given only as an example to illustrate the capacities of the modular system.

Using the fixing shown in Figure 28 where the adjustable supporting elements 3 are fastened to the flat coupling element 4, a treatment can be performed in traumatology for a malleolar, talar or calcaneal fracture of the heel and their combination by ligamentotaxis which may be also a dynamic one throughout the different phases of the treatment, as shown in Figure 29.

In the device shown hard implants defining three points of support below the fracture streaks are used. The implants are connected by modular coupling elements 7 to supporting elements, all or part of them adjustable in the form of compression-distraction mechanisms, a dosed traction along the arms being eventually performed throughout the phases of the treatment for diastasis of the ankle-joint. Here, the flat coupling element plays the role of an artificial joint bearing the burden created. By loosening the clamping nuts of the modular coupling elements 7, the optimum position for adjustment is selected by prolonging the appropriate arm formed by the supporting element.

CLAIMS

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1. A modular external fixation system comprising supporting elements with circular cross-sections with diameters $2r$ - one-piece and adjustable, wherein the one-piece supporting elements may be rectilinear and curved, furthermore comprising modular coupling elements having at least one hole into which a supporting element's end is inserted and at least one second hole into which an end of another supporting element or implant fixable to the bone is inserted, said modular coupling elements' holes into which said supporting elements' ends are inserted containing clamping arched areas, the arc's radius being at least equal to the radius r of the supporting elements' cross-section, while the holes into which the implants are inserted have two clamping surfaces comprising opposite arched areas the arc's radius corresponding to the implant's cross-section radius, said modular coupling elements comprising a screw joint for loosening and tightening of the supporting elements and the implants between the clamping surfaces of the modular coupling elements, said system being **characterized** by its comprising of at least two supporting elements whose ends are suitable for direct connection by a ball joint comprising two spherical parts - a spherical head and a spherical seat both with a radius R_{sph} , one of the parts being made of a harder material and bearing sharp edges or tips on its spherical surface and the other one having a smooth spherical surface and bearing a cover nut with an inner thread on one end which is tightened on a thread M cut into the outer cylindrical surface of the spherical seat, while the other end of the nut is shaped as a diameter greater than the diameter $2r$ of the supporting elements' cross-section and smaller than the diameter $2R_{sph}$ of the spheric head and/or the end of at least two supporting elements form a thread joint, where the first supporting element has a threaded stem and the second supporting elements has a threaded seat and/or the continuous parts of the supporting elements have an outer diameter $2r$, their outer surface being rifflled, where at said supporting elements being possibly strained compound cylindrical bodies, and said system comprise at least one modular coupling element for supporting elements, at least one modular coupling element-pin strainer and at least one modular coupling element for hard implants, as each modular coupling element is symmetric to a longitudinal axis where as the holes whereinto ends of supporting elements or implants are inserted are at least one and are perpendicular to the axis, and each modular coupling element comprising a stepped body whose axis coincides with said axis, at least one step having a diameter d and a length l , as the diameter d is greater than the diameter $2r$ of the supporting elements, into which step a part of at least one hole lies, said hole being pierced into the stepped body and having a diameter at least equal to the diameter $2r$ of the supporting element, while at least one clamping surface of the modular coupling element's holes, whereinto ends of supporting elements are inserted, is made of a material softer than the material of the other clamping surface, and furthermore the

screw joint for loosening and tightening the supporting elements and the implants is located on the modular coupling element's axis, as said axis and the axis of the coupled supporting element defining one and the same plane, whereby there is at least one more coupling element which is a flat body with a thickness h and holes on having a diameter D at least equal to the diameter d , of the step of the modular coupling element's stepped body, while the thickness h is greater than the length l of the step with a diameter d of the modular coupling element's stepped body.

2. A modular external fixation system, according to Claim 1, **characterized** by the fact that the coupling element is a flat ring bearing holes with a diameter D , located on concentric circumference.

3. A modular external fixation system, according to Claims 1 and 2, **characterized** by the fact that the spherical head is made of two parts fastened to one another and made of materials of various rigidity, the material of the upper hemisphere being softer than the material of the spherical head's base and the material of the spherical seat, as the spherical surface of said spherical seat having sharp-edged grooves or sharp tips.

4. A modular external fixation system, according to Claims 1, 2, and 3, **characterized** by the fact that the spherical seat is a grip.

5. A modular external fixation system according to Claims 1, 2, 3 and 4, **characterized** by its being a tube with an inner diameter d_1 whereinto a core made of elastic material is inserted, said core filling the tube, the walls of said tube being unrolled towards the core at least at one end, as the outer surface of the tube being riffled and the material of said tube having a greater rigidity than the core's material.

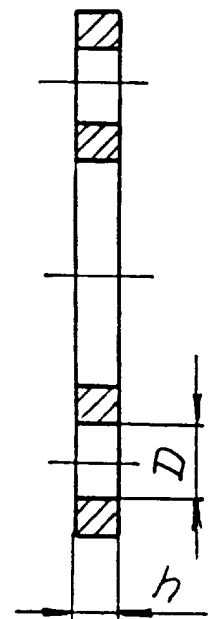
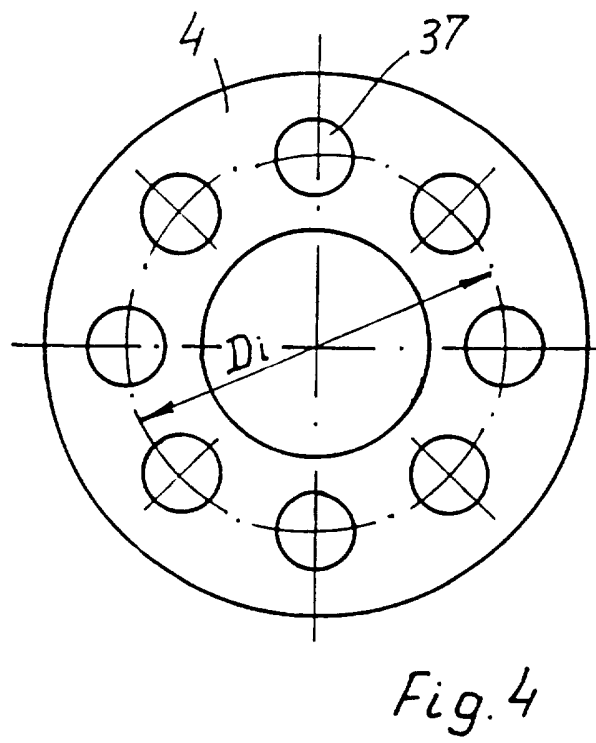
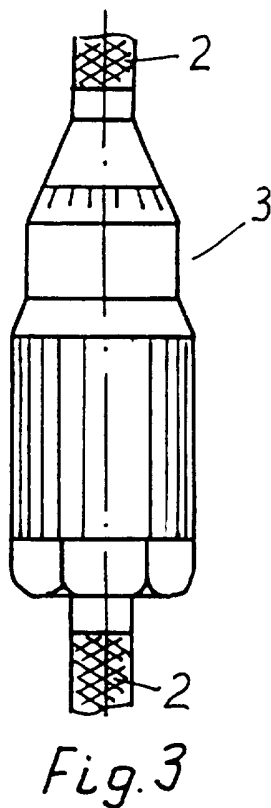
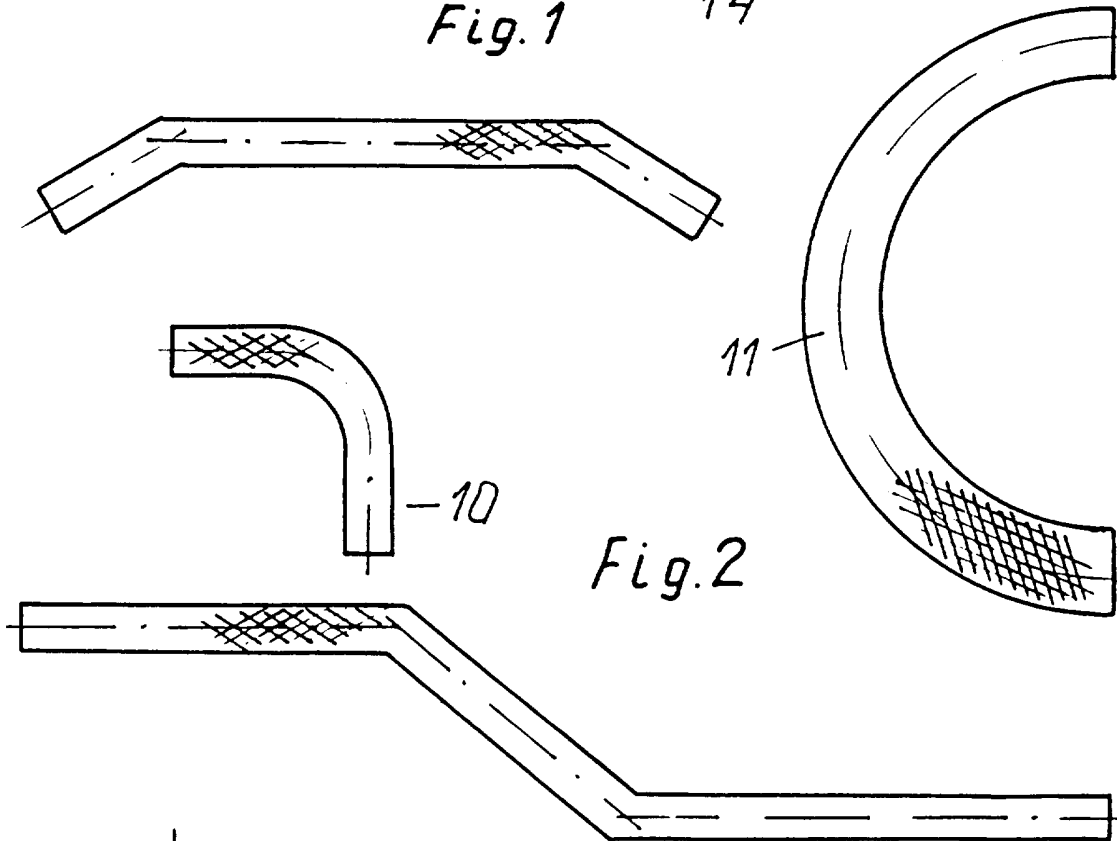
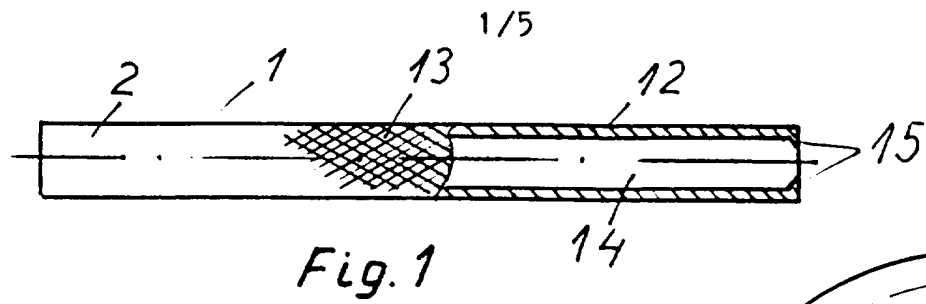
6. A modular external fixation system according to Claims 1 to 5, **characterized** by the fact that a modular coupling element for supporting elements has a central stepped body comprising a step which has a greater diameter d_1 and is located in the middle and/or has a central stepped body comprising two steps with a greater diameter d_1 fixed together by a cylindrical piece whose diameter is smaller than the diameter d_1 , other steps with a diameter d and a length l being made on both sides, part of each other step with a diameter d has a hole pierced perpendicularly to the stepped body's axis and whose diameter is at least equal to $2r$ and smaller than the diameter d , so that the supported walls are for mad on the step with a diameter d , as the axes of said holes being parallel or intersectional in space, said stepped body's ends being threaded, said thread M_1 having an outer diameter

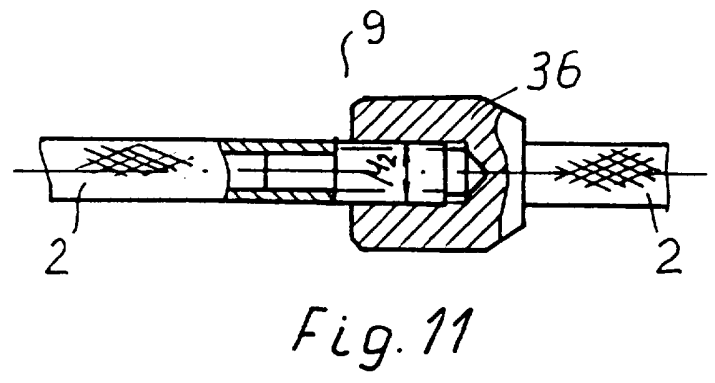
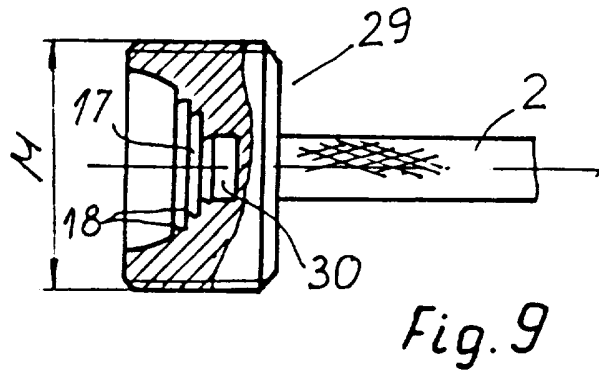
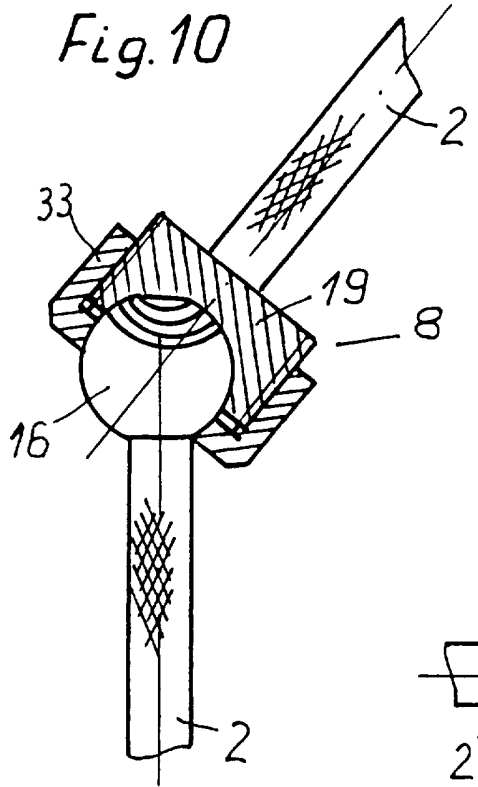
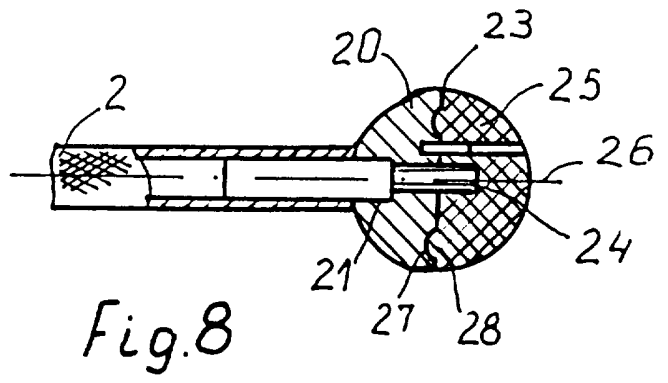
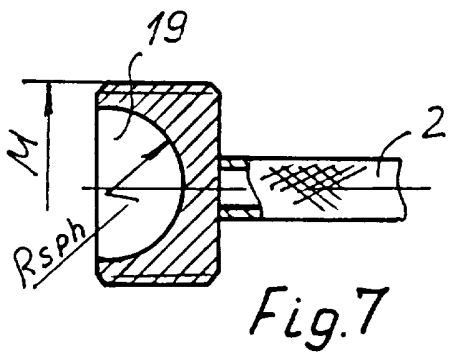
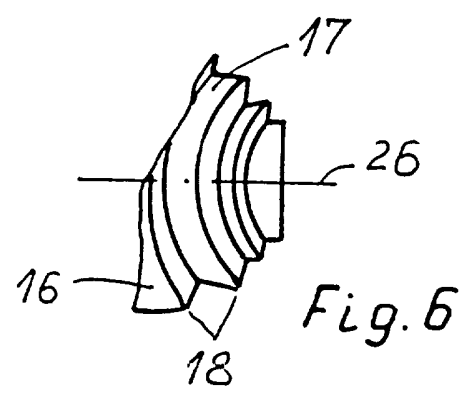
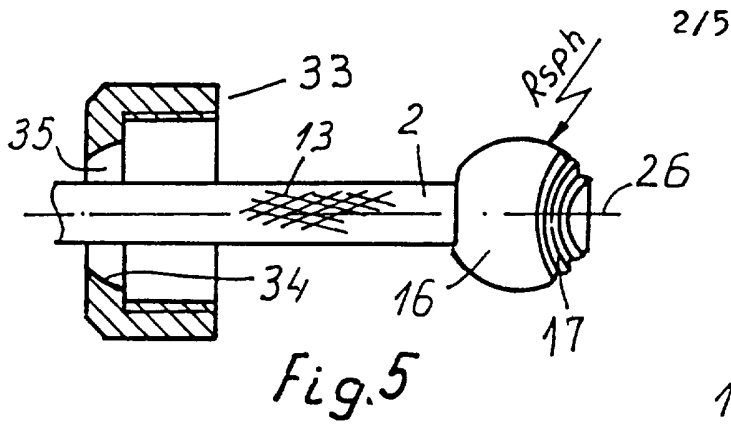
at least equal to the diameter d of the steps, whereby ring-shaped bodies are mounted on the stepped body, said ring-shaped bodies being made of a material softer than that of the stepped body and, the height of the ring being greater than the length l , at that at least one front surface of each ring-shaped body has to opposite co-axial arched slits in the form of segments of the ring's cylindrical surface, the arc's radius being at least equal to the radius r of the holes and the height of the segment being smaller than the radius r of the segment's arc, said ring-shaped bodies being fixed to said stepped body by nuts tightened on the thread $M1$ on the stepped body's ends.

7. A modular external fixation system, according to Claims 1 to 6, **characterized** by fact that a modular coupling element - pin strainer has a central stepped body comprising a step which has a greater diameter $d1$ and is located in the middle and/or by having a central stepped body comprising two steps with a greater diameter $d1$ fixed together by a cylindrical piece whose diameter is smaller than the diameter $d1$, as a step with a diameter d and a length l being made on one side of the step with a diameter $d1$, whereat a hole being pierced perpendicularly to the stepped body's axis, on the steps with diameters d and $d1$, its diameter being at least equal to $2r$ and smaller than the diameter d , and after the step with a diameter d an end with a thread $M1$ is made whose diameter is at the most equal to the diameter d , at that a ring-shaped body being mounted on said step with a diameter d , said ring-shaped body being made of a material softer than the stepped body's material, and the ring's height being greater than the length l , as at least one of the ring-shaped body's front surfaces having two opposite co-axial arched slits in the form of segments of the ring's cylindrical surface, the arc's radius being at least equal to the holes' radius r and the segment's height being smaller than the radius r , said ring-shaped body being fixed to the stepped body by a nut tightened on the thread $M1$, while the other end after the step with a diameter $d1$ has a step whose diameter is at least equal to the diameter d and whose periphery has a slot with a width at least equal to the transfixing pin's diameter, said slot being located perpendicularly to the stepped body's axis at a distance a from the front of the step with a greater diameter $d1$, said step ending with a thread $M1$ and bearing a fixation pin guide mounted on it, said fixation pin guide being a body which is symmetrical to a central axis and has a centered stepped hole whose greater diameter is at least equal to the diameter of the peripherally slotted step and the depth of this greater hole is at least equal to the length, of the peripherally slotted step, as the periphery of the fixation pin guide having a slit which forms a plane perpendicular to the central axis and having a width at least equal to the width of the stepped body's peripheral slot, said slit being at a distance a from the front of the fixation pin guide, as two holes being pierced into the

thick area against the slit and their diameter being at least equal to the implanted pin's diameter and their axes lying in the plane which passes through the middle of the slit, the fixation pin guide being retained by a nut tightened on the thread **M1** of the stepped body.

8. A modular external fixation system **characterized** by the fact that a modular coupling element for hard implants has a central stepped body comprising a step which has a greater diameter **d1** and is located in the middle and/or by having a central stepped body comprising two steps with a greater diameter **d1** fixed together by a cylindrical piece whose diameter is smaller than the diameter **d1**, as a step with a diameter **d** and a length **l** being made on one side of the step with a diameter **d1**, and a hole being pierced perpendicularly to the stepped body's axis on the steps with diameters **d** and **d1**, its diameter being at least equal to **2r** and smaller than the diameter **d**, as after the step with a diameter **d** an end with a thread **M1** is made whose diameter is at the most equal to the diameter **d**, whereat a ring-shaped body being mounted on said step with a diameter **d**, said ring-shaped body being made of a material softer than the stepped body's material, the ring's height being greater than the length **l**, as at least one of the ring-shaped body's front surfaces having two opposite co-axial arched slits in the form of segments of the ring's cylindrical surface, the arc's radius being at least equal to the holes' radius **r** and the segment's height being smaller than the radius **r**, at that said ring-shaped body being fixed to the stepped body by a nut tightened on the thread **M1**, while at the other end after the step with a greatest diameter **d1** a step is made whose diameter is at least equal to the outer diameter of the thread **M1**, on which step implant holders are mounted, said implant holders being two flat collars with a centered hole each, the front of each collar having arched slots by the central hole, into which slots the implants are inserted, and the position of the flat collars being fixed by a nut tightened on a thread **M1** cut into the step's end.





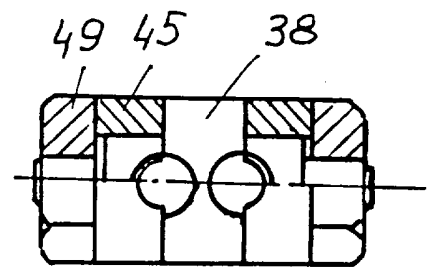
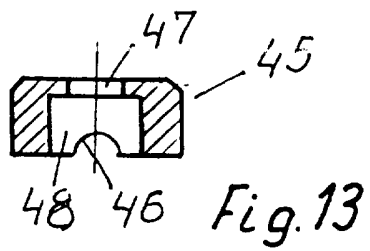
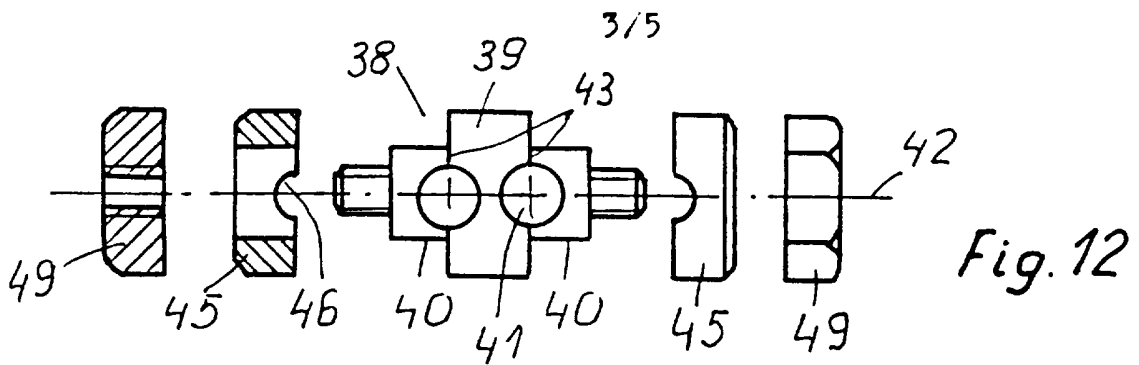


Fig. 14

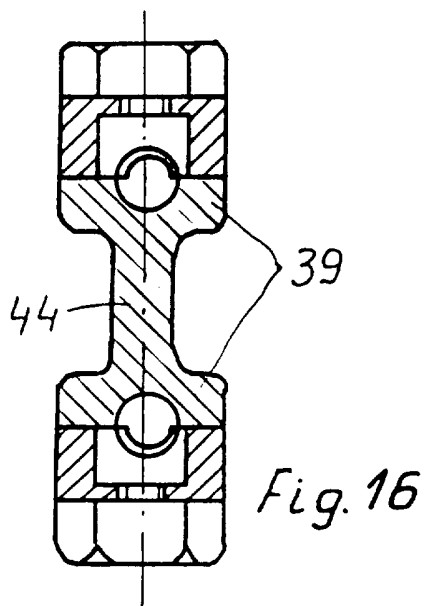


Fig. 16

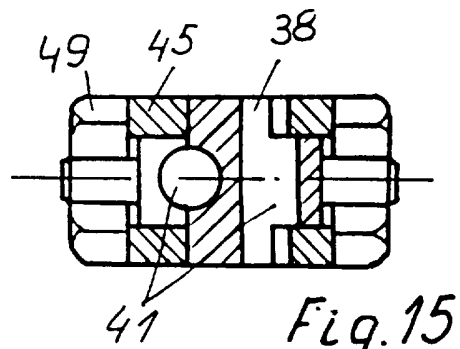


Fig. 15

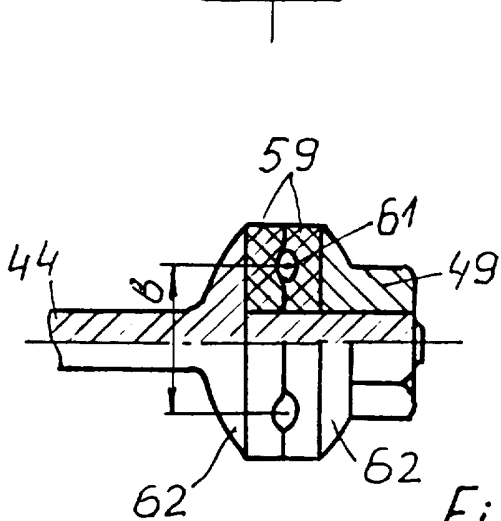


Fig. 22

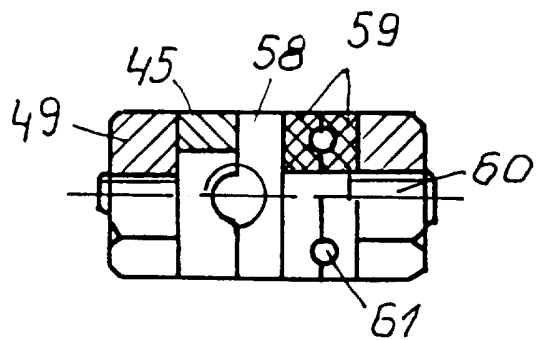


Fig. 21

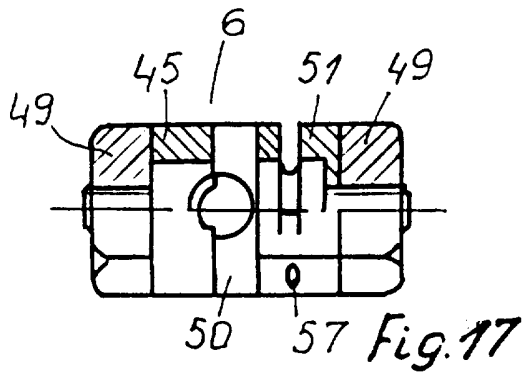


Fig. 18

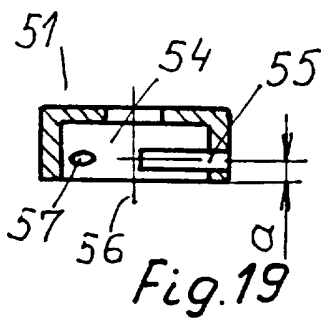
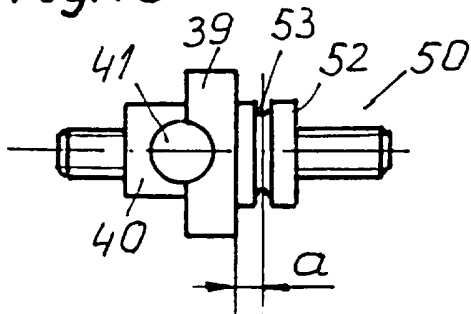


Fig. 19

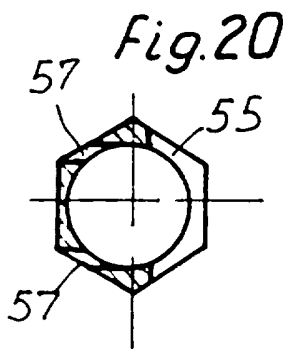


Fig. 20

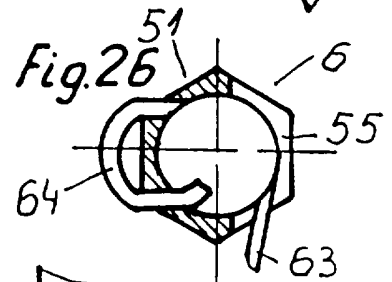


Fig. 26

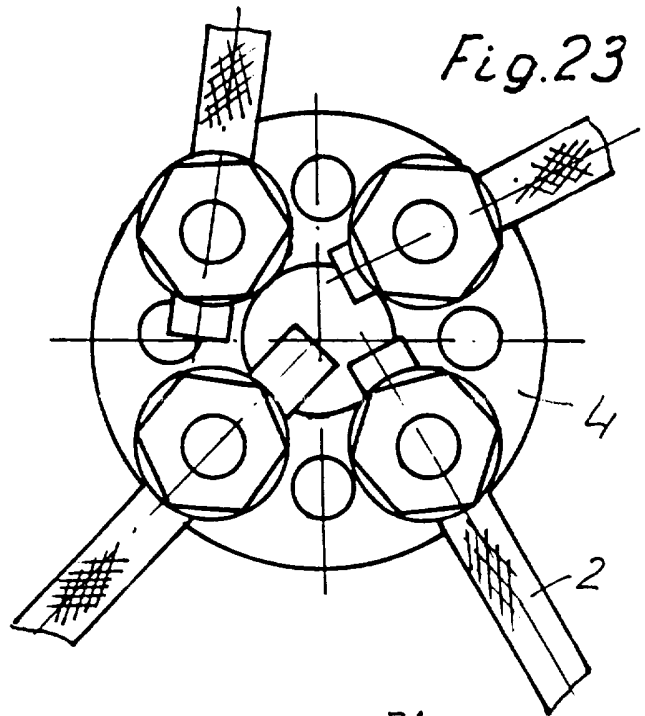


Fig. 23

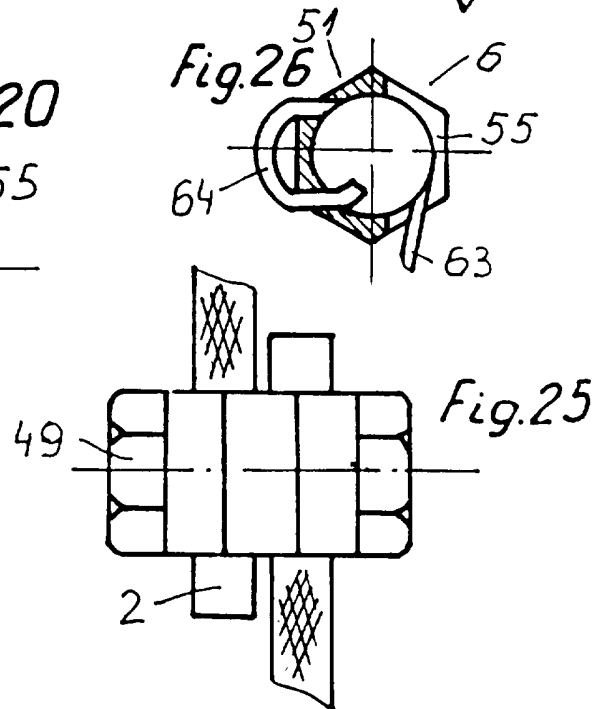


Fig. 25

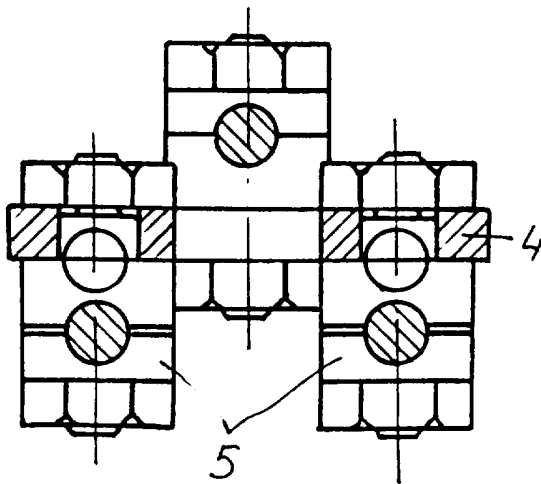


Fig. 24

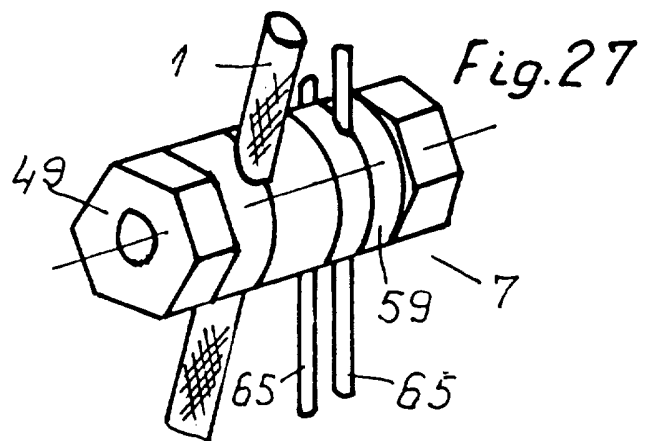


Fig. 27

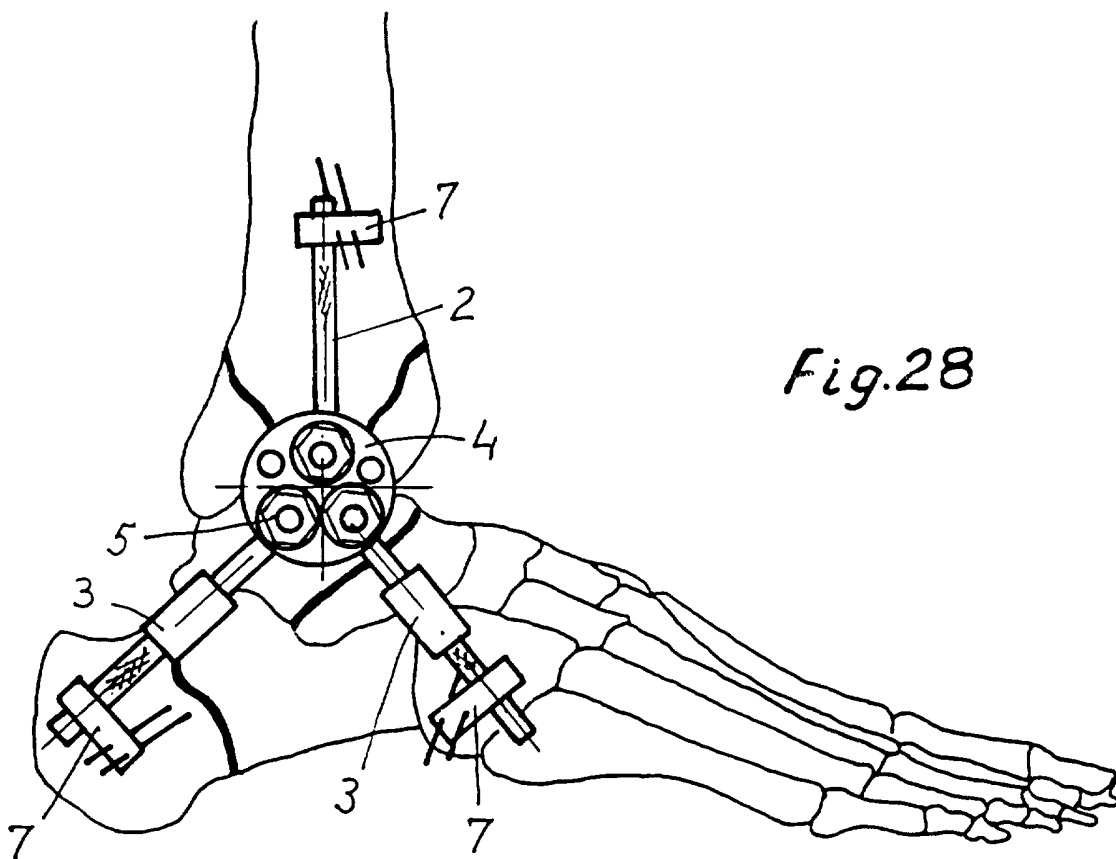


Fig.28

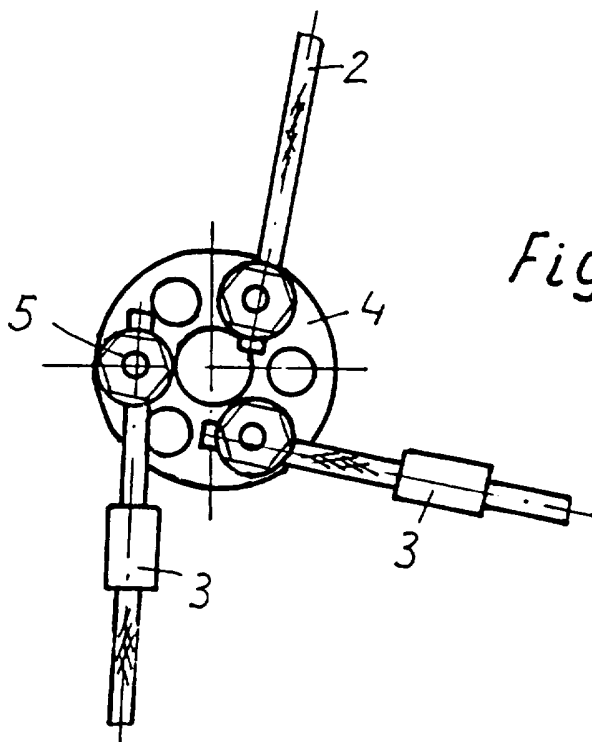


Fig.29

INTERNATIONAL SEARCH REPORT

Inter. Application No

PCT/BG 95/00010

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61B17/64 A61B17/60

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.
A	WO,A,92 12683 (CONFIDA) 6 August 1992 see abstract; figure 2 ---	1,8
A	EP,A,0 380 674 (VSESOYUZNY KURGANSKY NAUCHNY TSENTR) 8 August 1990 see abstract; figure 2 ---	1,8
A	EP,A,0 140 786 (SOREM) 8 May 1985 see abstract; figures 8,9 ---	1,8
A	EP,A,0 011 258 (ORTHOFIX) 28 May 1980 see page 10, paragraph 3; figure 10 ---	1,8
A	US,A,4 696 293 (CIULLO) 29 September 1987 see column 3, line 2; figure 1 ---	1,8
A	GB,A,1 496 738 (PRIOROVA) 30 December 1977 see claim 1; figures 2,3 ---	1,8
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

13 June 1996

Date of mailing of the international search report

21.06.96

Name and mailing address of the ISA

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Barton, S

INTERNATIONAL SEARCH REPORT

 Internat Application No
 PCT/BG 95/00010

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	DE,A,42 19 156 (WUESTHOFF) 16 December 1993 see figures 4,5 ---	1
A	DE,U,93 19 433 (RECKERT) 10 February 1994 see figure 2 ---	1,8
A	US,A,2 238 870 (HAYNES) 15 April 1941 see figure 3 ---	1,8
A	EP,A,0 192 440 (THACKRAY) 27 August 1986 see figure 1 ---	1,8
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International Application No PCT/BG 95/00010
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