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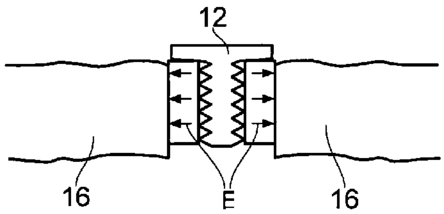
FIG. 1B



(57) Abstract: The present invention relates to a fixation device and in particular to a device which aids anchoring of orthopaedic fasteners and implants to bone. The invention also relates to a fixation apparatus and a method of fixation.

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FIXATION DEVICE

The present invention relates to a fixation device and in particular to a device which aids anchoring of orthopaedic fasteners and prosthetic implants to bone. The invention also relates to a fixation apparatus and a method of fixation.

The term fixation generally refers to locating and anchoring prosthetic implants and orthopaedic fasteners such as screws, pins, plates, cements and the like in surgical operations to heal tissue such as bone for example. However, locating such implants and/or fasteners does not always provide sufficient anchoring and in some cases is inappropriate and harmful. This problem is particularly evident, for example, in surgical operations to treat and repair bone fracture in patients with Osteoporosis. Osteoporosis is a disease of the bone whereby bone mineral density is reduced rendering the bone more brittle. Osteoporotic bone thus fractures more easily and is clinically more difficult to treat in terms of trauma and reconstructive surgery.

Surgical repair of bone fracture generally involves placing a plate over the fractured site so that the plate bridges the fracture, and anchoring the plate, using pins or screws, to the bone. The combination of plate and screws, locates, realigns and supports the bone about the fracture to aid healing.

However, screw fixation, especially in osteoporotic bone, is often poor as the screw does not firmly fix to the bone. Generally, to enable a conventional screw to be secured to bone, it must be screwed into a slightly undersized hole in the bone. However this subjects the bone to a substantial force which in some cases may damage or fracture the bone. Furthermore, the force required to maintain a plate in place is of course taken up by the screws. This force is transferred directly to the area of the bone with which it is in direct contact. Where an additional load is transferred to the plate, for example on movement of the patient, this additional load is also distributed among the screws. Such forces and loads tend to deform the surrounding bone and thus loosen the screws. To alleviate this problem, a greater number of screws maybe used, distributing and spreading the load over a larger number of contact points. Additional plates, cement and filler may also be used. However, such a solution may not always be desirable especially where it is required to remove the plate and screws at a later stage or, as mentioned above, where the patient has Osteoporosis.

A further problem associated with this type of surgical repair is the requirement to prepare the bone to receive the particular shape of screw or pin. In this regard, the depth of the hole drilled into the bone and the length of the screw must be within a precise tolerance. If the prepared hole is shorter than the screw, the screw will not seat properly and the plate may not be adequately secured to the bone. Furthermore, to provide adequate anchoring of the pin, it must be inserted into the bone to a sufficient depth. However, where the pin is inserted too deeply into the bone, the bone may break around the thread of the screw and lose all fixation. In this case, a larger screw would need to be inserted or the screw may need to be inserted in a new location. Bone breakage during this type of surgical procedure is particularly prevalent in patients having Osteoporosis.

It is an object of the present invention to address some or all of the above mentioned problems and to provide a device which allows for improved fixation in poor quality bone whilst reducing the load born directly by the bone.

Therefore, according to a first aspect of the present invention, there is provided a plug which is capable of expansion upon insertion into a bone cavity and is adaptable to receive a fastener or implant, thus anchoring the fastener or implant securely to the bone.

Preferably, the plug is engineered onto or into the fastener or implant before insertion of the plug into the bone cavity to enhance fixation of the fastener or implant.

Therefore, according to a second aspect of the present invention, there is provided a fixation apparatus comprising a fastener and a plug.

Typically, the fastener is in the form of a screw or pin and the plug includes a passage or passageway for receiving the screw. The fastener is thus fixated to the plug rather than directly to the bone. As such, forces taken up by the fastener are relayed to and thus shared with the plug rather than with the bone itself.

Preferably, the plug comprises a material which is capable of changing shape on receiving a stimulus. Ideally, the plug comprises a shape memory polymer (SMP) material but may also comprise a shape memory alloy, such as nitinol for example, or a combination of a shape memory alloy and an SMP.

Shape memory polymers (SMPs) are materials that have the ability to "memorize" a “permanent” macroscopic shape, be orientated or manipulated under temperature and/or stress to a temporary or dormant shape, and then be subsequently relaxed to the original or memorized, stress-free condition or shape. Relaxation is usually prompted or encouraged by the application of thermal, electrical, or environmental energy to the manipulated or orientated SMP. This relaxation is associated with elastic deformation energy stored in the SMP during orientation of the SMP. The degree of orientation of the SMP is the driving force that causes relaxation. Thus the greater the degree of orientation, the greater will be the force or energy stored in the SMP and hence the greater will be the force or energy driving relaxation of the SMP when triggered or prompted by an external energy source.

SMPs like other polymers can be grouped into two main categories; they can be amorphous, thus lacking any regular positional order on the molecular scale, or they can be semicrystalline which contain both molecularly ordered crystalline regions and amorphous regions in the same sample.

Plastic deformation of amorphous SMPs and SMP composites results in the formation of an orientated amorphous or semi-crystalline polymer network. Orientation of SMPs and SMP composites can be achieved by stretching, drawing or applying a compressive and/or shear force to the SMP. The SMP may be orientated by application of any one or a combination of these forces and can be carried out at ambient temperatures or elevated temperatures. Generally, the temperature of the SMP is raised above ambient temperature to around the glass transition temperature (Tg) of the SMP before application of the orientation force or forces. Raising the temperature of the SMP in this way helps prevent the SMP from rupturing when the orientation force is being applied thereto. The glass transition temperature is the temperature below which the physical properties of amorphous SMPs behave in a manner similar to a solid, and above which they behave more like a rubber or liquid allowing the SMP to undergo plastic deformation without risk of fracture. After the SMP has been orientated, the temperature is reduced and the SMP is fixed in a temporary or dormant configuration.

The orientated network is physically stable well below the glass transition temperature (Tg) where molecular mobility is low. However, near or above the polymer's glass transition temperature, molecular motion rapidly increases and causes the orientated network to relax, usually accompanied by physical changes in the dimensions of the SMP. During relaxation, the orientated SMP tends to recover the original dimensions of the unorientated SMP, hence the name shape "memory" material. However, recovery of the original shape depends primarily on the degree of crystallinity, orientation, the micro and nano-structures and the conditions under which the orientated network is relaxed. For copolymers other important factors are their detailed composition and their specific thermal properties, i.e. the glass transition and melting temperatures, of their components.

It is believed that the relaxation process occurs nearly at constant volume. The degree of recovery during relaxation, for a semi-crystalline orientated SMP, depends on its crystallinity and structure and complete recovery of its original shape is difficult. In contrast, amorphous orientated SMPs, copolymers and their composites can return substantially to their original shape under appropriate relaxation conditions.

The degree of orientation is the driving force that causes relaxation. The greater the degree of orientation, i.e. the force or forces applied to the SMP, the greater will be the driving force.

During relaxation, the orientated SMP releases stored internal forces or energy. For example, an SMP of cylindrical shape orientated by applying a stretching force uniaxially along its longitudinal axis will shrink in length and expand in diameter during relaxation under free boundary conditions, i.e. where no physical constraints are imposed. Hence, when the cylindrical shaped SMP relaxes, it will induce a shrinkage force along its longitudinal axis and also an expanding force in the radial direction. These longitudinal and radial forces are proportional to the degree of orientation and mass of orientated polymer. The greater the degree of orientation, i.e. the greater the forces applied to the

SMP during orientation, and the greater the mass of the SMP, the greater these longitudinal and radial relaxation forces will be. For SMPs of other geometries, the relaxation forces will also depend on the degree or magnitude of the orientation force, the direction of the applied orientation force, as well as the mass of the orientated SMP. The rate of relaxation or the rate of shape recovery of the SMP is dependent on sample geometry, processing conditions and more importantly on the mass and thermal diffusivity of the SMP.

The glass transition temperature of the SMP will vary based on a variety of factors, such as molecular weight, composition, structure of the polymer, and other factors known to one of ordinary skill in the art, but is generally in the region of between 35-150°C.

Preferably, the plug comprising the SMP is pre-stressed or orientated. However, it will be appreciated that the plug can be pre-stressed or orientated at any time prior to use or insertion into a bone.

The plug and passage are advantageously cylindrical in shape and the passage preferably lies centrally and along a longitudinal axis of the plug. The cylindrical shape of the plug is preferable as it provides an easy fit into a drilled hole of the bone which is also generally cylindrical in shape. Locating the passage centrally of the plug allows the stress loading on the screw to be spread evenly to and over the plug.

The cylindrical plug is typically orientated by stretching the plug along its longitudinal axis. Orientation in this manner lengthens the plug and reduces its diameter. Preferably, the plug is orientated until its diameter is less than the diameter of the hole prepared in the bone into which it will be placed. In this way, the plug can be inserted into the bone with little or no force. This is particularly important where the bone is brittle as such force may cause fracture or even breakage of the bone.

Preferably, the plug is also orientated about the passage by stretching the passage in the radial direction. This can be done, for example, by forming the passage having a diameter smaller than the diameter of the fastener to be inserted therein, and forcing through the formed passage an elongate member, such as a pin for example, with a diameter greater than the diameter of the formed passage. Forcing the pin in this manner stretches the passage in the radial direction.

Preferably, the fastener has a head portion and an elongate shank extending from said head portion. Preferably, the diameter of the head portion is less than or equal to the diameter of the relaxed plug. In this way, there is no overlap between the fastener and the bone. Any load transferred to the fastener is thus not taken up by the bone but transferred to and shared directly with the plug.

In use, and after the orientated plug has been inserted into the prepared bone cavity, the plug is relaxed, typically by transferring heat thereto. Relaxation of the plug causes it to expand radially towards the cavity wall until it completely fills the cavity. The force of the relaxing plug against the cavity wall securely anchors the plug therein. The material of the plug when relaxing also fills any irregularities in the cavity wall which further acts to anchor the plug in the cavity.

Relaxation of the plug also encourages radial contraction of the passage wall towards the fastener. Radial contraction of the passage is pronounced where orientation of the plug includes radial stretching. The force of the relaxing plug against the fastener provides a tight fitting grip around the fastener which dramatically improves anchoring of the fastener within the plug. Where the fastener is a screw, for example, the passage wall of the relaxing plug conforms to the shape of the thread, providing a further anchoring effect along the threads of the fastener.

Preferably, the fastener is a metal fastener. Advantageously, heat may be transferred to relax the plug via the fastener. For example, a heating probe can be applied to the head portion of the metal fastener which will conduct the heat along the length of the fastener and thus transfer the heat more evenly to the plug. The plug may advantageously include heat conductive particles, such as metal particles, to more evenly and quickly distribute the heat throughout the plug. The fastener may also include a channel extending along a length thereof, terminating in an opening at the head portion. This would allow the heating element or probe to be inserted directly into the screw and along the channel providing for improved heat transfer from the screw to the plug.

Alternatively, the screw can be of a non-metallic material, for example, PEEK or PE. The screw may also be of a SMP material which may be the same or different from the SMP material of the plug. Preferably, the SMP material of the plug and fastener are different. In this way, the plug and fastener will relax at different rates, which increases the frictional stresses between the expanding fastener and plug thus improving the anchoring effect of the fastener within the passage of the plug.

Preferably, the fixation apparatus comprises more than one plug and fastener. Preferably, the fixation apparatus includes a support member for placing over the fractured site so that the support member bridges the fracture. Preferably, the support member is a plate. The plate can be substantially flat or configured to accommodate the shape of bone to which it is attached. The plate may include holes for receiving the fasteners or may have a suitable number of holes formed therein prior to use. In use, the plate is anchored to the bone using a number of fasteners and plugs. The combination of plate, fasteners and plugs provides a way of locating, realigning and supporting the bone about the fracture to aid healing.

Therefore, according to a third aspect of the invention there is provided a method of bone fixation for repairing fractures comprising the steps of:-

forming cavities in the bone adjacent the fracture;

locating the fixation apparatus to the fractured area; and

expanding the plugs within the cavities thus anchoring the fixation apparatus to the bone.

Typically, the cavities are formed using a conventional surgical drill and are of a generally cylindrical shape mirroring the shape of a conventional drill bit. However, the cavity can be of any suitable shape; the plug being capable of expansion to fill the cavity regardless of its shape. For example, the cavity can have a square, elliptical or hexagonal cross section; the noncircular nature of the cavity further inhibiting rotational movement of the plug and thus slippage within the cavity.

Preferably, the surface of the cavity wall is non-smooth allowing the smp plug to relax and expand into the irregularities in the cavity wall giving the plug further purchase therein, thus further improving the anchoring of the plug in the cavity. Alternatively, the cavity may be formed to include one or more grooves in the wall of the cavity. Alternatively, or in addition, the cavity may be contoured allowing the smp plug to relax to fill the contour.

Locating the fixation apparatus generally includes the steps of inserting an orientated plug into each cavity formed. The plate is placed over the fracture such that the holes in the plate for receiving the fasteners are aligned with the passage of each plug. Each fastener is inserted through a hole in the plate and into the passage of the plug, thus fixing the plate to the plugs. Where the fastener is a screw, for example, it is more effectively introduced into the passage of the plug by a screwing action. The SMP plugs are then relaxed by stimulating molecular motion of the SMP resulting in radial expansion of the plug. Radial expansion of the plug wedges the plug within the cavity thus anchoring the plug and thus the fixation apparatus more securely to the fractured site. Relaxing the SMP plug also radially contracts the passage of the plug so that it more tightly secures the fastener therein further securing the fixation apparatus to the bone.

Preferably, stimulation of molecular motion is achieved by the application of energy to the SMP plug from an external source. Preferably, the energy applied is in the form of heat. Heat from a heating probe, for example, can be applied directly to the fastener which in turn would transfer the heat more evenly through and along the length of the plug providing for a more even expansion of the plug within the cavity. Preferably, the SMP is heated above the glass transition temperature (Tg) of the SMP. This temperature is dependent on the type of SMP used but is generally in the range of 45 to 135^{0}C.

Alternatively or additionally, the expansion step may be prompted or triggered by the application of a different form of energy, for example, a magnetic field, an electric current, ultrasound, electromagnetic radiation such as microwaves, visible and infrared light, or by a combination of any one of these forms of energy.

Stimulating molecular motion of the SMP may also be achieved by exposing the orientated SMP to a plasticizer. Exposure of the SMP to a plasticizer reduces the Tg of the SMP, thus increasing its molecular mobility. In this way, the molecular mobility of the orientated SMP may be increased sufficiently to cause the orientated network to relax. Where exposure of the orientated SMP to a plasticizer is not sufficient to relax the SMP, energy, in the form of heat for example, may also be applied to the SMP. In this way, the orientated SMP can be relaxed at a temperature less than would be necessary where the SMP is relaxed using heat alone. As such, the SMP can be shaped at lower temperatures, thus allowing the addition of temperature sensitive materials to the SMP. Temperature sensitive materials may include, for example, releasable bioactive agents such as monobutyrin, bone marrow aspirate, angiogenic and osteogenic factors which will aid bone fracture repair.

Plasticizers may be in the form of a biocompatible volatile liquid or gas. Examples of such gaseous plasticizers include but are not limited to, oxygen and carbon dioxide. Examples of such liquid plasticizers include but are not limited too, water and inorganic aqueous solutions such as sodium chloride solution.

Preferably, the SMP is biocompatible and can be resorbable or non-resorbable, or a combination of both. Example of suitable SMPs include but are not limited too polyetheretherketone (PEEK), polymethyl methacrylate (PMMA), polyethyl methacrylate (PEMA), polyacrylate, poly-alpha-hydroxy acids, polycapropactones, polydioxanones, polyesters, polyglycolic acid, polyglycols, polylactides, polyorthoesters, polyphosphates, polyoxaesters, polyphosphoesters, polyphosphonates, polysaccharides, polytyrosine carbonates, polyurethanes, and copolymers or polymer blends thereof.

Preferably, the SMP is a reinforced SMP. Preferably, the reinforced SMP comprises a composite or matrix including reinforcing material or phases such as fibers, rods, platelets, and fillers. More preferably, the polymeric material can include glass fibers, carbon fibers, polymeric fibers, ceramic fibers, or ceramic particulates.

Preferably, the plug is coated with an osteogenic material such as, for example, hydroxyapatite or calcium phosphate.

Preferably, the plug and/or fastener and/or support member is porous or semi-porous. Porosity of the fixation apparatus will allow infiltration thereof by cells from surrounding tissues, enhancing integration thereof by osteointegration, for example.

Preferably, one or more active agents are incorporated into the plug and/or fastener and/or support member. Suitable active agents include but are not limited too anti-osteoporotic agents, bisphosphonates, bone morphogenic proteins, antibiotics, anti-inflammatories, angiogenic factors, osteogenic factors, growth factors, monobutyrin, omental extracts, thrombin, modified proteins, platelet rich plasma/solution, platelet poor plasma/solution, bone marrow aspirate, and any cells sourced from flora or fauna, such as living cells, preserved cells, dormant cells, and dead cells.

Preferably, the active agent is incorporated into the plug and is released during the relaxation or degradation of the SMP. Advantageously, the incorporation of an active agent can also act to combat infection at the site of implantation and/or to promote new tissue growth.

Preferably, an outer surface of the smp plug is coated with a bonding or interfacial enhancing agent. Preferably, the bonding agent is at least partially melted when relaxing the smp plug. On relaxing the smp plug, the melted bonding agent is forced against and in some cases into the surrounding bone by the force of the relaxing plug. The bonding agent can be an adhesive, for example, or comprise a material which melts at the temperature required to relax the orientated smp plug. Preferably, the bonding agent is polycaprolactone (PCL).

Preferably, the bonding agent includes biologically active elements which may be released when relaxing the SMP plug. The bonding agent may also include mechanically modifying elements which modify the physical or mechanical properties of the SMP plug, for example, the degradation rate or flow properties of the SMP plug. Alternatively, the plug may include an outer modifying sleeve or coating which includes the biologically active elements and/or mechanically modifying elements.

Typically, the outer modifying sleeve or coating is less viscous than the SMP plug at the same temperature. The outer modifying sleeve or coating can cover the entire outer surface of the SMP plug or only a portion thereof. For example, the outer modifying sleeve can be in the form of strips. The outer modifying sleeve or coating can be soluble and can comprise a resorbable and/or non resorbable polymer.

Preferably the outer modifying sleeve or coating is hydrophilic which, on exposure to aqueous fluid, expands to form a gel capable of releasing the biologically active elements and/or mechanically modifying elements.

Embodiments of the invention will now be described by way of example only and with reference to the accompanying drawings, in which:-

Fig. 1A is a cross-sectional side view of a fixation apparatus according to the present invention including an orientated plug containing a fastener in the form of a screw, illustrating insertion thereof into a bone cavity, the bone cavity clearly having a larger diameter than the orientated plug;

Fig. 1B is a view similar to Fig. 1A showing the fixation apparatus secured within the bone cavity, the arrows labelled E clearly illustrating the radial expansion of the SMP plug towards the cavity walls after triggering the plug to relax;

Fig. 2A is a perspective view and from the side of an orientated cylindrical plug according to the invention having a central cylindrical passage;

Fig. 2B is a similar view of the orientated plug of Fig. 2A inserted into the cavity of a bone, clearly illustrating that the diameter of the orientated plug is less than that of the cavity for ease of insertion of the plug therein;

Fig. 2C is a view similar to that of Fig. 2B clearly showing the plug wedged in the cavity after relaxing of the plug, the arrows labelled E clearly illustrating radial expansion of the plug towards the cavity walls;

Fig. 2D is a view similar to that of Fig. 2C illustrating insertion of a fastener into the passage of the plug;

Figs 3A to 3E are plan view of various constructions and shapes of plug according to the present invention showing the passage located centrally;

Figs 4A to 4E are plan view of various constructions and shapes of plug similar to those of Figs 3A to 3E shown here without a passage;

Figs 5A to 5D illustrate insertion and expansion of the plug according to the present invention into cavities having different shapes, including cavities which in plan view resemble a hexagon, an ellipse and a square;

Figs 6A to 6C are side views, shown in part, illustrating insertion of the fixation apparatus (in part) according to the present invention into a bone cavity, the cavity wall having grooves into which the orientated plug relaxes on stimulation thereof providing for improved anchorage of the plug in the cavity, the arrows labelled E clearly illustrating radial expansion of the plug towards the cavity walls;

Figs 7A to 7C are side views similar to Figs 6A to 6C illustrating a different construction of groove in the cavity wall;

Figs 8a to 8d illustrate assembly of the fixation kit, including plug, fastener and plate to the fractured bone site according to the present invention;

Fig 9 is a plan view of fig. 8B;

Fig 10 is a view, shown partially in plan view, of fig. 8C;

Figs 11a to 11d are cross-sectional side views of contoured bone cavities having different configurations;

Figs 12a to 12d are pictorial views of the contoured bone cavities of figs 11a to 11d shown here with a relaxed plug container a fastener;

Fig 13 is a pictorial view of an orientated smp plug having a layer of polycaprolactone (PLC) coated on its outer curved surface, the smp plug shown here having a measurement ruler in the background to indicate size;

Fig 14a is a cross sectional side view, viewed through an optical microscope, of the plug of fig 13 relaxed in a bone cavity; and

Fig 14b is a cross sectional side view, viewed through an optical microscope, of the plug of fig 13 relaxed in a bone cavity without the layer of polycaprolactone (PCL).

Referring to the drawings and initially to Fig. 2a, there is shown a cylindrical orientated smp plug indicated generally by the reference numeral 2 having an outer wall 4 and a passageway 6 running centrally of the plug 2 and along the longitudinal axis thereof. The passageway 6 terminates at a leading end 8 of the plug 2 in an opening 10 suitable for receiving a metal screw 12. The passageway 6 is of a length to accommodate the length of the shaft of the screw 12.

In this embodiment, the plug 2 has been orientated by stretching it along its longitudinal axis. This results in an elongation of the plug 2 and a narrowing of its diameter.

Figs 2B to 2D illustrate placement of a single plug 2 only in a prepared cavity 14 in a bone 16 adjacent a fracture (not shown). However, it will be appreciated that a number of plugs 2 surrounding the fracture may be placed in a similar manner. In this embodiment, the plug 2 is inserted into the cavity 14 as shown in Fig. 2B and then relaxed as shown in Fig. 2C. Relaxation of the plug 2 is stimulated by the application of heat thereto which in this embodiment is applied using a heating probe (not shown). Relaxation of the plug 2 causes the plug 2 to expand radially towards the wall of the cavity 14 which wedges the plug 2 within the cavity 14, forming a tight fit and thus securely anchoring the plug 2 therein. This can be seen most clearly from Fig. 2C. After relaxation of the plug 2, an implant, which in this embodiment is the screw 12, is inserted into the passageway 6 of the plug 2 and fixed therein.

Figs 8A to 8D illustrate a further embodiment of locating the fixation apparatus, including orientated smp plugs 2a, 2b, metal fasteners 12a, 12b and plate 18, of the present invention to a fractured bone site 16 including a fracture 20. In this embodiment the bone 16 is prepared for receiving the fixation apparatus by drilling a cavity 14a, 14b on both sides of the fracture 20. The cavities 14a, 14b are sized to receive the orientated plugs 2a and 2b.

The plate 18 which includes through holes 22a and 22b, for receiving screws 12a and 12b, is placed over the plugs 2a and 2b such that the holes 22a and 22b are aligned with openings 10a and 10b of the plugs 2a and 2b respectively.

Each plug 2a, 2b is orientated prior to insertion into the cavities 14a, 14b. In this embodiment, each plug 2a, 2b has been orientated by stretching it along its longitudinal axis. This results in an elongation of the plug 2a, 2b and a narrowing of its diameter. The plug 2a, 2b is also orientated about the passageway 6a, 6b by stretching the passageway 6a, 6b in the radial direction. This is done by first drilling a passageway 6a, 6b having a diameter smaller than the diameter of the elongated shaft of the screw 12a, 12b to be inserted therein. Forcing a pin (not shown) with a diameter greater than the diameter of the passageway 6a, 6b stretches the passageway 6a, 6b in the radial direction. The diameter of the pin is equal to or marginally less than the diameter of the elongate shaft of the screw 12a, 12b so that it is stretched to a suitable size to receive the screw 12a, 12b.

The plate 18 is placed over the fracture 20 such that the holes 22a, 22b in the plate 18 for receiving the screws 12a, 12b are aligned with the openings 10a and 10b of the plugs 2a, 2b. Each screw 12a, 12b is inserted through the hole 22a, 22b in the plate 18 and into the passage 6a, 6b of the plug 2a, 2b, thus fixing the plate 18 to the plugs 2a, 2b. Where the fastener is a screw, for example, it is more effectively introduced into the passage of the plug by a screwing action. The plugs 2a, 2b are then relaxed by heating the SMP resulting in radial expansion of the plugs 2a, 2b towards their original shape. Radial expansion of the plugs 2a, 2b wedges them within the cavity, forming a tight fit and thus securely anchoring the plugs 2a, 2b therein and thus the fixation apparatus more securely to the fractured site. Relaxing the SMP plug also radially contracts the passage 6a, 6b of the plug 2a, 2b towards its original shape so that the passage 6a, 6b effectively grips the shaft of the screw 12a, 12b therein thus further securing the fixation apparatus to the bone.

Heat is applied to the plugs 2a, 2b using a heating probe 24, which is applied directly to the heads of the screws 12a, 12b. The metal screws 12a, 12b conduct the heat along the shaft of the screws and radiate the heat to and along the length of the plugs 2a, 2b.

To illustrate the performance of the fixation apparatus of the present invention, tests were undertaken to compare the anchoring strength of the fixation apparatus and that of a normal screw threaded bolt.

Test A included the insertion of a standard metal, screw threaded bolt into the plug of the present invention. The plug was formed from a die-drawn smp composed of PLA-co-DL 70:30 (65% wt) and $CaCO_3$ (35% wt). The plug with bolt was inserted into a slightly oversized hole in a 20 pounds per cubic feet (pcf) Sawbones block and then heated with water at 80°C for approximately 4 min to relax the plug. Test B used the same type of plug and bolt as in test A, but in this case, the plug only was inserted into the slightly oversized hole and heated. After heating, the bolt was then screwed into the plug. Test C simply included the insertion of the same type of bolt into a same-size hole drilled in 20pcf Sawbones. All the bolts were pulled out of the Sawbones at a rate of 10mm/min. The results are given in table 1 below and show that the SMP plug improves fixation of the bolt.

Table 1

Test	Failure load (N)
A) Bolt and sleeve heated	220
B) Sleeve heated, bolt screwed in	190
C) Bolt screwed in, no sleeve.	129

It will be appreciated that the plug 2a, 2b may be orientated such that the diameter of the passageway 6a, 6b is slightly larger than the diameter of the shaft of the screw 12a, 12b. As with insertion of the plug into the cavity, this allows for ease of insertion of the screw into the plug requiring minimal force. This is of course advantageous where the bone is brittle and forcing the plug or screw may damage or break the bone.

Referring now to figs 11a to 11d and figs 12a to 12d, there is shown, in part, four samples of bone having bone cavities 14, each cavity having a different contouring. A orientated shape memory plug 2 comprising a mixture of PLLA-CO-DL and CaCO3 (25mm length X 13mm outer diameter) and containing a metal fastener 12 of 8mm in diameter was placed into each of the cavities 14. Each plug 2 was heated for 15min at 175^C using a 4 mm diameter heating probe. In each case, the SMP plug 2 was observed to relax and expand into the contouring of the cavity 14. The SMP plugs 2 were then allowed to cool after which the fixation force was measured as follows:-

Each sample of bone containing relaxed plug 2 as described above was placed on a cylindrical support on an Instron 5566 test machine(not shown). A rigid metal probe of 8mm diameter, connected rigidly to a 10kN load cell, was pressed against the one end of the plug 2 at 2mm/min. The maximum force to push out the plug 2 in each case was recorded and is shown in table 2 below.

Table 2

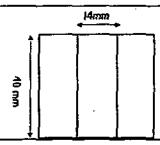
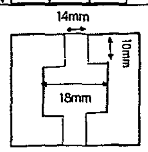
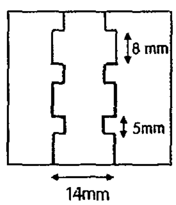
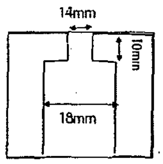
Sample	Geometry of Cavity	Pushout force
Fig 11a		200 N
Fig 11b		1365 N
Fig 11c		1472 N

Fig 11d		2400 N

Referring now to fig 13, 14a and 14b, two orientated cylindrical smp plugs 2 were prepared, each having a length of 25mm and an outer diameter of 15 mm. The smp plug 2 shown in fig 14a is coated on the exterior curved surface thereof with PLC fibre 200 which is 0.65 mm thick and extends centrally along, and approximately 2/3 of the length of, the smp plug 2. The orientated plug 2 shown in fig 14b does not contain the coating of PLC; in ever other respect it is identical with the smp plug 2 of fig 14a. Both orientated smp plugs 2 of figs 14a and 14b were placed in bone cavities in 20 PCF Sawbones block to produce test sample a and b respectively. The cavities in each sample were 40mm deep and 18.78mm in diameter. Each sample was then immersed in hot water at approximately 90°C for 10 minutes. The samples were then cooled by immersion in cold water for 15 minutes.
Each sample was sectioned and examined with an optical microscope to determine the effect of the PCL on the smp plug-Sawbones block interface.

It was observed in the case of the smp plug of fig 14a that the PCL coating melted, and as the SMP plug relaxed, the PCL was forced into the Sawbones block, penetrating its pores improving the bond between the smp plug and the Sawbones block.

To further investigate the effect of an smp plug having a PLC coating, two orientated cylindrical smp plugs were prepared each having a diameter of 15mm and a length of 27 mm. In each case, a stainless steel sleeve was inserted through a central passage running along the central longitudinal axis of the smp plug. The stainless steel sleeve had a 4mm internal diameter and a 4.7 mm external diameter. One of the smp plugs was coated on a central portion of the exterior curved surface thereof with PLC fibre, the coating extending approximately 2/3 of the length of the smp and being 0.65mm thick.

Each smp plug was placed in a cavity in a 20 pcf Sawbones block. Each cavity was 17.3 mm in diameter and 40mm deep The smp plugs were then relaxed by placing a 4mm diameter heating probe into the stainless steel sleeve. The probe was heated to 175°C for 15 minutes. The probe was then removed and the smp plugs were allowed to cool to room temperature.

Each smp plug was then mechanically tested using a “push-out” test. The Sawbones block with smp plugs was mounted on a ring support and the each smp plug, in turn, was pushed out using an Allen key having a diameter of 8mm, at a speed of 1mm/min. The peak force required to move each smp plug, and thus break the anchoring bond of the smp plug in the cavity, was recorded. In both cases this was the force required to start the smp plug moving in the cavity. The results are shown in table 3 below.

Table 3

Sample	Peak pushout force
SMP plug (containing no PCL coating)	208 N
SMP plug (containing PCL fibre coating)	1586N

The anchoring strength for the smp plug containing PCL fibre coating was found to be 662 % stronger than the control.

It will also be appreciated that the SMP plug may also be relaxed after insertion into the cavity but prior to insertion of the screws.

It is envisaged that fasteners other than orthopaedic screws may be used, for example, nails or pins. Furthermore, whilst the fixation apparatus is particularly useful for repairing fracture in brittle bones where the bone may be unable to withstand the placement of a screw, nail or pin or indeed the forces which would subsequently be applied thereto, the fixation apparatus may also be advantageously applied to normal bone.

It is also envisaged that the fixation apparatus may include a plug without a passageway. This would enable the surgeon, for example, to drill a hole with specifically required dimensions allowing selection of an appropriate screw, nail or pin.

It will be appreciated that the passageway may run the full length of the plug giving the plug a tubular configuration or may extend along a part thereof. The length of the passageway, however, must be sufficiently long to accommodate the length of the shaft of the fastener.

It is envisaged that the fixation apparatus, which comprises a kit or a kit-of-parts including the plug, fastener and support member, may also be pre-assembled or partially assembled.

The plug, fixation apparatus and method of application are not limited to the embodiments hereinbefore described but may be varied in both construction and detail within the scope of the appended claims.

Claims

1. A fixation device, comprising a plug which is capable of expansion upon insertion into a bone cavity and is adaptable to receive a fastener or implant.

2. A fixation device as claimed in claim 1, wherein the plug includes a passageway for receiving the fastener.

3. A fixation device as claimed in claim 2, wherein the passageway lies centrally and along a longitudinal axis of the plug.

4. A fixation device as claimed in claim 1 or claim 2, wherein the plug comprises a material which is capable of changing shape on receiving a stimulus.

5. A fixation device as claimed in any preceding claim, wherein the plug comprises a shape memory polymer or a shape memory alloy or a combination of a shape memory alloy and a shape memory polymer.

6. A fixation device as claimed in any preceding claim, wherein the plug is porous or semi-porous.

7. A fixation device as claimed in any preceding claim, wherein an outer surface of the plug is coated with a bonding agent.

8. A fixation device as claimed in any preceding claim, wherein the plug includes an outer modifying sleeve or coating which includes biologically active elements and/or mechanically modifying elements.

9. A fixation apparatus comprising a fixation device as claimed in any of claims 1 to 8 and a fastener.

10. A fixation apparatus as claimed in claim 9, wherein the fastener comprises a head portion and an elongate shaft extending therefrom, the diameter of the head portion being less than or equal to the diameter of the plug.

11. A fixation apparatus as claimed in any of claims 9 to 10, wherein the fixation apparatus includes a support member.

12. A fixation apparatus as claimed in claim 11, wherein the support member is a plate.

13. A fixation apparatus as claimed in claim 12, wherein the plate is substantially flat or configured to accommodate the shape of bone to which it is attached.

14. A fixation apparatus as claimed in any of claims 9 to 13, wherein the fastener is metallic or non-metallic, or comprises a shape memory polymer, or comprises a shape memory alloy, or any combination thereof.

15. A fixation apparatus as claimed in any of claims 9 to 13, wherein the fastener and/or support member is porous or semi-porous.

16. A method of bone fixation for repairing fractures comprising the steps of:-
forming at least one cavity on the bone adjacent the fracture;
locating the fixation apparatus to the fractured area; and
expanding the plug within the cavity thus anchoring the fixation apparatus to the bone.

17. A method of bone fixation as claimed in claim 16, wherein the plug is orientated along its longitudinal axis.

18. A method of bone fixation as claimed in claim 16 or 17, wherein the plug is orientated in the radial direction.

19. A method of bone fixation as claimed in any of claims 16 to 18 wherein the step of expanding the plug includes exposing the orientated SMP to a plasticizer.

20. A method of bone fixation as claimed in any of claims 16 to 19, wherein the step of expanding the plug includes applying energy to the plug.

21. A method of bone fixation as claimed in claim 20, wherein the energy is heat, or a magnetic field, or an electric current, or ultrasound, or electromagnetic radiation, or a combination thereof.

22. A method of bone fixation as claimed in any of claims 16 to 21, wherein the step of forming the cavity includes forming irregularities or a groove or grooves in a wall of the cavity.

23. A prosthetic implant comprising a fixation device as claimed in any of claims 1 to 8.

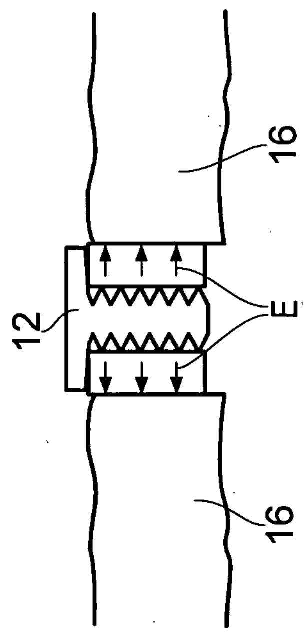


FIG. 1B

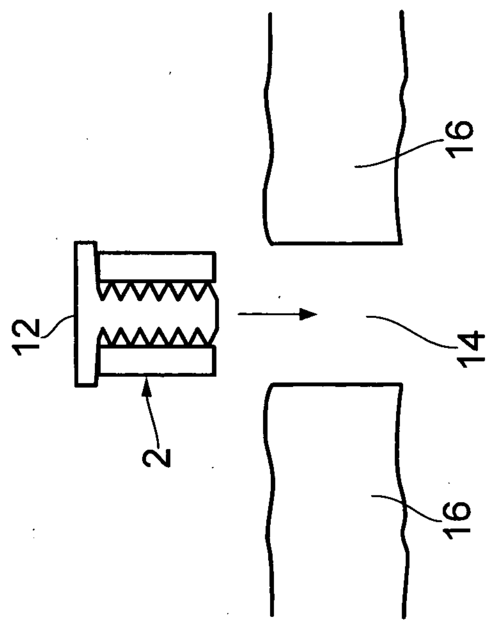


FIG. 1A

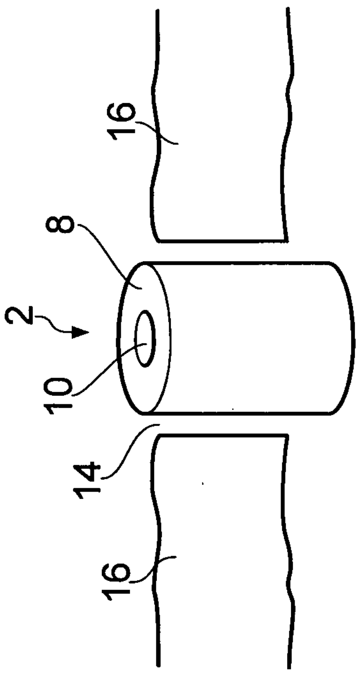


FIG. 2B

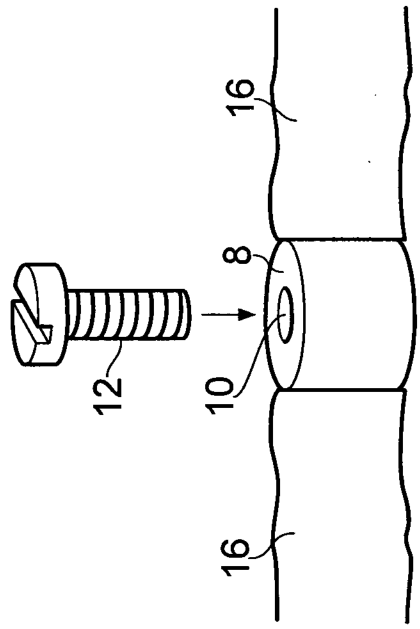


FIG. 2D

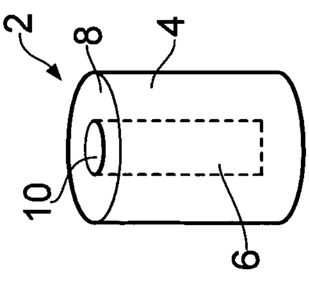


FIG. 2A

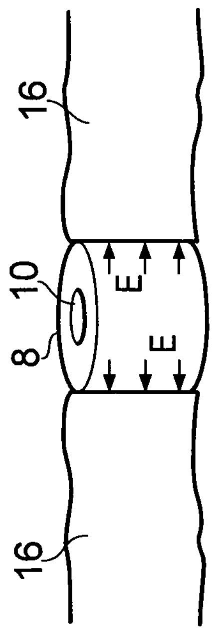


FIG. 2C

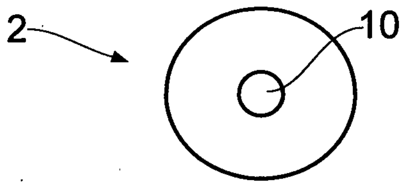


FIG. 3A

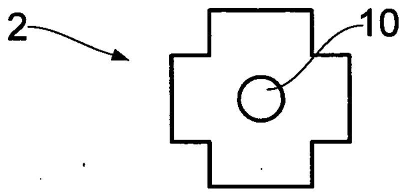


FIG. 3B

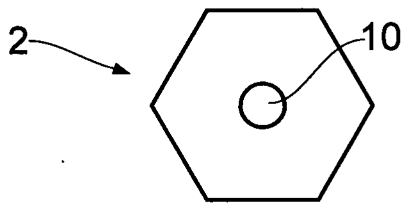


FIG. 3C

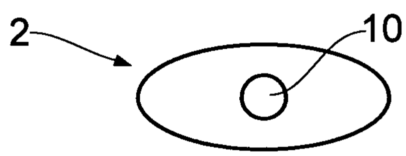


FIG. 3D

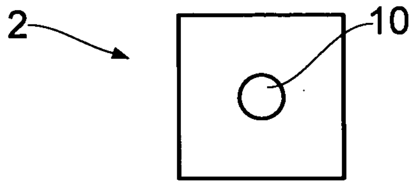


FIG. 3E

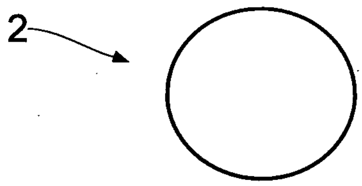


FIG. 4A

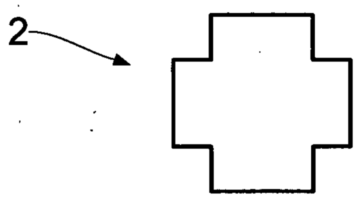


FIG. 4B

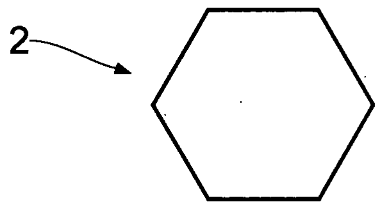


FIG. 4C

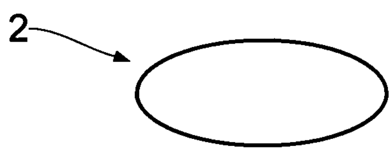


FIG. 4D

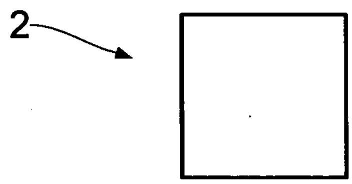


FIG. 4E

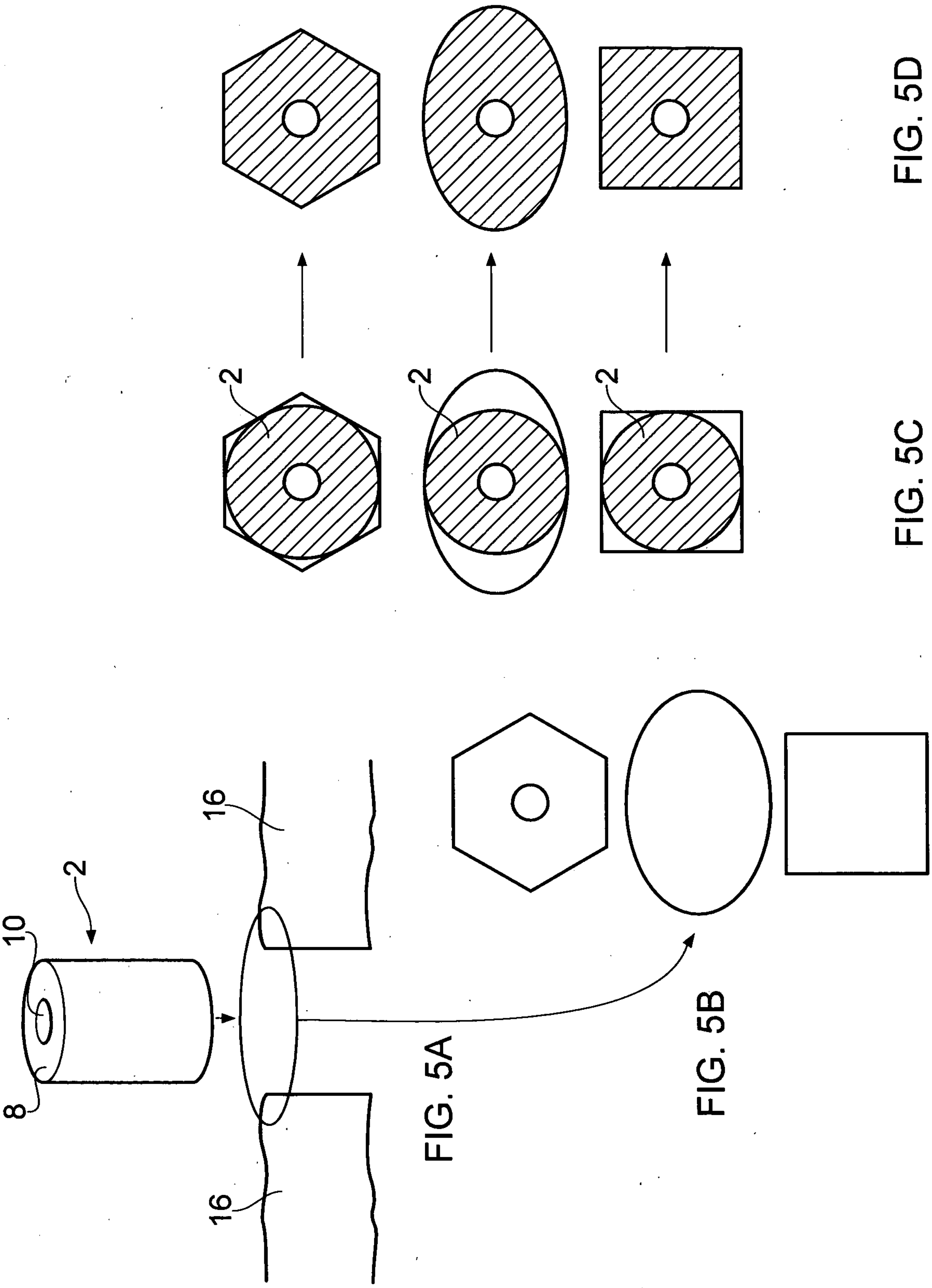


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

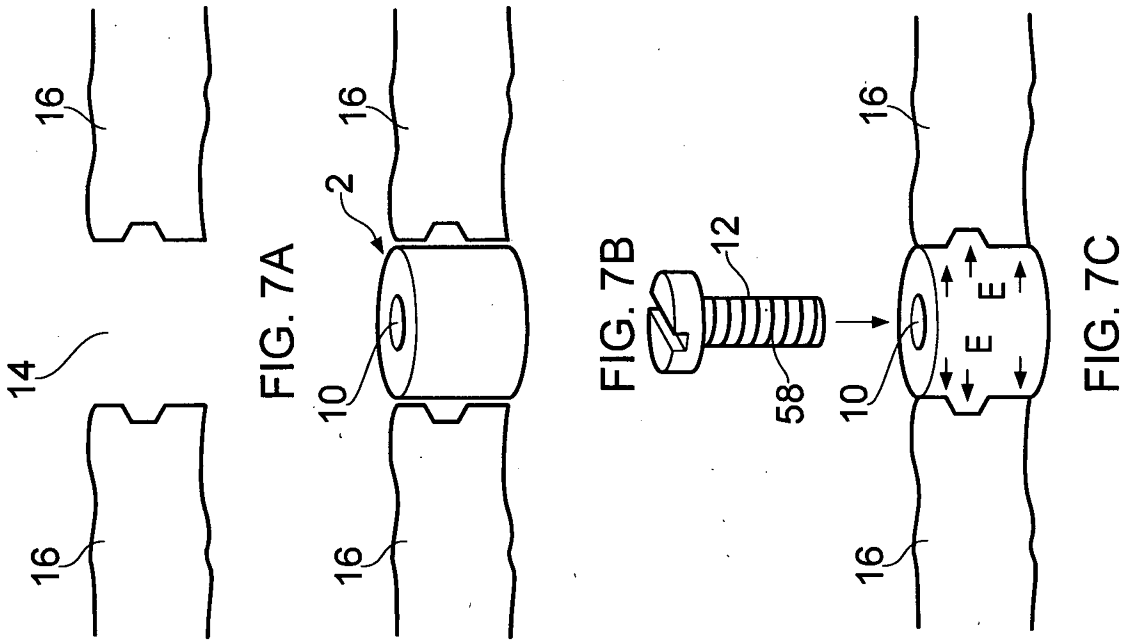


FIG. 7A FIG. 7B FIG. 7C

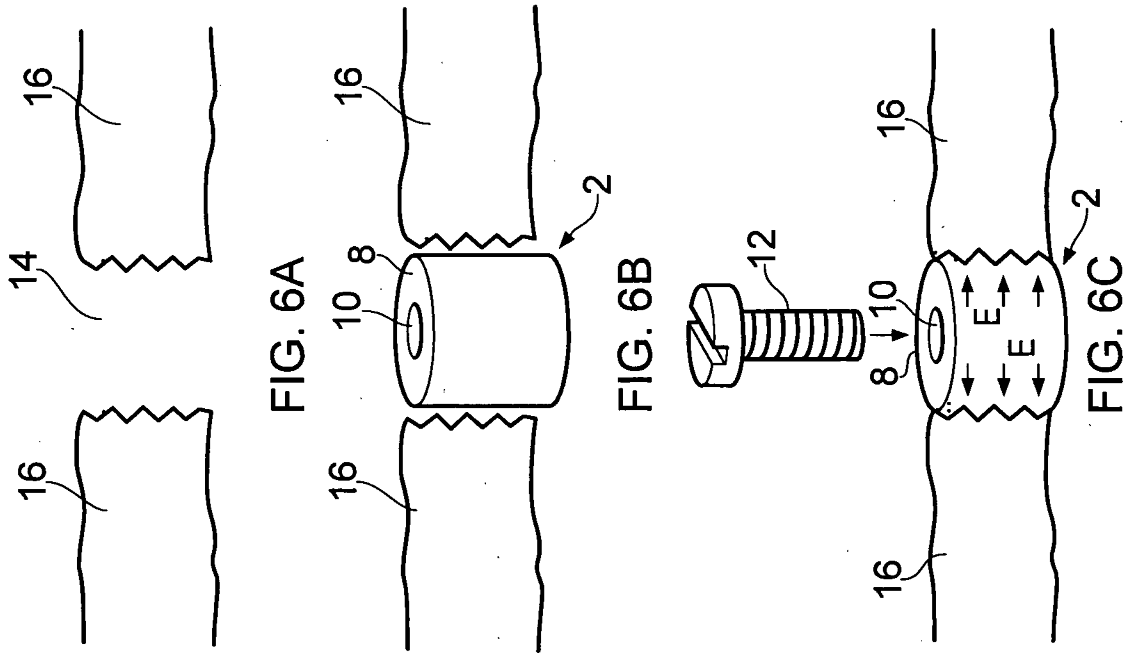


FIG. 6A FIG. 6B FIG. 6C

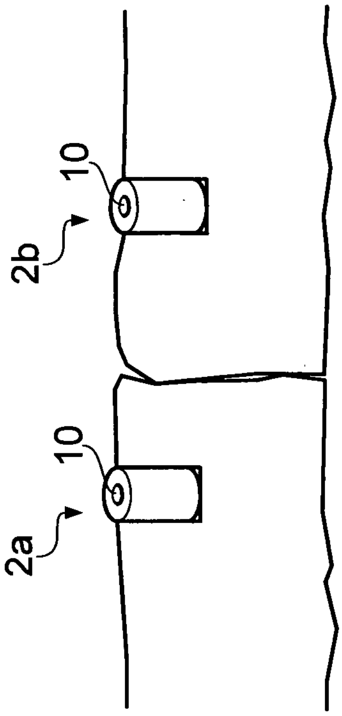


FIG. 8B

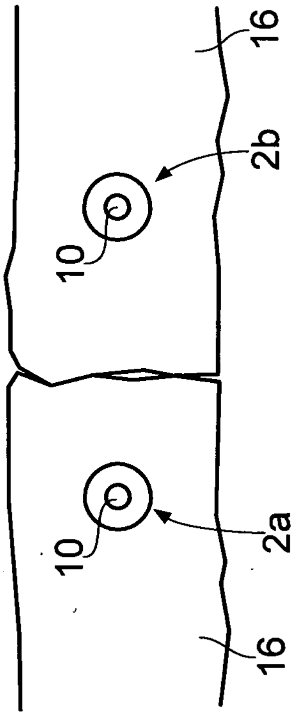


FIG. 9

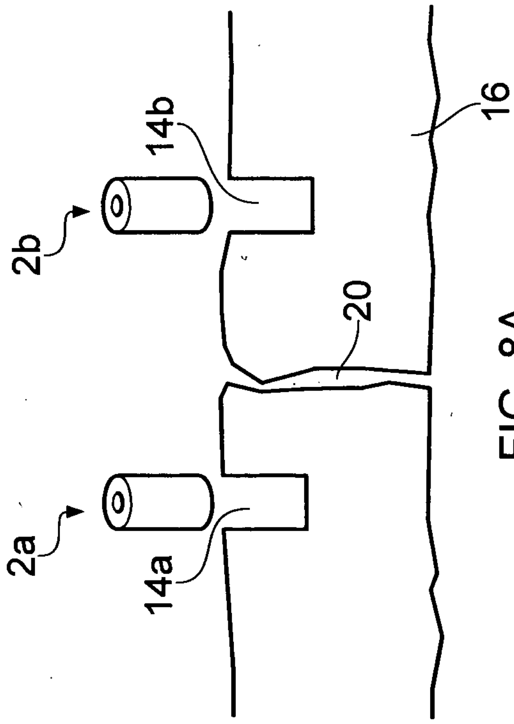


FIG. 8A

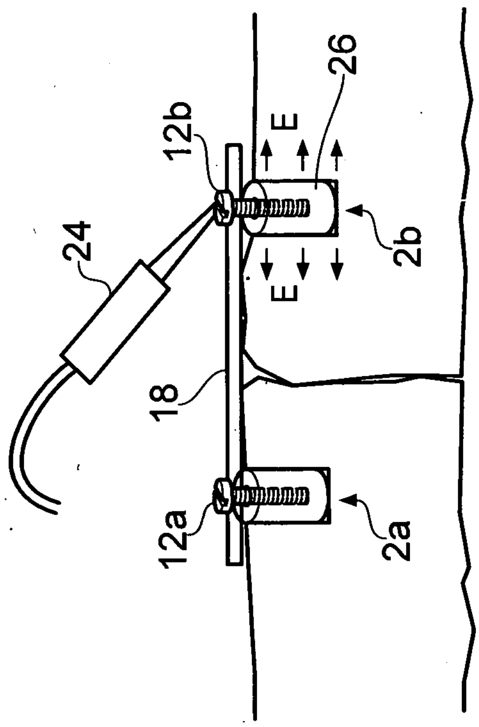


FIG. 8D

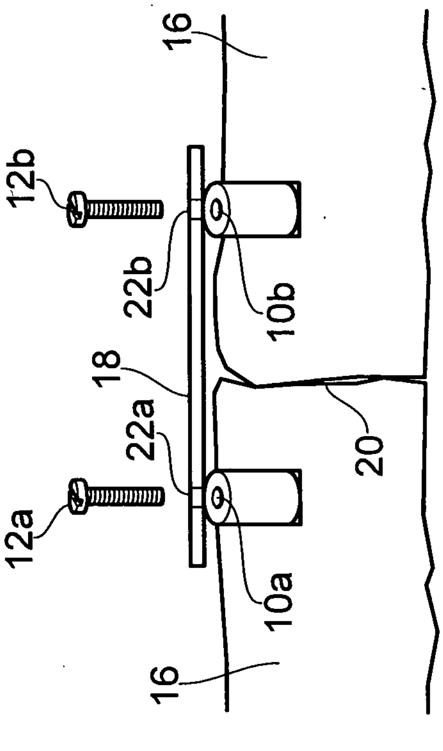


FIG. 8C

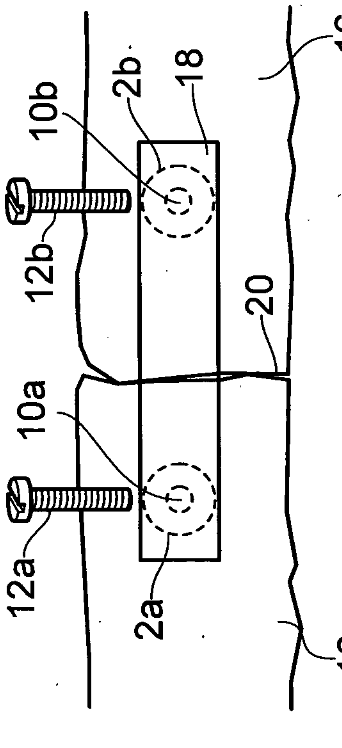


FIG. 10

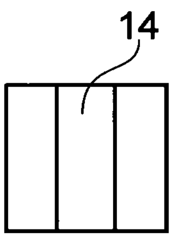


FIG. 11a

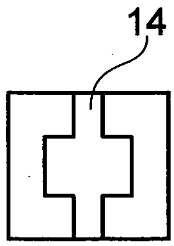


FIG. 11b

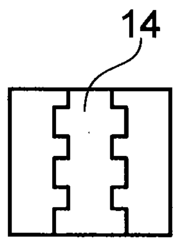


FIG. 11c

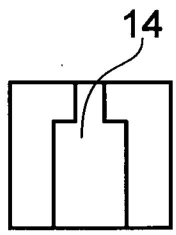


FIG. 11d

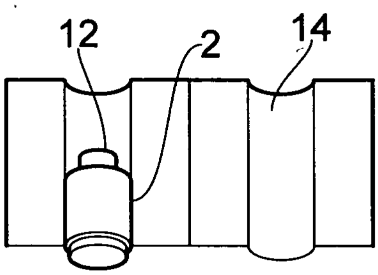


FIG. 12a

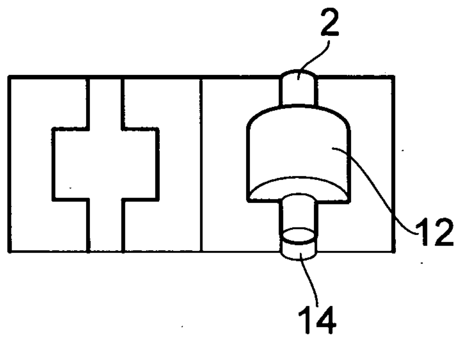


FIG. 12b

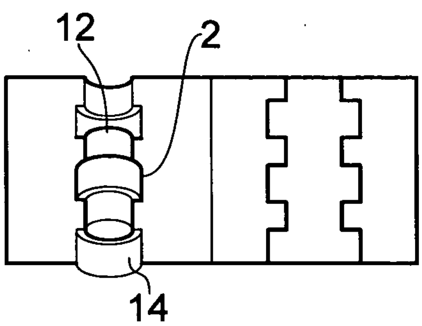


FIG. 12c

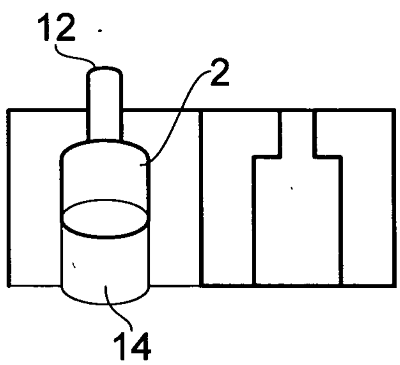


FIG. 12d

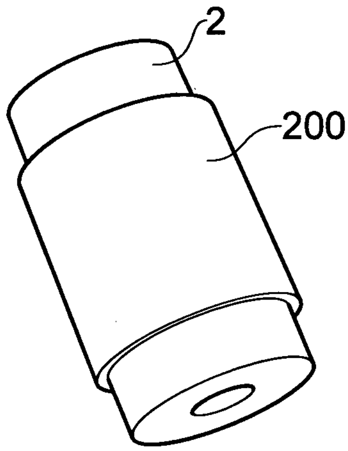


FIG. 13

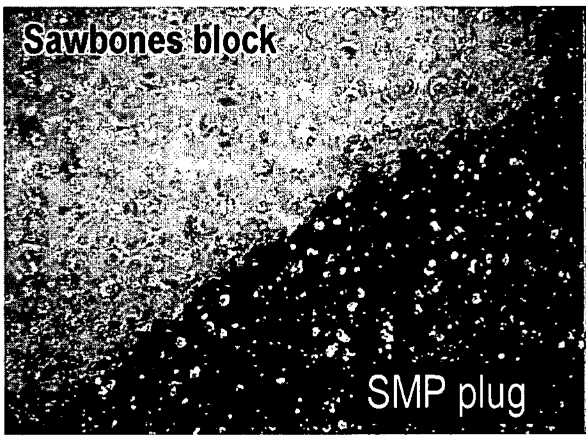


FIG. 14b

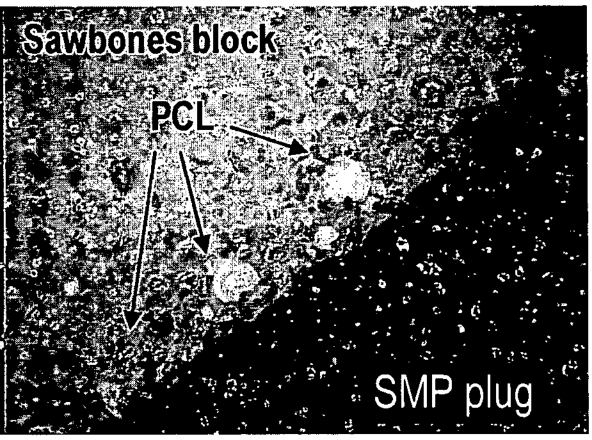


FIG. 14a

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/001322

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/68

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)
A61B A61C

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 084 050 A (DRAENERT) 28 January 1992 (1992-01-28) abstract; figures column 2, line 53 - column 3, line 16 column 5, lines 49-60	1-4,6-9, 14,15,23
X	US 2004/030341 A1 (AESCHLIMANN ET AL.) 12 February 2004 (2004-02-12) paragraphs [0090] - [0092]; figures 2,20-22,29	1-4, 6-15,23
X	US 2006/095138 A1 (TRUCKAI ET AL.) 4 May 2006 (2006-05-04) abstract; figures 1a,1b,3a-3c,5a,5b paragraphs [0035] - [0037]	1-10,14, 15

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family 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	Date of mailing of the international search report
3 July 2008	11/07/2008

Name and mailing address of the ISA/	Authorized officer
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	Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/001322

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/039818 A (THE UNIVERSITY OF BRITISH COLUMBIA) 20 April 2006 (2006-04-20) abstract; figures page 4, line 28 - page 5, line 5 -----	1-9,14, 15
X	WO 2006/011127 A (NITI MEDICAL TECHNOLOGIES LTD.) 2 February 2006 (2006-02-02) abstract; figures 26a,26b column 26, line 22 - page 27, line 6 -----	1,4,5,23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2008/001322

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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. [X] Claims Nos.: 16-22
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/001322

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 5084050	A	28-01-1992	DE	3445738	A1	19-06-1986
			WO	8603666	A1	03-07-1986
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