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(54) Title: MEDICAL DEVICES CONTAINING SHAPE MEMORY POLYMER COMPOSITIONS

(57) Abstract: The present invention relates at least in part to surgical devices whichcomprise a shape memory polymer material composition. Particularly, although not exclusively, the present invention relates to a fixation device e.g. an anchor device e.g. a suture anchor which comprises a shape memory material. Included in the present invention are anchor devices e.g. suture anchors which are formed entirely of a shape memory polymer material. Embodiments of the present invention comprise hybrid suture anchors, particularly suture anchors which are formed from a shape memory polymer material and a non-shape memory material. Methods of securing an anchor in a bone or tissue are also included in the present invention.

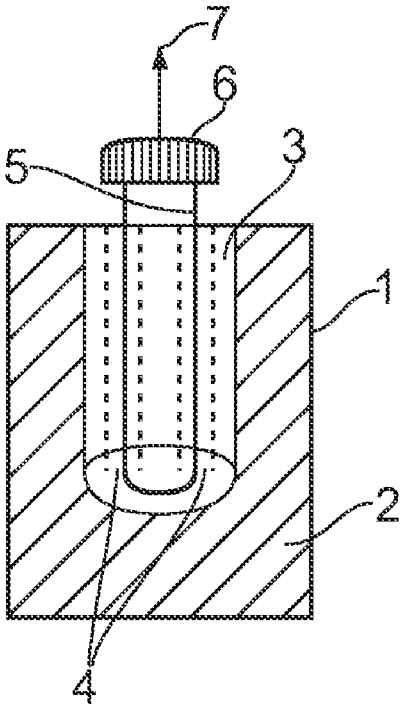

FIG. 1

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Medical Devices Containing Shape Memory Polymer Compositions

Field of the Invention

The present invention relates at least in part to surgical devices which comprise a shape memory polymer material composition. Particularly, although not exclusively, the present invention relates to a fixation device e.g. an anchor device e.g. a suture anchor which comprises a shape memory material. Included in the present invention are anchor devices e.g. suture anchors which are formed entirely of a shape memory polymer material. Embodiments of the present invention comprise hybrid suture anchors, particularly suture anchors which are formed from a shape memory polymer material and a non-shape memory material. Methods of securing an anchor in a bone or tissue are also included in the present invention.

Background to the Invention

Suture anchors and sutures are used in a number of orthopaedic procedures to reattach soft tissue to bone. Examples of procedures that involve the use of anchors and/or sutures include: procedures in the shoulder for example rotator cuff repair and treatment of glenohumeral instability (e.g. repair of Bankart and SLAP lesions); procedures in the hip region e.g. repair of the labrum in the hip and procedures in the foot and ankle region e.g. repair of ligaments/tendons.

Suture anchors usually fail because the anchor pulls out, the suture cuts out the eyelet of the anchor or simply the suture breaks.

Often, it is desirable to use suture anchors with the smallest possible diameter, yet which still provide adequate fixation strength, particularly when carrying out repairs on joints with limited bone volume. Smaller anchors require smaller drill holes, and are less traumatic for the patient. They also provide more flexibility to the surgeon in positioning the anchor or anchors. A problem associated with reducing the size of an anchor is that there is generally a reduction in fixation strength. This reduction in fixation strength generally limits the minimum size of anchors that can be used. This problem can be worsened if the quality of the bone is poor, which may especially be the case in older patients. A further disadvantage of current methods and systems is caused by the accidental drilling of oversized holes. This can occur if the drill is inadvertently moved or allowed to “wobble” during drilling. If a conventional anchor is then placed in an oversized hole the fixation strength can be greatly reduced.

Conventional suture anchors are typically formed from metals, bioresorbable polymers (such as polylactide or polylactide-co-glycolide) (PLGA) or non-bioresorbable polymers (such as PEEK). To improve fixation in bone the anchor design may include external ridges, ribs, fins or barbs; alternatively it may include an external screw thread. Other devices may use a pin to mechanically expand flanges on the anchor that aid fixation.

Due to the complex geometry of the anchors they are usually manufactured by injection moulding techniques, hence only a limited amount of molecular orientation can be imparted to the polymeric implant.

There remains a need to provide suture anchors and other fixation devices which can function in a range of bone qualities. There remains a further need to provide suture anchors and other fixation devices which are smaller in diameter than existing anchors and which offer equal or better fixation strength.

It has been proposed that shape memory polymers (SMPs) can be used in tissue anchors to improve fixation. International Patent with publication number WO 2008/118782 (Cotton et al,) describes an anchor made from polylactide-co-glycolide (PLGA) and calcium carbonate where the device deforms at body temperature to increase fixation.

US 8,069,858 (Gall, Medshape Solutions, Inc) describes an anchor that comprises a shape memory polymer portion that is triggered by a physical force below the activation temperature of the polymer. The device described in US8069858 appears to require mechanical activation in order for the device to change shape.

It is an aim of embodiments of the present invention to address the disadvantages of the prior art.

Summary of the Invention

In a first aspect of the present invention, there is provided a fixation device for use to secure itself and/or a further device in a cavity, the fixation device comprising a Shape Memory Polymer (SMP) material, wherein the SMP material is capable of radial expansion when activated such that the fixation device expands radially in at least a section of its length.

Aptly, the fixation device is selected from a pin, a tac, a screw, a rod, a nail, a plate, an anchor and a wedge.

Aptly, the fixation device is a surgical device.

Aptly, the fixation device is a suture anchor.

Aptly, the fixation device is capable of undergoing radial expansion and longitudinal contraction and/or a geometry change when the SMP material is activated. Aptly, the fixation device undergoes a geometry change upon activation. Aptly, the fixation device undergoes a dimensional change upon activation.

In one embodiment, the suture anchor comprises an anchor body comprising a distal portion and a proximal portion. Aptly, the anchor body comprises a passage extending from the distal portion toward the proximal portion. Aptly, the passage is a through passage.

Aptly, the anchor body comprises one or more circumferential ribs. In one embodiment, the circumferential ribs extend from the outward surface of the anchor body following activation of the SMP material. Aptly, the circumferential ribs only protrude from an outer surface of the device upon activation of the SMP material.

Aptly, the fixation device comprises screw threads along its length.

Aptly, the fixation device is formed integrally from a single piece of SMP material.

Aptly, the fixation device comprises a portion comprising the SMP material and a further portion comprising a non-SMP material. Aptly, the further portion consists of the non-SMP material. In one embodiment, the further portion is formed by a process of overmoulding. In one embodiment, the further portion is formed by injection moulding.

As used herein, the term “non-SMP material” is taken to include materials which do not possess shape memory qualities, i.e. do not change shape back towards an initial shape when heated or otherwise activated. Examples of such materials as described herein. Aptly, the non-SMP material may be a polymer which has not undergone programming to impart shape memory qualities thereto. Aptly, the non-SMP material comprises a plastic e.g. a moulded plastic.

Aptly, the fixation device comprises one or more circumferential ribs composed of the non-SMP material.

Aptly, the fixation device is for the delivery of a fluid. In one embodiment, the device comprises a chamber which comprises a fluid. Aptly, the radial expansion is capable of causing the fluid to be released from the chamber to the environment surrounding the device.

Aptly, the device comprises an inner portion which comprises the SMP material.

In an embodiment, the device comprises one or more limbs which extend outwardly upon activation of the SMP material. Aptly, the limbs comprise the SMP material.

Aptly, the SMP material comprises a polymer selected from the group consisting of 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.

Aptly, the SMP material comprises a polyester.

Aptly, the SMP material comprises a polylactide. Aptly, the SMP material comprises poly(L-lactide) e.g. a co-polymer thereof. Aptly, the SMP material comprises a poly(D,L-lactide) co polymer. In one embodiment, the SMP material comprises a poly(DL-lactide-co-glycolide) (PDLGA) co polymer e.g. a PDLGA co polymer having a ratio of 85 (DL-lactide):15 (glycolide). Alternatively, the ratio is e.g. 70:30, 75:25, 80:20 or 90:10.

In one embodiment, the SMP material further comprises a filler. Aptly, the SMP material comprises a bioceramic material. Aptly, the bioceramic is selected from a calcium phosphate, a calcium carbonate and a calcium sulphate and combinations thereof. Aptly, the SMP material is buffered to enhance strength retention. Suitable buffering agents include calcium carbonate.

Aptly, the SMP material further comprises a plasticiser, a bioactive agent and/or a pharmaceutical agent. Further details of suitable plasticisers, bioactive agents and pharmaceutical agents are disclosed herein. Aptly, the non-SMP material comprises a biocompatible polymer and/or a biocompatible composite. In one embodiment, the non-SMP material is resorbable.

In one embodiment, the non-SMP material is selected from polylactide, polyglycolide, polycaprolactone, poly(lactide-co-glycolide), polydioxanone, polyurethane, a blend of one or more thereof, and a copolymer thereof. Aptly, the non-SMP material is a polymer that has not undergone programming to impart shape memory properties.

Aptly, the non-SMP material is non-resorbable. In one embodiment, the non-SMP material is a non-resorbable polymer selected from the group consisting of polyetheretherketone (PEEK), a polyurethane and a polyacrylate.

Aptly, the device has a diameter of less than about 3mm. In one embodiment, the device has a diameter of approximately 2mm or less e.g. 1mm, 1.2m, 1.5mm or 1.7mm.

In a further aspect of the present invention, there is provided a method of repairing a soft tissue comprising; placing a device as described herein and having a flexible member coupled thereto in a cavity in a bone, passing the flexible member through a soft tissue located adjacent to the bone and tying the flexible member to secure the soft tissue to the bone; and activating the SMP material such that the device undergoes a radial expansion in at least a section of its length.

Aptly, the method is carried out on a human patient. Aptly, the method is carried out on an animal patient.

Aptly, the step of activating the SMP material comprises applying heat to the SMP material. Aptly, the method comprises contacting the SMP material with a heated probe.

Aptly, the method comprises a first step of forming the cavity in the bone and placing the device in the cavity. Aptly, the flexible member is a suture.

Aptly, the soft tissue is selected from a tendon, a ligament, a muscle, and cartilage and a combination thereof. Aptly, the method is for the repair of a rotator cuff.

In one embodiment, the method is for the repair of an anterior cruciate ligament (ACL). Aptly, the method is for the treatment of glenohumeral instability e.g. repair of Bankart and SLAP lesions. Aptly, the method is for the treatment of hip labral tear.

According to an aspect of the present invention, there is provided shape memory sutures that expand in thickness and shrink in length suitable for use in wound closure. Aptly, the

suture is mechanically attached to a fixation device described herein. Aptly the suture is inserted with the fixation device e.g. anchor into a cavity drilled on the bone and passed through the tissue to be fixed.

In an embodiment, multiple anchors are provided to fixate multiple sutures.

Brief Description of Drawings

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

Figure 1 illustrates an embodiment of the present invention situated in Sawbones;

Figure 2 illustrates the push out force of a shape memory polymer material (SMP) suture anchor as illustrated in Figure 1 after 9 days of immersion. A poly (DL-lactide-co-glycolide) (85:15) (PLC) die drawn rod 9mm in diameter was inserted into a hole drilled onto Sawbones (20pcf), ensuring that it remained "loose" i.e a force of 0N was initially required to pull the rod out of the hole. The PLC rod comprises 35% w/w calcium carbonate. The Sawbones with the PLC rod (anchor) was immersed in water at 37C for 9 days. The push-out force was measured with the Instron apparatus operated at 1mm/min;

Figures 3a and 3b illustrate an SMP suture anchor of the present invention which shortens and expands radially upon activation to fixate into the surrounding bone;

Figures 4a to 4d illustrate alternative embodiments of a suture anchor according to the present invention comprising multiple fixation ribs;

Figures 5a to 5c illustrate alternative embodiments of a suture anchor according to the present invention comprising upward directing fixation ribs;

Figures 6a to 6b illustrate alternative embodiments of a suture anchor according to the present invention comprising SMP levering elements;

Figures 7a and 7b illustrate an SMP suture;

Figures 8a and 8b illustrate an SMP anchor comprising fixation elements;

Figures 9a and 9b are cross sectional views of the anchor of Fig.8a and 8b;

Figures 10a and 0b illustrate an SMP anchor with multiple axle fixation elements;

Figure11a and 11b are cross sectional views of Fig.10a and 10b;

Figures12a and12b show an SMP anchor with fixation elements;

Figures 13a and 13b are cross sectional views of Fig.12c-12b;

Figures 14a and 14b show an SMP anchor with folded fixation elements;

Figures 15a and 15b show an SMP anchor with fixation elements contained within an oriented section of the device;

Figures 16a and 16b show an SMP clip;

Figures 17a to 17d show various tissue closure SMP devices according to the present invention;

Figures 17e illustrates performance data from SMP sutures;

Figures 18a and 18b illustrate an embodiment of the present invention which comprises a SMP fluid delivery device;

Figures 19a and 19b illustrate an embodiment of the present invention which comprises a SMP fluid delivery device;

Figures 20a and 20b are cross sectional views of Fig.19a and19b;

Figure 21 illustrates a SMP suture sleeve which forms a fixation aid post insertion;

Figure 22 illustrates an SMP anchor with a suture hole and activation region (hole);

Figures 23a to 23c illustrate an embodiment of the present invention comprising a SMP suture anchor which is capable of relaxing in the longitudinal direction following implantation;

Figures 24a to 24c illustrate an embodiment of the present invention comprising an anchor with a dedicated SMP portion which directs a portion of the anchor into a fixation position;

Figure 25 illustrates an embodiment of the present invention comprising an SMP anchor with a dedicated SMP portion which clamps and fixes the suture following relaxation of the polymer;

Figure 26a and 26b illustrate an embodiment of the present invention comprising an SMP suture containing two different areas of memory orientation. Following relaxation a portion of the SMP relaxes in the longitudinal direction to fix the anchor in place;

Figure 27a illustrates an embodiment of the present invention comprising an SMP anchor with multiple suture eyelets in a vertical direction;

Figure 27b illustrates an embodiment of the present invention comprising an SMP anchor with suture eyelets in a longitudinal direction;

Figure 27c illustrates an embodiment of the present invention comprising an SMP anchor with shaped grooves to accommodate a suture material;

Figure 28a and 28b illustrate an embodiment of the present invention comprising an anchor with an SMP pin which directs a portion of the anchor into a fixation position following relaxation;

Figure 29a and 29b illustrate an embodiment of the present invention comprising an SMP suture tack with a SMP portion which shortens in the vertical direction and lengthens in the longitudinal direction to fixate the device;

Figure 30a illustrates an embodiment of the present invention comprising an anchor with an SMP collar which fixates the suture following relaxation;

Figure 30b and 30c illustrate an embodiment of the present invention comprising a barbed suture anchor with an SMP portion running longitudinally through the length of the device. Following relaxation of the SMP the barbed portion is forced outwards causing fixation;

Figure 30c illustrates an alternative embodiment of Fig. 30b;

Figure 31a and 31b illustrate an embodiment of the present invention comprising an injection moulded pronged suture anchor. Shape memory properties are added to the prongs via compression moulding;

Figure 32a and 32b illustrate an embodiment of the present invention comprising a suture anchor with an SMP portion which causes the suture to be secured by a fixation element following relaxation of the SMP;

Figure 32c illustrates a SMP tube used in Fig 10a-10b;

Figure 33a and 33b illustrate an embodiment of the present invention comprising a suture anchor with an SMP element which upon relaxation causes the device to fixate (figure 33a – post fixation);

Figure 34a and 34b illustrate an embodiment of the present invention comprising a suture anchor with an SMP portion. Following relaxation in the longitudinal direction the anchor fixates into the tissue;

Figure 34c and 34d illustrate an embodiment of the present invention comprising a suture anchor with an internal SMP feature which causes the device to fixate following relaxation;

Figure 35 illustrates the device of three embodiments of the present invention which comprise an SMP portion;

Figure 36 is a graphical representation of a slotted SMP rod prototype according to the present invention;

Figure 37 is a graph showing the pull-out test results in 10PCF Sawbones, 2.6mm holes as described in Example 7;

Figure 38 is a graph showing the pull-out testing of SMP rod anchors in 10PCF Sawbones in standard and oversized holes as described in Example 8;

Figure 39 is a graph showing the results of pull-out testing in laminated 15/30PCF “Sawbones” foam as described in Example 9;

Figure 40 is a graphical representation showing pre- and post-recovery appearance of tested devices – Left hand side: Hybrid Anchor Prototype 3; right hand side 2.7mm SMP rod anchor;

Figure 41 illustrates a knotless suture anchor produced using methods described in Example 12;

Figure 42 illustrates a suture anchor as described in Example 13;

Figure 43 illustrates a suture as described in Example 14;

Figure 44 illustrates an embodiment of the present invention which comprises an SMP portion and a non-SMP portion;

Figure 45 shows further views of the non-SMP portion of the device of Figure 44;

Figure 46 illustrates a further embodiment which comprises a suture anchor device which is composed entirely of an SMP material;

Figure 47 illustrates a tool for aiding insertion of the suture anchor illustrated in Figure 46. The tool also includes a heater; and

Figure 48 shows further views of the suture anchor illustrated in Figure 46.

Detailed Description of Embodiments of the Invention

Further details of embodiments of the present invention are described below.

The present invention comprises the use of a shape memory polymer (SMP) material. In an embodiment, the SMP material resides in a deformed state below a certain temperature, known as the glass transition temperature (Tg) and is activatable from the deformed state to the relaxed state above this temperature. Generally, polymeric materials that display shape memory properties show a large change in modulus of elasticity at the glass transition temperature (Tg). Shape-memory properties are utilized by taking advantage of this characteristic. Namely, a macroscopic body of polymeric shape memory material to which a definite shape (the original shape) has been imparted by a common method for moulding plastics, can be softened by providing the article with energy and heating to a final

temperature (Tf) higher than the Tg of the polymer, but lower than the melting temperature (Tm). At this temperature, the material can be deformed so as to form a different macroscopic shape (the deformed state). In the deformed state an oriented polymer network is formed. The polymeric material is then cooled to a temperature lower than the Tg, whilst maintaining its deformed state.

A device of the invention comprises a polymeric shape memory material. Shape memory polymers, which can be resorbable or non-resorbable, are known in the art and any biocompatible polymeric shape memory material can be used in the context of the present invention. Aptly, the SMP material comprises a polymer selected from the group consisting of polymethyl methacrylate (PMMA), polyethyl methacrylate (PEMA), polyacrylate, poly-alpha-hydroxy acids, polycaprolactones, polydioxanones, polyesters, polyglycolic acid, polyglycols, polylactides, polyorthoesters, polyphosphates, polyoxaesters, polyphosphoesters, polyphosphonates, polysaccharides, polytyrosine carbonates, polyurethanes, and copolymers or polymer blends thereof.

Aptly, the SMP material comprises a polylactide. In one embodiment, the SMP material comprises poly(L-lactide). In one embodiment, the SMP material comprises poly(D-lactide).

In one embodiment, the SMP material comprises a poly(D,L-lactide) co polymer.

Aptly, the SMP material comprises a poly(DL-lactide-co-glycolide) (PDLGA). Aptly, the SMP material comprises polyglycolide.

Aptly, the SMP material comprises polycaprolactone and/or a co-polymer comprising polycaprolactone.

Aptly, the SMP material comprises an L-lactide/DL-lactide co-polymer.

Aptly, the SMP material comprises lactide/caprolactone copolymer.

Aptly, the SMP material comprises a poly(L-lactide) and polyglycolide copolymer.

In the context of the present invention, deformation of the polymeric shape memory material is generally achieved prior to implantation of the device, generally during manufacture. The input of heat sufficient to reach Tf achieved using electrical and/or thermal energy sources and this is followed by deformation of the polymeric material. Deformation leads to an

oriented polymer network and can be achieved by processes including zone drawing, hydrostatic extrusion, die drawing, compression flow molding, thermoforming, rolling and roll drawing.

When the polymeric material is heated again to a temperature higher than the glass transition temperature of the SMP material, but lower than the Tm, the deformed state disappears and the polymeric material relaxes to recovered its original shape. The input of energy necessary to cause the polymeric material to relax from its deformation state to its relaxed state is known as activation. The glass transition temperature of the polymer material 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 and may be in the region of between 35-60°C or greater. Aptly, the glass transition temperature is up to about 130 °C. Aptly, the glass transition temperature is about 70 °C or more e.g. 80 °C, 90 °C, 100 °C, 110 °C or 120 °C.

Embodiments of the present invention relate to devices which alter shape *in situ* through recovery of a SMP material towards its original shape. As used herein the terms “recovery” and “recover” are interchangeable with the terms “relaxation” and “relax” and are terms well known to the person skilled in the art.

In one embodiment, the fixation device is selected from a pin, a rod, a nail, a screw, a plate, an anchor and a wedge.

Aptly, the fixation device is an intramedullary nail.

In one embodiment, the fixation device is an anchor. Aptly, the anchor is a suture anchor. Aptly, the anchor is a knotless suture anchor. Aptly, the anchor comprises one or more grooves on an outer surface thereof which are sized to accommodate one or more sutures therein. Aptly the suture anchor comprises a non-SMP material component and an SMP material component. Aptly, the non-SMP material component comprises the grooves. In one embodiment, the grooves extend the length of the device on two opposing outer surfaces of the anchor and across a distal end of the anchor.

In one embodiment, the suture anchor is composed entirely of an SMP material and the SMP material component comprises the grooves.

Embodiments of the present invention may provide an advantage over prior art suture anchors in that the anchor eyelet failure may be reduced and/or the failure load increased. Embodiments of the present invention may provide a suture anchor which has a greater fixation strength in poor-quality and/or low density bone e.g. osteoporotic bone.

Tissue anchors such as suture anchors may fail during insertion when they are screwed in. Embodiments of the present invention may also provide an advantage in that, since they do not require screwing in during insertion, failure may be avoided.

Compared with standard conventional anchors, embodiments of the present invention provide an anchor which has a smaller cross-section and/or length while maintaining equivalent or higher pull-out strength.

In an embodiment, the present invention provides a fixation device e.g. a suture anchor which comprises a portion comprising an SMP material and a portion comprising a non-SMP material. Such an embodiment may provide an advantage that initial fixation may be achieved by the non-SMP material portion and subsequently the fixation strength of the device may be further enhanced over time by the SMP material portion. In one embodiment, the SMP material is activated at body temperature (e.g. approximately 37°C) and the SMP material portion expands when placed in the body to further fix the device in place.

Fixation devices comprising an SMP material portion and a non-SMP material portion may also be advantageous in that complex design features and shapes can be formed by conventional injection moulding of a non-SMP material and fixation can be enhanced by the SMP material component which can be a simple shape, for example a rod or cylinder, made by a process such as die-drawing. Aptly, the device can be made by placing an SMP material component in a mould and injection moulding a non-SMP material into the mould, thus overmoulding the non-SMP material onto the SMP material component.

The non-SMP elements of the device may be made of any biocompatible polymer or composite, either resorbable or non-resorbable. Examples of resorbable materials include polylactide, polyglycolide, polycaprolactone, poly(lactide-co-glycolide), polydioxanone, polyurethane or any blend or copolymer of these materials. Examples of non-resorbable polymers include polyetheretherketone (PEEK), polyurethanes, polyacrylates etc. the polymer may be blended with fillers including bioceramics such as, for example, calcium phosphates, calcium carbonates, calcium sulphates and the like.

The SMP components may be made of any of the polymers described herein suitably processed to impart shape memory properties. Methods of imparting shape memory properties include processes to orient the polymer chains and include die drawing, zone drawing, hydrostatic extrusion, rolling, roll drawing, compression moulding. The SMP component may also include plasticizers to modify the glass transition temperature/activation temperature. It may also include other additives such as iron oxide nanoparticles to enable activation by a magnetic field. Activation of the SMP component may be by heat (including body temperature), absorption of a plasticizer such as water, electromagnetic field, ultrasound or any other method or combination of methods.

Compared with standard conventional anchors the SMP anchor allows the use of a smaller drill hole/anchor while maintaining equivalent or higher pull-out strength. Another advantage is greater fixation strength in poor-quality or low density bone (e.g. osteoporotic bone). Yet another advantage is that fixation can be achieved in oversized holes – for example if the hole is accidentally over-drilled. The device can be very simple and in some embodiments does not require feature such as ribs, ridges or barbs. Aptly, the device is easier to insert than conventional fixation devices. In other embodiments, the device may comprise one or more barbs, ribs or ridges. Aptly, the barbs, ribs or ridges are used to improve the fixation of the device once the SMP material has been activated.

An advantage of embodiments of the present invention which comprise SMP material components and non-SMP components is that initial fixation can be achieved by a conventional non-SMP part and then fixation strength can be further enhanced over time by an SMP component that is activated at body temperature. This does not necessarily require any external heating/energy source to activate the SMP.

Another advantage is that complex design features and shapes can be made by conventional injection moulding of a non-SMP and fixation further enhanced by the SMP component that can be a very simple shape such as a rod or cylinder made by processes such as die-drawing. No complex process or apparatus is required to programme the SMP device.

The devices of the present invention can be manufactured using known techniques for forming SMP materials for example die drawing.

Aptly, the device may be manufactured using a method which includes a step of overmoulding non-SMP material and therefore producing a device which includes non-SMP material portions.

Aptly, the device may be manufactured by a method comprising cold forging so as to impart a complex shape to the device.

Details of process for the manufacture of hybrid devices can be found in our co-pending patent applications which have a common priority to the present patent application. The subject matter of our co-pending patent applications and the priority applications are hereby incorporated herein by reference in their entirety.

In an embodiment, one or more active agent is incorporated into the device. Suitable active agents include bone morphogenic proteins, antibiotics, anti-inflammatories, angiogenic factors, osteogenic 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. It will be appreciated that other bioactive agents known to one of ordinary skill in the art may also be used. Aptly, the active agent is incorporated into the polymeric shape memory material, to be released during the relaxation or degradation of the polymer material. Advantageously, the incorporation of an active agent can act to combat infection at the site of implantation and/or to promote new tissue growth.

Aptly, the SMP material comprises a filler. In one embodiment, the filler comprises an inorganic component. Aptly, the filler comprises calcium carbonate, calcium hydrogen carbonate, calcium phosphate, dicalcium phosphate, tricalcium phosphate, magnesium carbonate, sodium carbonate, hydroxyapatite, bone, phosphate glass, silicate glass, sodium phosphate, magnesium phosphate, barium carbonate, barium sulphate, zirconium carbonate, zirconium sulphate, zirconium dioxide, bismuth trioxide, bismuth oxychloride, bismuth carbonate, tungsten oxide and combinations thereof.

Aptly, the SMP material comprises approximately 0.5% or greater by weight of a filler as described herein. Aptly, the SMP material comprises 0.5%, 1%, 2%,3%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40% or greater by weight of a filler.

The present invention contemplates the use of electrical and thermal energy sources to heat the polymeric material. However, the polymer material could be relaxed via other methods

known to those of ordinary skill in the art, including, but not limited to the use of force, or mechanical energy, and/or a solvent. Any suitable force that can be applied either preoperatively or intra-operatively can be used.

One example includes the use of ultra sonic devices, which can relax the polymer material with minimal heat generation. Solvents that could be used include organic-based solvents and aqueous-based solvents, including body fluids. Care should be taken that the selected solvent is not contra indicated for the patient, particularly when the solvent is used intra-operatively. The choice of solvents will also be selected based upon the material to be relaxed. Examples of solvents that can be used to relax the polymer material include alcohols, glycols, glycol ethers, oils, fatty acids, acetates, acetylenes, ketones, aromatic hydrocarbon solvents, and chlorinated solvents.

Aptly, the SMP material portion of the device is activated by way of heating when inserted into the cavity. In one embodiment, the SMP portion of the device is activated by contacting the SMP material portion with a heated probe or the like.

In one embodiment, the SMP material portion is activated by contact with an aqueous media which has a temperature of about 37°C i.e. body temperature. Aptly, the SMP material comprises a plasticizer which lowers the Tg of the SMP material so that it is activated by contact with an aqueous media having a temperature close to body temperature e.g. about 37°C. Thus, in one embodiment the SMP material portion is capable of activation upon insertion into a patient's body.

Reduction of the SMP material's Tg may be achieved by inclusion of a plasticiser. Aptly, the SMP material comprises a plasticiser. Plasticisers or mixtures thereof suitable for use in the present invention may be selected from a variety of materials including for example organic plasticisers and those that do not contain organic compounds.

Aptly, the plasticiser is selected from DL-lactide, L-lactide, glycolide, ε-Caprolactone, N-methyl-2-pyrolidinone and a hydrophilic polyol e.g. poly(ethylene) glycol (PEG).

Plasticisers or mixtures thereof suitable for use in the present invention may be selected from a variety of materials including organic plasticisers and those that do not contain organic compounds.

Aptly, the plasticiser is an organic plasticiser e.g. a phthalate derivatives such as dimethyl, diethyl and dibutyl phthalate; a polyethylene glycol with a molecular weight e.g. from about 200 to 6,000, glycerol, glycols e.g. polypropylene, propylene, polyethylene and ethylene glycol; citrate esters e.g. tributyl, triethyl, triacetyl, acetyl triethyl, and acetyl tributyl citrates, surfactants e.g. sodium dodecyl sulfate and polyoxymethylene (20) sorbitan and polyoxyethylene (20) sorbitan monooleate, organic solvents such as 1,4-dioxane, chloroform, ethanol and isopropyl alcohol and their mixtures with other solvents such as acetone and ethyl acetate, organic acids such as acetic acid and lactic acids and their alkyl esters, bulk sweeteners such as sorbitol, mannitol, xylitol and lycasin, fats/oils such as vegetable oil, seed oil and castor oil, acetylated monoglyceride, triacetin, sucrose esters, or mixtures thereof.

Aptly, the plasticiser is selected from a citrate ester; a polyethylene glycol and dioxane.

In an embodiment, the device comprises reinforced polymeric material. Aptly, the reinforced polymeric material comprises a composite or matrix including reinforcing material or phases e.g. fibers, rods, platelets and fillers. Aptly, the polymeric material can include glass fibers, carbon fibers, polymeric fibers, ceramic fibers and/or ceramic particulates. Other reinforcing material or phases known to one of ordinary skill in the art could also be used.

Once the device has been produced, it may be sterilized for example by exposing it to radiation (e.g. gamma radiation) or treating it with gases (e.g. chemical sterilization such as exposure to ethylene oxide gas). Methods of sterilizing devices are known in the art, and the skilled person may select a method appropriate for the device in question.

Description of Embodiments

In the drawings like reference numerals refer to like parts.

Amorphous poly(D,L lactide-co-glycolide) with 35% w/w $CaCO_3$ (PLC) fibres were prepared using a twin screw extruder. The fibres were pelletised and consolidated into isotropic long cylindrical rods with various diameters ranging from 5mm to 20mm using a ram extrusion technique. Oriented rods 3mm and 9mm in diameter were prepared by die drawing the isotropic rods (5mm and 20mm, respectively) using a conical die at 60C and a drawing speed of 20mm/min.

Figure 1 illustrates an artificial construct **1** which was made to replicate the in-vivo use of the proposed suture anchors. Two holes **4** were drilled along the long axis of a die drawn

cylindrical PLC rod 9mm in a diameter **3**. A polyester suture **5** was inserted (making a U turn) through both holes mimicing a suture anchor.

The rod was inserted into a hole drilled onto Sawbones™ (20pcf) **2** ensuring that it remained "loose" i.e a force of 0N was initially required to pull the rod out of the hole. The Sawbones™ with the rod in the hole was immersed into water at 80°C for 10 seconds and the rod expanded quickly into the hole, forming a tight interference with the cavity walls. The suture was clamped **6** to a spring balance and a force of 180N **7** was reached just before the sutures broke. The expanded rod did not come out and it was concluded that the relaxation of shape memory anchor was responsible for the tight fit.

Figure 3a illustrates a cylinder **8**, made of shape memory material, with a single or double central hole or holes **9** through which a suture is fed **10**. The anchor is inserted into a pre-drilled hole in the bone **10** with a press fit. Upon heating, the cylinder **8** will shorten along its y-axis, the central hole(s) will shrink in diameter and the outside edges of the cylinder will "accordion" resulting in circumferential ribs **11** thus digging into the surrounding bone and providing an interference fit, increasing the interfacial resistance and providing a solid anchor as demonstrated in Fig.3b. Figure 3b illustrates the suture anchor once the shape memory material has been activated.

Figure 4 illustrates embodiments of the present invention comprising accordion shapes that have a single rib 11 as shown in Figure 4a, a triple rib 11a, 11b and 11c as shown in Figure 4b or a quadruple rib 11a, 11b, 11c, and 11d as shown in Figure 4c.

It is envisaged that other embodiments may comprise between 1 and 10 ribs. The ribs may be either pointed or curved, the curved embodiment being shown in Figure 4d. The ribs may be either continuous or non continuous along the length of the cylinder. The device may or may not comprise a central bore in these embodiments.

Figure 5 illustrates a further embodiment which will, upon heating, have circumferential ribs (11g, 11h, 11i, 11j, 11k,) that point upwards in a similar manner to a barb (see Figure 5a). As above, the central hole will close as the length of the cylinder decreases. The number of circumferential barbs can be between 1 and 10 (Fig 5b-5c).

A further embodiment is illustrated in Figure 6a which comprises an anchor **12** that levers itself into the drill hole **13**. The anchor will initially have downward pointing barbs **14** on its surface which fit into the drill hole as part of the total diameter of the anchor.

Figure 6b illustrates the embodiment of Figure 6a upon activation e.g. by heating in which the diameter 15 of the anchor increases and the length 16 decreases. At the same time, the barbs **14** flip through ninety degrees to secure the anchor in place, but also to drive the anchor into the full depth of the drill hole, ensuring there is no gap behind it. The number of barbs can vary between 1 and 10.

Figure 7a illustrates a shape memory polymer suture thread **17.** Upon heating, small sections **18** of the thread will contract to elicit either pointed or round circumferential ribs along the length of the suture. Figure 7b illustrates the suture thread following activation e.g. by heating. The ribbing increases the grip and stability of the suture in the tissue. The ribbing may be barbed for example.

Figures 8a and 8b illustrate a device of an embodiment of the present invention to effect fixation by utilising the shape changing nature of SMPs. An SMP anchor tube **19** has holes **20**, from which spikes **21** emerge following activation of the SMP material structure **22**.

Figure 9a and 9b shows a detailed cross sectional view of the device illustrated in Figure 8. The spikes **21** may be continuous with the SMP and composed of the SMP material or may be a different material physically connected to the SMP structure **19**. When activated, as shown in Figure 9b, the SMP structure **22** undergoes a vertical contraction, causing straightening of bent components, to force spikes **21** out of the device **19**. This allows insertion, subsequent activation of the SMP **21** and thus enhanced fixation. Spikes which emerge due to SMP transformation may be used in multiple axes around the circumference of the device and/or numerous times along the length of the device.

Figures 10a and b illustrate a device of an embodiment of the present invention to effect fixation by utilising the shape changing nature of SMPs. The device has holes **24**, from which spikes **26** emerge following activation of the SMP structure **25**.

Figure 11 is a cross sectional view of the device envisaged in Figure 10. The pre-activated form of the device is shown in Figure 11a. The spikes **26** may be continuous with the SMP and composed of SMP or may be a different material physically connected to the SMP structure **25**. When activated, as shown in Figure 11b, the SMP structure **25** undergoes a vertical contraction, causing shortening/widening of the SMP component **25**, to force spikes **26** out of the device **23** to allow insertion, subsequent activation of the SMP **25** and thus enhanced fixation. Spikes which emerge due to SMP transformation may be used in

multiple axes around the circumference of the device and/or numerous times along the length of the device.

Figure 12 illustrates a device of an embodiment of the present invention to effect fixation by utilising the shape changing nature of SMPs. Figure 12a shows a device pre-activation An SMP anchor tube **27** has holes **28**, from which spikes **29** emerge following activation (as shown in Figure 12b) of the SMP structure **30**.

Figures 13a and 13b show a cross sectional view of the device depicted in Figure 12. The spikes **29** may be continuous with the SMP and composed of SMP or may be a different material physically connected to the SMP structure **30**. When activated, as shown in Figure 13b, the SMP structure **30** undergoes a vertical contraction, causing shortening/widening of the SMP component 30, to force spikes **29** out of the device **27**. This will allow insertion, subsequent activation of the SMP **30** and thus enhanced fixation. Spikes which emerge due to SMP transformation may be used in multiple axes around the circumference of the device and/or numerous times along the length of the device.

Figures 14a and 14b illustrate a device to effect fixation by utilising the shape changing nature of SMPs. An SMP anchor tube **31** has fins which are folded in **32**, in the unactivated (Fig.14a) state, but these unfold (Fig.14b) when activated to effect enhanced fixation. Folded fins which emerge due to SMP transformation may be used in multiple axes around the circumference of the device and/or numerous times along the length of the device.

Figures 15a and 15b illustrate a device to effect fixation by utilising the shape changing nature of SMPs. An SMP anchor tube **33** has thinner orientated sections **34** along the length. The thin sections 34 have spikes **35** mounted on them to allow insertion. The spikes **35** may be continuous with the SMP and composed of SMP or may be a different material physically connected to the SMP structure **34**. When activated, as shown in Fig.15b, the SMP structure **34** undergoes a vertical contraction, causing shortening/widening of the SMP component **35**, to force spikes **35** radially outward to allow insertion, subsequent activation of the SMP **35** and thus enhanced fixation. Spikes which emerge due to SMP transformation may be used in multiple axes around the circumference of the device and/or numerous times along the length of the device.

A device to effect a closure action is shown in Figures 16a and 16b. Figure 16a shows the device pre-activation. The SMP clip component **35** is activated (as shown in Fig.16b) to

effect closure **36** of a clip device to cause a clipping (or pinching) action on activation of the SMP.

Figures 17a to 17d illustrate various embodiments comprising a range of devices to effect fixation by utilising the shape changing nature of SMPs. A pin **37** (which has a geometry with a regular cross section, or alternatively a cross section which tapers to a point such as a needle) is shown in Figures 17a to 17d. On activation, the device transforms geometry from pin **37** to a helical structure 38 (Figure 17a); a planar zig-zag structure 39 (Figure 17b), a loop structure 40 (Figure 17c) or a knot structure 41 (Figure 17d).

This device may also be used to effect closure to bring tissues together. Amorphous poly (D,L lactide-co-glycolide) (PDLAGA) with 35% w/w $CaCO_3$ (PLC), PDLAGA and poly(D,L lactide) (PDLA) fibres were prepared using a twin screw extruder. The fibres were drawn using the zone drawing technique in which the fibre is pulled at constant force through a local heater at 60°C.

Figure 17e illustrates the shrinkage properties of orientated fibres at 30°C. PDLAGA, PLC and PDLA drawn fibres were immersed into water at 30C and 37C. In Figure 17e, it is shown that at 30 °C after 9 days the shrinkage of PLC and PDLAGA are very similar, but at 16 days and thereafter PDLAGA shrinks and swells more than PLC. PDLA at 30°C only shrinks about 6% after 23 days. At 37 °C PLC, PDLAGA and PDLA drawn fibres shrink completely after 1 day in water at 37C, recovering the dimensions of the undrawn fibres.

Figure 18a and 18b illustrate a device to deliver a fluid upon activation by utilizing the shape changing nature of SMPs. A device **42**, shown in a pre-activation form in Figure 18a, comprises a vessel for fluid **43** acts to deliver the fluid on activation of the SMP **44** (as shown in Figure 18b), by causing a contraction of the internal volume of the device. The fluid may be a cement, drug, curing agent, material repair agent, antibiotic etc. A thin membrane may be used to prevent premature delivery of fluid. The expulsion of a fluid may be used as a cement or glue to effect fixation.

Figures 19a and 19b illustrate a device to deliver a fluid upon activation. A device **45** comprising a vessel for fluid acts to deliver the fluid **49** through a designated release point **48** on activation of the SMP component **47** in combination with a restricting end piece **46**.The fluid may be a cement, drug, curing agent, material repair agent and/or antibiotic. A thin membrane may be used to prevent premature delivery of fluid. Figure 19a illustrates a pre-activation form and Figure 19b illustrates the device on activation of the SMP material.

Figure 20a and Figure 20b show a cross sectional view of the device of Figure 19. The fluid **49** is contained within a cavity enclosed by the walls of the device **45**, and end pieces 46 which may be continuous with the SMP component **47** or made of non-SMP material but physically connected to the SMP component **47**.

On activation (shown in Figure 20b) of the SMP component **47**, the SMP component **47** reduces length, and increase thickness, bringing end pieces **46** closer together and causing fluid **49** to be expelled through orifice **48**. A thin membrane may be used to prevent premature delivery of fluid through the orifice **48**. The expulsion of a fluid may be used as a cement or glue to effect fixation.

Figure 21 illustrates a thin die-drawn polymer sleeve **50a** which is placed over a suture **51a**. The internal diameter is approximately the same as the suture diameter. A knot **51b** is provided in the distal end of the suture. Optionally the distal end of the sleeve is tapered to aid penetration into tissue. The sleeve and suture are pushed through the tissue **52**, probably, but not necessarily, through a pre-formed hole until the sleeve clears the tissue. Heat is then applied to the sleeve when the suture is in tension and the sleeve polymer relaxes forming a washer **50b** which will securely stop the knot from being pulled back through the tissue. This forms an anchor for the suture to be used to hold parted tissue to the first tissue.

Figure 22 illustrates a plug of die-drawn polymer **53** with two holes **(54, 55)** for use as a suture anchor into bone **56** tissue. The first hole **54** is off-centre in the plug and has a suture passed through it and tied off in a knot. The second hole **55** is for insertion of a heater tool to permit the polymer to 'relax' and expand to form a secure fastening into the hole. The suture is then anchored securely into the bone.

Figure 23 illustrates a suture anchor which is formed from a round SMP billet by forming it into a long anchor when drawn. This can be released into a thick cylinder shaped material upon activation by an appropriate stimulus. Figure 23a depicts an oval shaped suture anchor **57** with a centrally orientated hole **58** which accommodates the suture material **60**. The device can be inserted into a prepared anchor site (Figure 23b), which can be an orthopaedic site with cortical 61 and cancellous bone **62** containing a hole **59**. The device **57** is deployed by inserting it vertically into the pre-prepared hole **57**, with the suture material **60** running through the device **58**. Upon activation (shown in Figure 23c), the anchor device **57**

flips into a longitudinal direction and forms a circular disc shape fixating the suture **60** into the anchor site **59**.

Alternatively, anchor devices can be modified with shape memory materials to aid fixation in a site. Figure 24a depicts a pronged device **63** which can be composed of either shape memory material or non-shape memory material, a suture **65** and an additional activation aid **64**. This activation aid can be composed of a shape memory material and can be in an orientation or shape. Fig 24b illustrates an example orthopaedic site with cortical **67** and cancellous bone **68**, with a pre prepared anchor site **66** containing the exemplary device **63.** A suture **65** can be threaded under the device **63**. Upon activation Fig 24c the device prongs **63** move outwards. This is assisted by the activation aid **64** which can be composed of shape memory material and relaxes in the longitudinal direction forcing the device prongs further.

Shape memory materials can also be used to aid the fixation of the suture material within the device. Figure 25 shows a threaded anchor device **66** with a shape memory component **67a**. The suture material **68** is fed through the small gap **67b** in the shape memory component **67a** into a wider cavity **67c**. The threaded device is screwed into place then the shape memory component **67a** is activated, fixating the suture material firmly in place.

Anchors can be manufactured with alternative stressed components which allows for the tailoring of material properties to aid fixation. Figure 26a depicts a shape memory device **70** with two different stressed material components; area **71** a low stress area and area **72** a high stress area. The device **70** is inserted in a pre-prepared anchor site **75** within a cortical **73** and cancellous **74** bone structure, with a suture material **69a** threaded through a device hole **69b**. Upon activation, as shown in Figure 26b, the high stress portion **72** of the device **70** deforms so that the final diameter increases fixating the device with the cancellous bone **74**. The lower stress portion **71** also deforms to fixate within the cortical bone **73**.

Shape memory anchors can be modified geometrically or physically to accommodate suture materials. Figure 27a shows a shape memory anchor **76** with multiple holes **77a-c** in the vertical direction to accommodate a figure of eight **78** suture configuration. Alternatively the holes **79** can be in the longitudinal direction as depicted in Figure 27b to accommodate alternative suturing configurations **78** in the device **76**.

Alternatively the geometry of the shape memory device can be modified as to accommodate the suture materials, as shown in Figure 27c. The tapered oval device **80** has central

grooves **81** machined out so the suture material **78** can be fixated within these following activation.

Shape memory anchors can be also utilised to fixate pins and other orthopaedic devices within the body. Figure 28 illustrates a shape memory anchor **83** with a split prong configuration **86** and a tapered hole **84** for receiving a pin **85** or other device. Figure 28b illustrates an activated device where the pin **85** has been pushed into the central tapered hole **84**. The devices fixation prongs **86** relax in the longitudinal direction and the pin **84** has been fixated within the device **83**.

Fixation devices such as tacs and pins can also be constructed from shape memory materials with various properties to enable enhanced fixation. These anchors can also be used in conjunction with other orthopaedic devices such as sutures and plates. Figure 29a depicts a shape memory tac **87** which has an SMP portion **88** and a non-SMP head. The tac can optionally contain a hole **90** for threading sutures **91** or other devices through. Upon activation (Fig 29b) the SMP portion's (**88**) width (y) becomes wider and the shaft shorter, thus fixating the device with the application site. The non-SMP head portion **89** retains its original geometry and fixates the device on top of the surface.

Fixation screws such as those depicted in Figure 30a can be modified with SMP to aid fixation of both the implant and additional intrinsic devices such as sutures. The threaded screw **92** contains a shape memory collar **93** running the circumference of the device **93**, with an optional hole **95** running longitudinally through the centre of the device to house the suture material **94**. Upon activation the shape memory collar **93** grips the suture **94** and fixates the device **92** in place.

In addition Figure 30b to d shows additional examples of tac fixation devices modified with shape memory material to aid fixation. Figure 30b shows a tac fixation device **96** with an internal shape memory component **97** which contains a hole **98** for a suture material **99**. The device also contains a head portion **100** with additional fixation aids **101** positioned on the lower half of the tac **102**. Upon activation (as shown in Figure 30c) the lower half **102** of the shape memory portion **97** relaxes forcing it outwards and engaging the fixation aids **101** into the surrounding tissue. The suture hole **98** also constricts fixing the suture **99** in place. The tac can also have shape memory portions along alternative lengths of the device as shown in Figure 30d. The device **96** contains a shape memory portion **97** in the central region **102** of the device with fixation aids **101** also positioned within this area. Upon activation the

shape memory portion **97** relaxes in the longitudinal direction forcing the fixation aids **101** in an outward direction.

Various processing methods can be used to generate shape memory devices. Figure 31a depicts an injection moulded shape memory device **103** with two forked prongs **105** situated in the bottom half of the device **104** and a suture hole **106.** This open position device is cold pressed forcing shape memory properties into appropriate regions of the device. Figure 31b shows the cold compressed device with the forked prongs **105** situated within region **104** device in a closed position. The forks **105** have the shape memory properties and will expand outwards upon activation by an appropriate stimulus.

Shape memory materials may be used as a locking mechanism within existing devices to fixate various items or to initiate a change in another material. Figure 32a depicts a shape memory anchor device **107**, with shape memory portions **109** and gripping member **108** within the shape memory portions **109**. The suture material **101** is passed through the gripping member **108** and within the gripping member containment zone **111**. Upon activation (as shown in Figure 32b) the shape memory portions **109** relax causing the gripping member **108** to fixate the suture **110** within gripping member containment zone **111**. Alternatively the gripping member **108** can be solely composed of shape memory material within a non shape memory device. Upon activation the gripping member **108** will relax fixating the suture in place within the device. Shape memory tubes may also be used in combination with sutures to fixate them within an appropriate surgical site. Figure 32c shows a SMP tube **112** with a suture **110** running through the centre.

Shape memory may also be used to activate non- shape memory devices. Figure 33b shows a pre-activation barbed anchor device **112** with an eyelet **113**, a suture material **114** running through the eyelet **113,** and a shape memory portion **115** contained within a particular segment of the device **116**. Upon activation (as shown in Figure 33a) the shape memory portion **115** relaxes and forces the top segment of the device **116** outwards causing fixation.

If a shape memory device moves during relaxation it may result in a loss in tension of the suture material. Fig 34a depicts a device which overcomes the problems associated with the loss of tension and positioning of suture materials. The device **117** contains a shape memory portion **118** and a shape memory/non-shape memory portion **119** with an eyelet **122,** and a suture attachment region **120** threaded through the eyelet **122**. The suture **121** is threaded through the suture attachment region **120**. The device is then inserted into a pre-prepared site (Fig 34b) in cortical **123** and cancellous bone **124**. Upon relaxation the shape memory

portion **118** forms a bar structure fixating and tensioning the suture **121** through the suture attachment region **120** into the device.

Figure 34c depicts an alternative embodiment where the device **117** is composed of a shape memory material **118** with an outer skin composed of a non-shape memory skin **119**. The device also has an additional suture attachment region **120** which allows for a suture material **121**. Upon relaxation (Fig 34d) the shape memory portion **118** relaxes in a longitudinal direction forcing the suture **121** to be tensioned and positioned within the suture attachment region **120**.

Figure 44 and Figure 45 illustrate an embodiment of the present invention, a device **200** which comprises an SMP material portion and a non-SMP material portion. In particular, Figure 44 illustrates a schematic representation of a process used to make the device **200**. The device **200** is formed from an SMP material component **202** and a non-SMP component **204** e.g. moulded plastic. The non-SMP component **204** includes one or more grooves **210a, b** on an outer surface thereof which are sized to accommodate one or more sutures **206,208.** The sutures pass down the length of the groove on a first lateral surface, around the distal end **212** of the anchor and up the opposing lateral surface. In use, the SMP material component is activated, causing radial expansion of the SMP material component, and causing the sutures to be held against the surface of the cavity in which the anchor is placed.

Figure 46 illustrates a further embodiment which comprises a suture anchor device **300** which is composed entirely of an SMP material. The device **300** includes one or more grooves **310a, b, c, d** on its outer surface which are sized to accommodate a suture as described above. The device **300** includes one or more central channels **314a, b** to accommodate the guide rods of the tool **400**.

Figure 47 illustrates a tool **400** for aiding insertion of the suture anchor illustrated in Figure 46. The tool **400** includes a pair of guide rods **402a,** b which fits into the channels **314a, b** of the device to aid insertion. The tool also includes a heater, which may be supplied by the guide rods.

Examples

Example 1

Hybrid Anchor Prototype 1

To produce a rod for die-drawing, 500g of poly(DL-lactide-co-glycolide) (PDLGA) 85:15 supplied by Purac Biomaterials was vacuum dried at 50°C for 3 days. The dried polymer was stored in sealed bags containing desiccant sachets until needed. The polymer was then extruded using a Prism extruder with a 3mm die, air-cooled haul-off belt, caterpillar haul-off with an air-cooling ring placed between the belt and caterpillar haul-offs. The polymer was fed to the extruder at 750g/hr using a computer controlled pellet feeder and a screw speed of 225 rpm. The extrusion conditions used are shown below.

	Heater zones (°C)					Pressure	Torque
	Inlet	1	2	3	Die	Bar	Nm
Set	0	150	180	190	190	-	-
Recorded	95	156	187	198	188	19-20	8.6-9.9

The haul-off and belt speeds were varied to produce rod diameters between ~3.5 and 1 mm. The rod was chopped in to 0.5 to 1 m lengths as it emerged from the caterpillar haul off. The rods were packed in a plastic tube with desiccant and placed in a freezer.

Shape-memory polymer rod was then produced by die-drawing. Die-drawing of rod produced above was carried out by pulling the rod through a heated die fitted to an Instron 5569 Universal Testing Machine fitted with a 1kN load cell. The die had a 1.5mm diameter and was controlled at a temperature of 65°C. The diameter of the rod pre-drawing was 3.17mm and post-drawing 1.40mm, giving a draw ratio (final length/initial length) of 5.13.

Draw ratio was calculated as:

$$\frac{(\text{Pre-draw diameter})^2}{(\text{Post-draw diameter})^2}$$

The shape-recovery properties of this rod were tested by heating either in air at 80°C or in water at 37°C. Sample lengths were measured periodically until there was no further change in shape.

The recovery ratio and % shape recovery were calculated as follows:

Recovery ratio = Pre-recovery length / Post recovery length

$$\% \text{ Shape Recovery} = \frac{\text{Pre-recovery length - Post recovery length}}{\text{Pre-recovery length - (Pre- recovery length / Draw ratio)}} \times 100$$

In air at 80°C the rod had a Recovery Ratio of 4.5 and a % Shape Recovery of 96.6%. In water at 37°C it had a Recovery Ratio of 4.32 and a % Shape Recovery of 95.5%.

A hybrid SMP anchor was produced by modification of a standard PEEK anchor (BIORAPTOR 2.3PK, produced by Smith & Nephew). 5.5mm deep holes 1.6mm in diameter were drilled in the ends of the anchors, which were then cut on both sides for the full length of the hole. 5mm lengths of the 1.4mm diameter SMP rod were then fitted into the hole. This was labelled Prototype 1 – see Figure 35.

Example 2

Hybrid Anchor Prototype 2

The dried PDLGA of Example 1 was moulded to produce rods approximately 6mm in diameter by 55mm long using a Haake MiniJet Injection Moulder. The moulding conditions were:

Cylinder	190 °C
Mould	40 °C
Injection Pressure	800 bar for 10 seconds
Post Pressure	450 bar for 5 seconds

To produce a shape-memory strip from this rod, the rod was compressed in a press. The moulded rod was heated in an oven between metal plates at 50°C; 0.8mm shims were also placed between the plates to set the desired thickness of the SMP. The plates were then removed from the oven, transferred to a hydraulic press with platens cooled to below 20°C.

The press was then closed immediately and pressure of 200kN applied before the plates or rod had cooled, once the plates and SMP strip product had cooled, the press was opened and SMP strip removed.

A maximum deformation ratio for the SMP strip was calculated as follows:

$$\text{Maximum deformation ratio} = \frac{\text{Original diameter x Original length}}{\text{Strip thickness x Strip length}}$$

The initial rod had a diameter of 5.35mm and a length of 54.52mm; the SMP strip had a thickness of 1.22mm and a length of 60.66mm, giving a deformation ratio of 3.94.

To produce a hybrid anchor using the SMP strip, a 1.3mm wide slot was cut into a BIORAPTOR 2.3PK device and a cut was then made from the top of the slot to the end of the anchor. The slot was filled with an SMP strip cut from the middle of the moulded sheet to fit. This was labelled Prototype 2 – see Figure 35.

Example 3

Hybrid Anchor Prototype 3

Injection moulded rods as described in Example 2 were die-drawn as described in Example 1 except that a 3mm or 2.75mm die was used and the die temperature was 55°C or 58-62°C respectively. The initial diameter of the rods was 5.25mm and the final diameter was either 2.9mm (for the 3mm die) or 2.7mm (for the 2.75mm die).

The 2.9mm samples had a mean draw ratio of 3.21. The recovery properties were measured in water at 37°C as described in Example 1 and the rods were found to have a shape recovery of 99.1%.

The 2.7mm samples had a mean draw ratio of 3.79. The recovery properties were measured in water at 37°C as described in Example 1 and the rods were found to have a mean recovery ratio of 3.4 and a mean shape recovery of 95.41%.

The die-drawn SMP rods were cut to lengths of 4.5mm. The end 4.5mm was removed from BIORAPTOR 2.3PK anchors and replaced by a piece of SMP rod to produce a hybrid anchor. This was labelled Prototype 3 – see Figure 35.

Example 4

2.7mm diameter SMP rod prototypes

The die-drawn 2.7mm rods described in Example 3 were used. The rods were cut to the same length as the BIORAPTOR™ control anchors (11.5mm) and a slot was made at one end to accommodate a suture (Figure 36).

Example 5

1.9mm diameter SMP rod prototypes

A PDLGA 85:15 rod with diameter 3.3mm was produced by extrusion as described in Example 1. The rod was then die-drawn as in Example 1 except that a 2mm die was used

with a drawing temperature of 60°C. The die-drawn SMP rod had a final diameter after drawing of 1.9mm and a draw ratio of 2.99. The recovery properties were measured in water at 37°C as described in Example 1 and the rods were found to have a mean shape recovery of 98.5%.

The rods were cut to the same length as the BIORAPTOR™ control anchors (11.5mm) and a slot was made at one end to accommodate a suture (Figure 36).

Example 6

0.71mm diameter SMP rod prototypes

PDLGA 85:15 rod with diameter 1.57mm was produced by extrusion as described in Example 1. The rod was then die-drawn as in Example 1 except that a 0.75mm die was used with a drawing temperature of 60°C. The die-drawn SMP rod had a final diameter after drawing of 0.71mm and a draw ratio of 4.89. The recovery properties were measured in water at 37°C as described in Example 1 and the rods were found to have a recovery ratio of 3.73 and a shape recovery of 92.0%.

The SMP rod was cut into 5mm lengths and left unslotted.

Example 7

Pull-out testing of Hybrid Anchors in 10PCF “Sawbones™” Foam

The pull-out force was measured using an Instron 5569 fitted with a 1kN load cell. The samples were tested in 10 PCF (pounds per cubic foot) solid rigid polyurethane foam (Sawbones AB, Sweden). The Sawbones foam was cut to produce strips with a 3 x 3 cm cross section to fit in a slotted aluminium support fitted in the lower Instron grip. Holes were drilled in the block using the BIORAPTOR drill (2.6 mm) and drill guide, or other drills, with a spacing of a minimum of 5 x the diameter of the device. The hole dimensions used are shown in the table below.

Table 1: Hole dimensions used for pull-out tests.

Device(s)	Hole dimensions (mm)		
	Diameter	Depth	Spacing
Biroaptor 2.3 PK	2.6	20	18
Combination prototypes 1, 2 & 3			
2.7 mm diameter SMP rods			
1.9 mm daimeter SMP rods			
Biroaptor 2.3 PK	3.0	20	18
Combination prototype 3			
2.7 mm diameter SMP rods			
0.71 mm diameter SMP rods	1.5	10	12
	1.0	10	12

Anchors were inserted into the Sawbones test blocks using the BIORAPTOR™ insertion tool, or for the devices that would not fit the tool, a stiff wire was used. For each experiment, four replicate samples were prepared and tested. For wet testing, the holes were filled with water before device insertion.

Control samples were tested immediately after insertion, shape memory test samples were incubated in water at 37°C to activate shape recovery. The incubation time used was 40 hours for diameters between 2 and 3 mm, 24 hours for diameters less than 2 mm. All samples were allowed to cool to room temperature before testing.

The devices were pulled out of the block by the suture at a rate of 508 mm min^{-1} (20 inches min^{-1}). The maximum load was recorded.

Table 2 and Figure 37 show the pull-out test results for the hybrid anchor devices from 10PCF Sawbones foam. This material is a model for relatively poor quality, low density bone. The results show increased pull-out strength for the activated (post-recovery) SMP-hybrid anchor prototypes 1 and 3 compared to the BIORAPTOR™ control, especially Prototype 3, which had a >400% increase in pull-out force.

Anchor used	Test Conditions	Pull out force (lb)							
		1	2	3	4	Mean	Max	Min	SD
Control: Bioraptor	Dry	18.0	18.0	13.7	12.5	15.5	18.0	12.5	2.66
	Wet	11.6	13.1	13.4	15.8	12.7	15.8	13.4	2.25
Prototype 1, SMP rod in hole, Wet	Pre-recovery								
	Post-recovery	23.5	22.5	23.5	22.3	22.6	23.5	20.5	1.47
Prototype 2, SMP in slots, Wet	Pre-recovery								
	Post-recovery	12.5	13.8	11.7	11.2	12.3	13.8	11.2	1.15
Prototype 3, 2.7 mm SMP, Wet	Pre-recovery	24.8	19.5	20.8	24.8	22.5	24.8	19.5	2.58
	Post-recovery	79.4	75.2	82.1	66.0	68.1	79.4	66.0	11.04
Prototype 3, 3 mm SMP, Wet	Pre-recovery	20.0	13.7	20.5	19.0	20.3	20.0	13.7	5.91
	Post-recovery	86.5	86.5	80.2	87.5	85.3	87.5	80.2	3.47

Table 2: Pull-out test results in 10PCF Sawbones, 2.6mm holes

Example 8

Pull-out testing of SMP rod devices in 10PCF "Sawbones" foam in standard and oversized holes.

Pull-out testing was carried out as described in Example 7 with the SMP rod devices. A 2.6mm hole was used which was a "standard size" for the control BIORAPTOR™ and the 2.7mm rod devices but was oversized for the 1.91mm SMP rod anchor. A 3mm hole was used as an oversized hole for the BIORAPTOR™ control and the 2.7mm SMP rod anchor. The pull-out testing results are shown in Table 3 and Figure 38.

Anchor used (in standard hole unless stated otherwise)	Test Conditions	Pull out force (N)							
		1	2	3	4	Mean	Max	Min	SD
Control Bioraptor	Dry	15.0	13.0	13.7	12.5	13.6	15.0	12.5	2.65
	Wet	11.8	13.1	10.4	12.8	12.7	13.8	10.4	2.25
	Wet 3 mm hole	0.9	0.8	0.9	0.8	0.8	0.9	0.8	0.01
SMP 1.91 mm e rods, Wet	Pre-recovery	5.8	1.9	1.1	2.8	2.9	5.8	1.1	2.04
	Post-recovery	53.3	57.4	51.8	46.1	51.3	57.4	46.1	5.12
SMP 2.7 mm e rods, Wet	Pre-recovery	15.0	19.7	16.1	19.1	16.7	19.7	15.0	0.82
	Post-recovery	117.3	134.8	112.1	122.1	119.1	134.8	112.1	8.99
SMP 2.7 mm e rods in a 3mm hole, Wet	Pre-recovery								
	Post-recovery	108.7	121.9	113.8	104.8	114.8	121.9	104.8	7.47

Table 3: Pull-out testing of SMP rod anchors in 10PCF Sawbones in standard and oversized holes

From the results shown in Figure 38 it can be seen that an activated 2.7mm SMP anchor has a >800% increase in pull-out strength compared to a similarly sized BIORAPTOR control, in a standard hole.

In the oversized hole the BIORAPTOR™ control does not have any significant pull-out-strength. On the other hand the 2.7mm SMP rod has a very similar pull-out strength in both the standard and oversized holes.

The 1.9mm rod in a 2.6mm hole still showed a >300% increase in pull-out-strength compared to the BIORAPTOR control in the same sized hole.

Example 9

Pull-out testing of hybrid anchor and SMP rod anchor in laminated 15/30PCF Sawbones foam in standard holes.

Hybrid Prototype 3, and the 1.91mm and 2.7mm SMP rod anchors, were tested for pull-out strength as described in Example 7 but in this case using a 15PCF "Sawbones" solid rigid polyurethane foam laminated with a 2mm thick layer of 30PCF foam. This model represented normal quality cancellous bone with a denser cortical bone layer. In this case the hole size was 2.6mm. The BIORAPTOR™ control was tested dry and wet. All the SMP-containing anchors were tested wet before or after incubation at 37°C to activate the SMP.

The results of the pull-out testing are shown in Table 4 and Figure 39.

Anchor used	Test Conditions	Pull out force (lb)							
		1	2	3	4	Mean	Max	Min	SD
Control Bioraptor	Dry	106.3	115.6	118.3	111.4	112.7	118.3	106.3	5.66
	Wet	94.0	90.9	79.2	88.6	87.6	94.0	79.2	7.80
SMP 1.91 mm x rods. Wet	Pre-recovery	7.6	12.9	4.9	3.0	7.1	12.9	3.0	4.91
	Post-recovery	58.6	87.4	68.3	37.8	63.2	68.6	27.6	19.44
SMP 2.7 mm x rods. Wet	Pre-recovery	94.6	111.7	94.4	72.0	93.2	111.7	72.0	16.37
	Post-recovery	220.7	262.6	221.1	206.4	240.7	262.6	206.7	14.79
Prototype 3: 2.7 mm SMP. Wet	Pre-recovery	154.2	121.1	136.1	116.6	142.8	154.2	116.6	36.74
	Post-recovery	191.9	215.6	204.4	197.4	198.7	215.6	197.4	12.63

Table 4: Pull-out testing in laminated 15/30PCF "Sawbones" foam

As shown in Table 4 and Figure 39, pull-out forces were much higher than in the "poor quality bone" (10PCF foam) model.

The 1.91mm SMP rod anchor again showed its ability to have good fixation in an oversized (2.6mm) hole.

The 2.7mm SMP rod anchor had a 185% increase in pull-out strength compared to the control BIORAPTOR anchor post-recovery.

The 2.7mm hybrid anchor – Prototype 3 – had a 128% increase in pull-out-strength post-recovery compared to the BIORAPTOR control.

Example 10

Pull-out testing of 0.71mm diameter SMP rod anchors in 10PCF "Sawbones" foam

The 0.71mm SMP rod anchors were difficult to handle and test due to their small size. They were tested for pull-out strength as described in Example 7 with 10PCF "Sawbones" solid rigid polyurethane foam with 1mm and 1.5mm holes. The results are shown in Table 5.

Anchor used	Test Conditions	Pull out force (N)							
		1	2	3	4	Mean	Max	Min	SD
Control Bioraptor in a standard 2.6 mm hole	Dry	18.0	18.0	13.7	12.5	15.5	18.0	12.5	2.86
	Wet	11.8	13.1	18.4	15.6	12.7	15.6	10.4	2.25
0.71 mm ø SMP rod. Post recovery (wet).	1.5 mm hole	4.9	4.0	3.8	3.7	4.1	4.9	3.7	0.54
	1.0 mm hole	8.8	10.8	6.4	9.5	7.8	10.8	5.5	2.38

Table 5: Pull-out testing of 0.71mm SMP rod anchors in 10PCF "Sawbones" foam

Although the pull-out forces are lower than the BIORAPTOR™ control the results show that the SMP device can have appreciable fixation even in oversized holes. Furthermore, while the pull-out strength in the 1.0mm hole is approximately 60% that of the BIORAPTOR, the size of the SMP device is only around one quarter that of the control.

Example 11

Appearance of devices post-recovery

After pull-out testing samples were photographed to record their appearance and the degree of shape-change. Examples are shown in Figure 40.

In all cases, during shape recovery, the SMP in the devices expanded to a larger diameter than the insertion hole. This accounts for the increase in pull-out force observed compared to the control and pre-recovery devices. The SMP did not expand as far in in the 15 PCF sawbones as in the 10 PCF. This is because the 15 PCF sawbones is denser and hence stiffer than the 10 PCF Sawbones, giving more resistance to the expansion of the SMP.

Example 12

Knotless suture anchor

4.3 mm diameter Poly(D,L lactide-co-glycolide) 85:15 rods were prepared using a twin screw extruder. The rods were then die drawn through a 2.0 mm die at 85°C at a rate of 30mm min^{-1}, yielding SMP rod with a diameter of approx. 1.35 mm. The SMP rod was cut to produce approx. 10 mm lengths and pressed to produce a more rectangular cross section: The SMP rod and 0.8mm thick metal shims were placed between metal plates and pressed with a force of 50 kN at 20°C. A 1.0 mm diameter hole was then drilled in the bottom of the device then cleaned up using a scalpel and the end of the device rounded using needle files to yield devices typically 10.20 long, 1.89 mm wide and 0.83 mm thick (figure 41). Two lengths of size 1 ULTRABRAID™ (Smith and Nephew) were then threaded through the hole in the device.

The device was implanted into a 1.8 mm diameter 15 mm deep hole in a 15 PCF Sawbones block so that the top of the device was 2 mm below the surface of the block.

The sutures were marked where they entered the implantation hole, red on one side, blue on the other. Holding the device in place within the hole the sutures were pulled one at a time from the blue side, to pull them through the device. Movement of the markings on the sutures demonstrating that they moved freely through the implanted device and that the tension could be adjusted. The devices were activated to lock the sutures and fix the anchor by immersing the Sawbones block in water and incubating at 37°C for 3 days.

To simulate the use of the device in -vivo, the suture limbs on the side on which they were pulled were cut with a scalpel, leaving only the two “tensioned” limbs.

The fixation strength of the devices was tested by pulling them out of the block and measuring the force required. To do this both suture legs were pulled at the same time, at a rate of 508 mm min-1 (20 inches min-1). Three devices were tested and a mean maximum pull-out force of 45.0 N was recorded.

Example 13

Small suture anchor example 1 (1.4 mm diameter hole).

4.3 mm diameter Poly(D,L lactide-co-glycolide) 85:15 rods were prepared using a twin screw extruder. The rods were then die drawn through a 2.0 mm die at 85°C at a rate of 30mm min^{-1}, yielding SMP rod with a diameter of approx. 1.35 mm. These rods were then cut to produce 7 mm lengths and a slot cut in the bottom (figure 42) into which was fitted a #2 ULTRABRAID™ suture (Smith and Nephew).

The device was inserted by placing it in a syringe needle with the point removed, holding the needle against a 1.4 mm diameter, 8 mm deep hole in 15 PCF sawbones and pushing the device in to the hole by inserting a metal rod down the syringe needle. The devices were activated by immersing the Sawbones block in water and incubating at 37° for 2 days. The fixation strength of the devices was tested by pulling them out of the block and measuring the force required. To do this both ends of the suture were pulled at the same time, at a rate of 508 mm min-1 (20 inches min-1). Four devices were tested and mean maximum pull-out force of 43.8 N was recorded.

Example 14

1.60 mm diameter Poly(D,L lactide-co-glycolide) 85:15 rods were prepared using a twin screw extruder. The rods were then die drawn through a 0.75 mm die at 80°C at a rate of 30mm min^{-1}, yielding SMP rod with a diameter of approx. 0.58 mm. These rods were then cut to produce 12 mm lengths which were folded in half (figure 43 represented by "A") and mounted over a USP size 1 braided multifilament suture (Trogue Ref:75221) (figure 43 – see "B").

The device was then mounted in a delivery tube, such that the two ends of the device were held parallel, protruding from the end with the suture gripped between them. The device was delivered into a 1mm diameter, 8 mm deep hole in 15 PCF Sawbones, by placing the device ends into the hole, then and pushing the device in to the hole by inserting a metal rod down the delivery tube. Three devices were prepared and activated by immersing the Sawbones block in water and incubating at 37° for 3 days. The fixation strength of the devices was tested by pulling them out of the block and measuring the force required. To do this both ends of the suture were pulled at the same time, at a rate of 508 mm min-1 (20 inches min-1). A mean maximum pull-out force of 20.3 N was recorded.

Example 15 – use of overmoulding to produce hybrid device

An over-moulding tool for a screw with a thread was made from steel. A length of polyurethane (PU) die-drawn billet was placed in the mould and overmoulded with the same PU polymer using the Cincinnati Milacron injection moulding machine to produce an overmoulded screw. Immersion in hot water again showed shape recovery of the over-moulded screw.

A screw made in this way was cut in half and polished with diamond paste to reveal its cross-section. This was examined using scanning electron microscopy. No boundary was visible between the die-drawn SMP rod and the overmoulded polymer.

The examples show that suture anchors incorporating SMP show:

- Increased fixation strength especially in poor quality bone;
- Fixation strength that is largely independent of bone quality;
- Fixation strength that is tolerant of overdrilling of the hole;

- Small anchors, with diameter less than 2mm e.g. 1 mm, 1.2, 1.4. 1.6 or 1.8mm , are feasible; and
- Cavities of less than 2mm diameter can be made in the bone e.g. cavities of 1mm, 1.2mm, 1.4mm, 1.6mm or 1.8mm.

Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of them mean "including but not limited to" and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

Features, integers, characteristics or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of the features and/or steps are mutually exclusive. The invention is not restricted to any details of any foregoing embodiments. The invention extends to any novel one, or novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

CLAIMS

1. A fixation device for use to secure itself and/or a further device in a cavity, the fixation device comprising a Shape Memory Polymer (SMP) material, wherein the SMP material is capable of radial expansion when activated such that the fixation device expands radially in at least a section of its length.

2. The fixation device according to claim 1, which is selected from a pin, a screw, a rod, a nail, a plate, an anchor and a wedge.

3. The fixation device according to claim 2, which is a suture anchor and is for fixing in a cavity in a bone.

4. The fixation device according to claim 3, which is capable of undergoing radial expansion and longitudinal contraction and/or a geometry change when the SMP material is activated.

5. The fixation device according to claim 3 or claim 4, wherein the suture anchor comprises an anchor body comprising a distal portion and a proximal portion.

6. The fixation device according to claim 5, wherein the anchor body comprises a passage extending from the distal portion toward the proximal portion.

7. The fixation device according to claim 6, wherein the passage is a through passage.

8. The fixation device according to any of claims 5 to 7, wherein the anchor body comprises one or more circumferential ribs.

9. The fixation device according to claim 8, wherein the circumferential ribs are extend from the outward surface of the anchor body following activation of the SMP material.

10. The fixation device according to any of claims 1 to 7, which comprises screw threads along its length.

11. The fixation device according to any preceding claim, which is formed integrally from a single piece of SMP material.

12. The fixation device according to any of claims 1 to 8, which comprises a portion comprising the SMP material and a further portion comprising a non-SMP material.

13. The fixation device according to claim 10, wherein the further portion consists of the non-SMP material.

14. The fixation device according to claim 11 or claim 12, wherein the further portion is formed by a process of overmoulding.

15. The fixation device according to any of claims 10 to 12, which comprises one or more circumferential ribs composed of the non-SMP material.

16. The fixation device according to any preceding claim, wherein the SMP material comprises a polymer selected from the group consisting of 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.

17. The fixation device according to claim 16, wherein the SMP material comprises a polylactide.

18. The fixation device according to claim 17, wherein the SMP material comprises poly(L-lactide).

19. The fixation device according to claim 17, wherein the SMP material comprises a poly(D,L-lactide) co polymer, wherein optionally the SMP material comprises a poly (L-co DL lactide) co polymer having a ratio of 70 (L-lactide): 30 (DL-lactide).

20. The fixation device according to claim 16, wherein the SMP material comprises a poly(DL-lactide-co-glycolide) (PDLGA) co polymer.

21. The fixation device according to claim 20, wherein the ratio of the co-polymer is 85:15.

22. The fixation device according to any preceding claim, wherein the SMP material further comprises a filler.

23. The fixation device according to claim 22, wherein the SMP material comprises a bioceramic material.

24. The fixation device according to claim 23, wherein the bioceramic is selected from a calcium phosphate, a calcium carbonate and a calcium sulphate and combinations thereof.

25. The fixation device according to any preceding claim, wherein the SMP material further comprises a plasticiser, a bioactive agent and/or a pharmaceutical agent.

26. The fixation device according to any of claims 12 to 25 wherein the non-SMP material comprises a biocompatible polymer and/or a biocompatible composite.

27. The fixation device according to claim 26 wherein the non-SMP material is resorbable.

28. The fixation device according to claim 25 or claim 26 wherein the non-SMP material is selected from polylactide, polyglycolide, polycaprolactone, poly(lactide-co-glycolide), polydioxanone, polyurethane, a blend of one or more thereof, and a copolymer thereof.

29. The fixation device according to any of claims 12 to 25, wherein the non-SMP material is non-resorbable.

30. The fixation device according to claim 29, wherein the non-SMP material is a non-resorbable polymer selected from the group consisting of polyetheretherketone (PEEK), a polyurethane and a polyacrylate.

31. The fixation device according to any preceding claim, wherein the device has a diameter of less than about 3mm.

32. The fixation device according to claim 31, wherein the device has a diameter of approximately 2mm.

33. A method of repairing a soft tissue comprising; placing a device according to any preceding claim in a bone, passing a flexible member through a soft tissue located adjacent to the bone; tying the flexible member to secure the soft tissue to the body

and activating the SMP material such that the device undergoes a radial expansion in at least a section of its length.

34. The method according to claim 33, wherein the step of activating the SMP material comprises applying heat to the SMP material.

35. The method according to claim 34, which comprises contacting the SMP material with a heated probe.

36. The method according to any of claims 33 to 35, comprising a first step of forming a cavity in the bone and placing the device in the cavity.

37. The method according to any of claims 33 to 36, wherein the flexible member is a suture and optionally wherein the device has the flexible member coupled thereto prior to placement in the cavity.

38. The method according to any of claims 33 to 37, wherein the soft tissue is selected from a tendon, a ligament, a muscle, and cartilage and a combination thereof.

39. The method according to any of claims 33 to 38, wherein the method is for the repair of a rotator cuff.

40. The method according to any of claims 33 to 38, wherein the method is for the repair of an anterior cruciate ligament. (ACL).

41. The method according to any of claims 33 to 38, wherein the method is for the treatment of glenohumeral instability.

42. The method according to any of claims 33 to 38, wherein the method is for the treatment of hip labral tear.

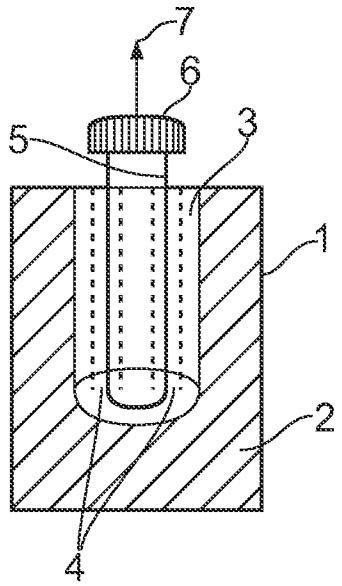
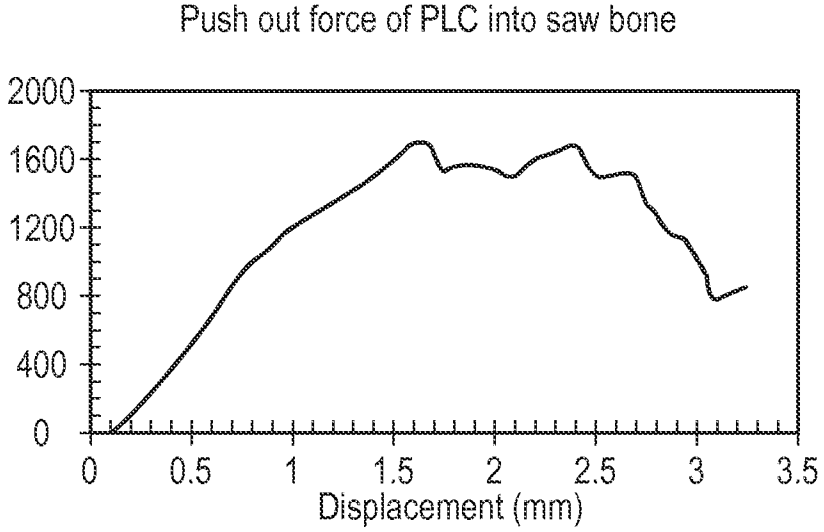


FIG. 1



Push-out force of PLC die drawn rod inserted into sawbone after 9 days in water at 37C

FIG. 2

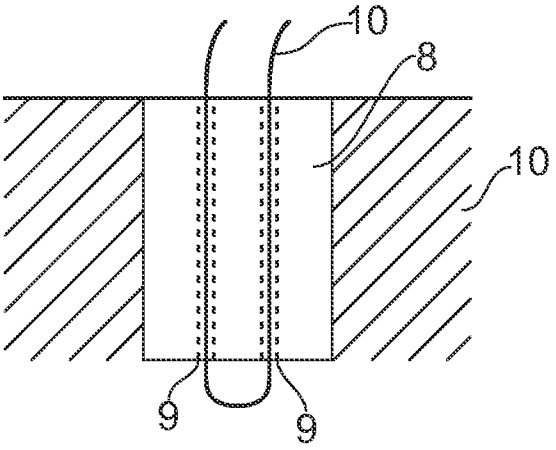


FIG. 3a

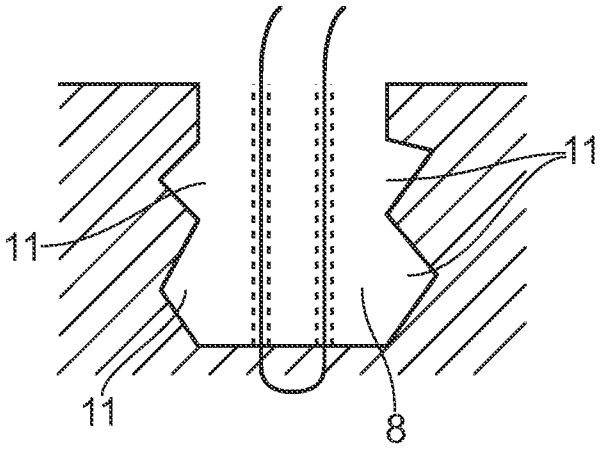


FIG. 3b

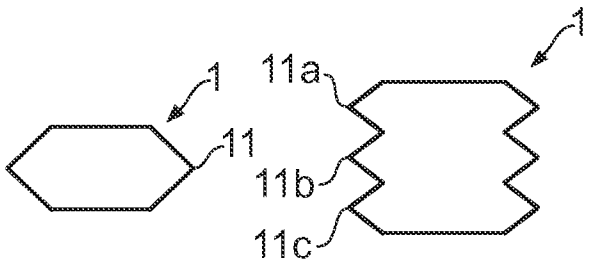


FIG. 4a FIG. 4b

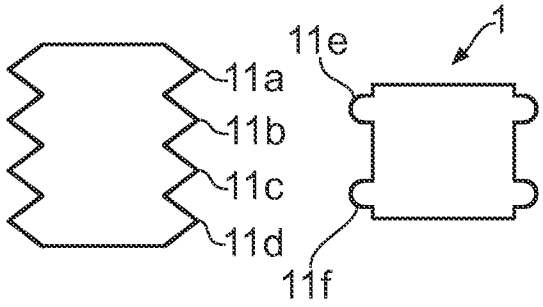


FIG. 4c FIG. 4d

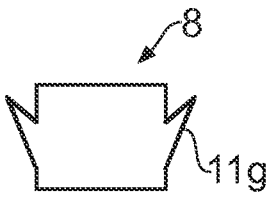


FIG. 5a

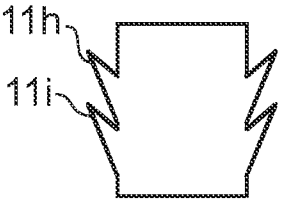


FIG. 5b

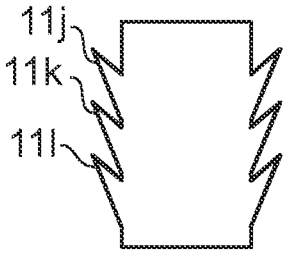


FIG. 5c

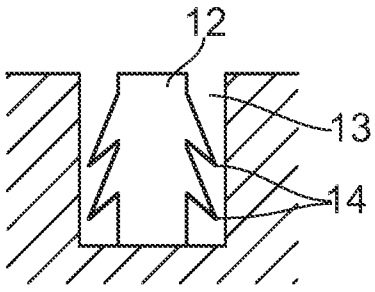


FIG. 6a

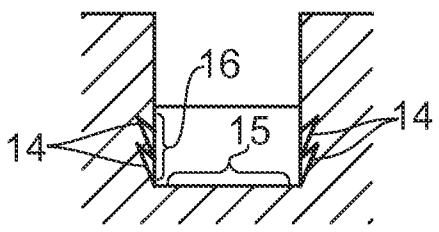


FIG. 6b

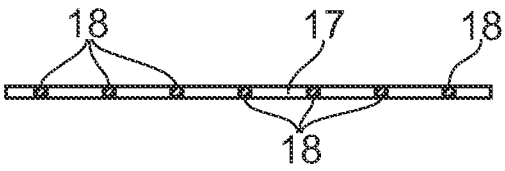


FIG. 7a

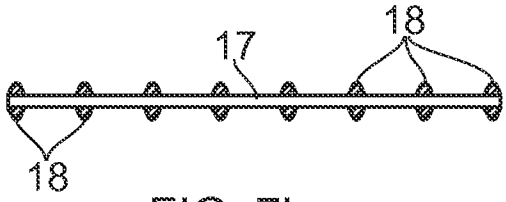


FIG. 7b

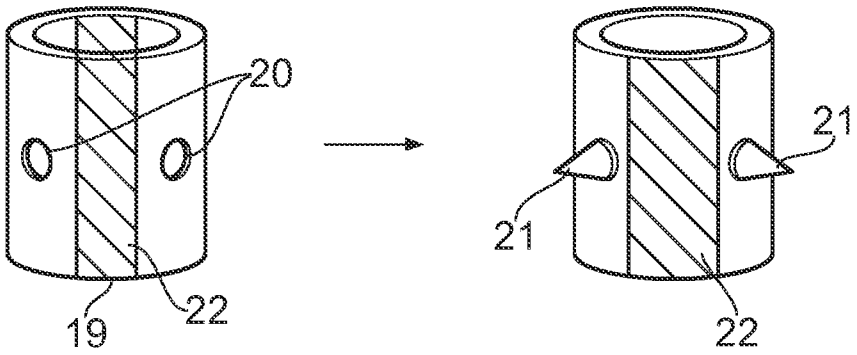


FIG. 8a

FIG. 8b

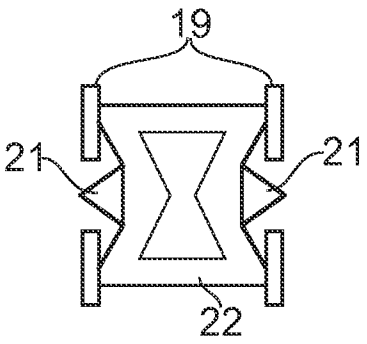


FIG. 9a

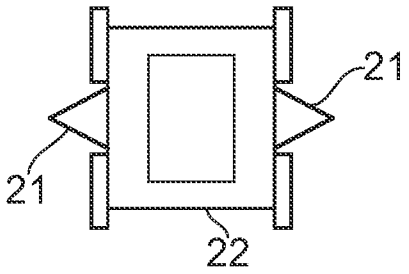


FIG. 9b

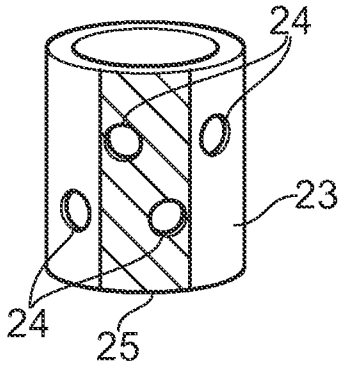


FIG. 10a

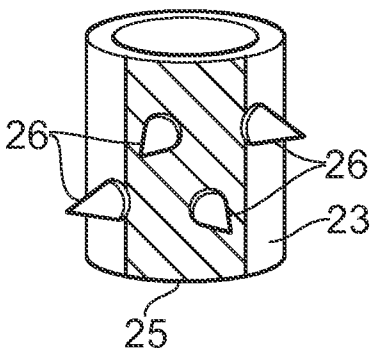


FIG. 10b

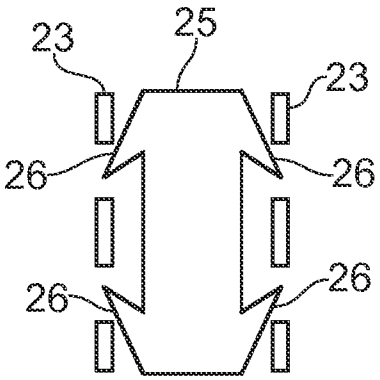


FIG. 11a

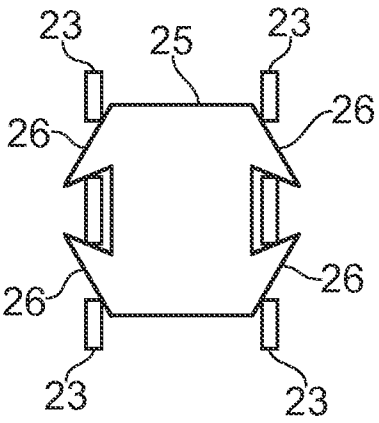


FIG. 11b

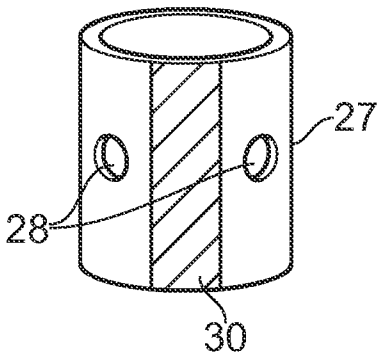


FIG. 12a

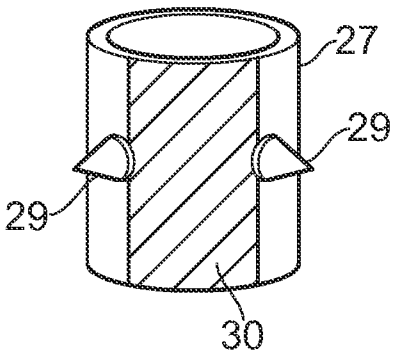


FIG. 12b

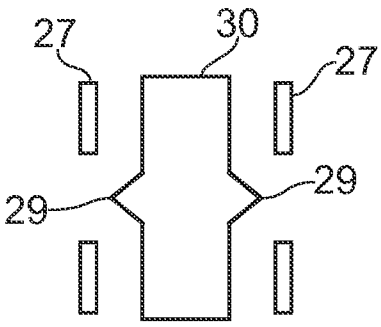


FIG. 13a

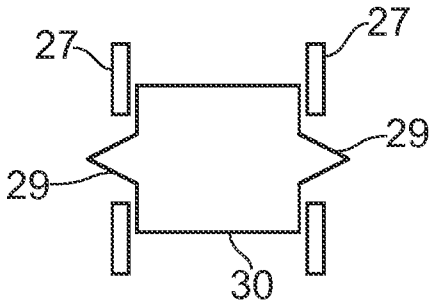


FIG. 13b

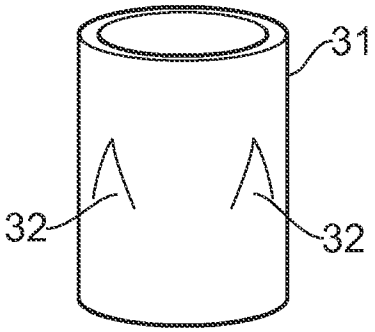


FIG. 14a

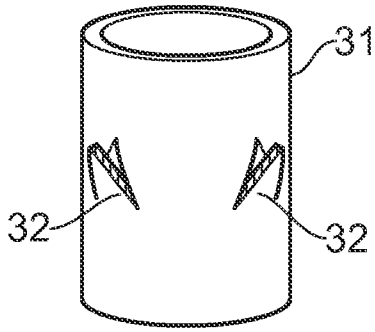


FIG. 14b

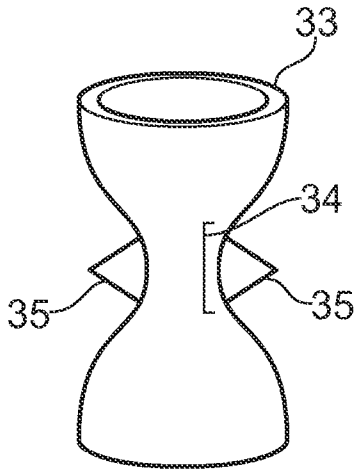


FIG. 15a

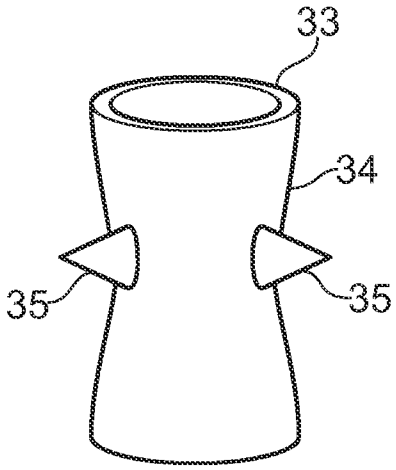


FIG. 15b

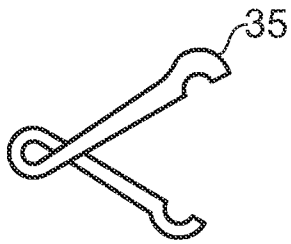


FIG. 16a

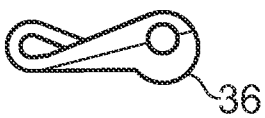


FIG. 16b

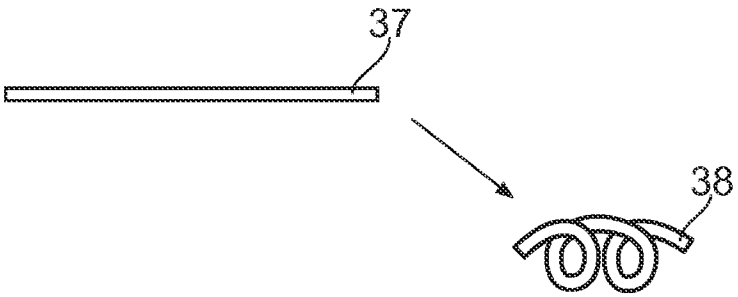


FIG. 17a

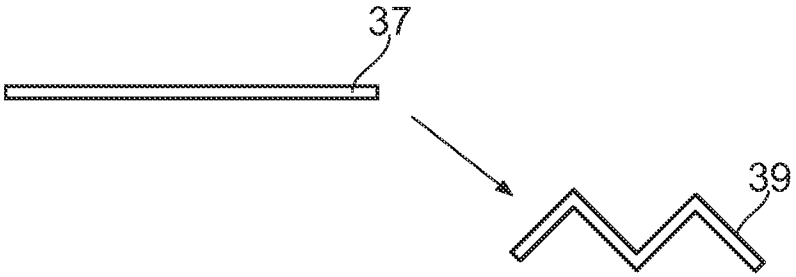


FIG. 17b

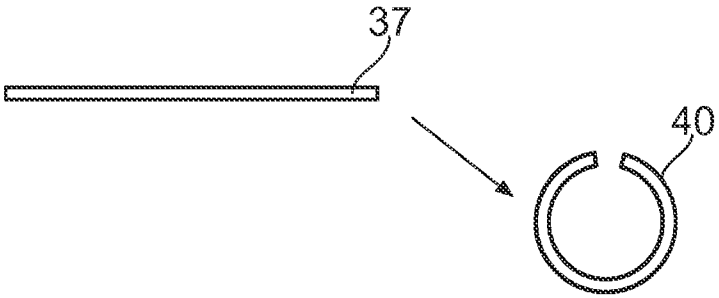


FIG. 17c

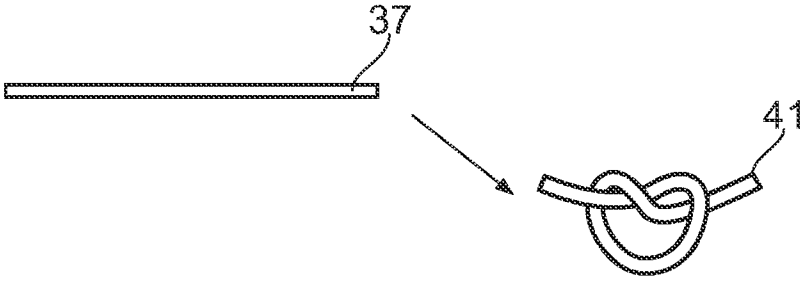
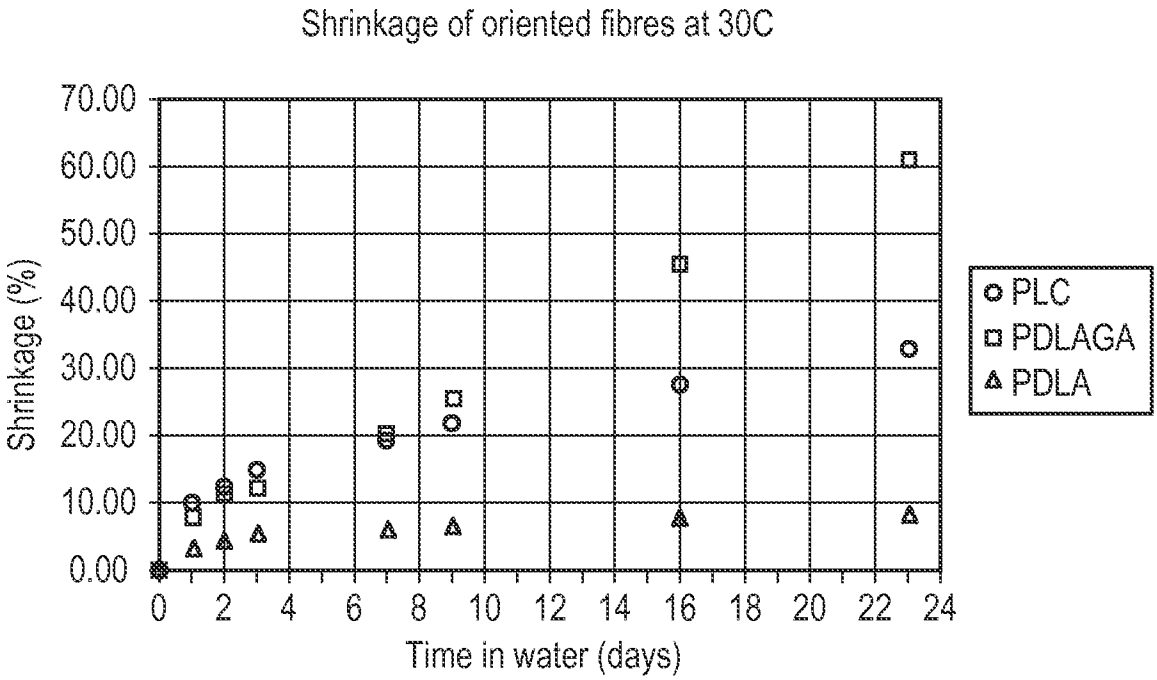


FIG. 17d



Shrinkage of PLC, PDLAGA and PDLA oriented fibres at 30C

FIG. 17e

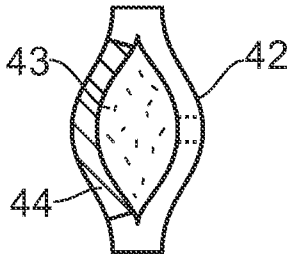


FIG. 18a

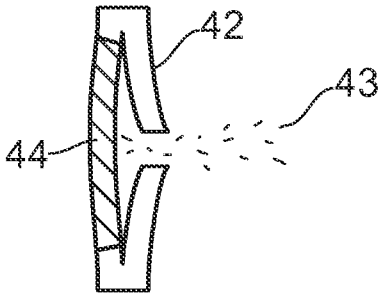


FIG. 18b

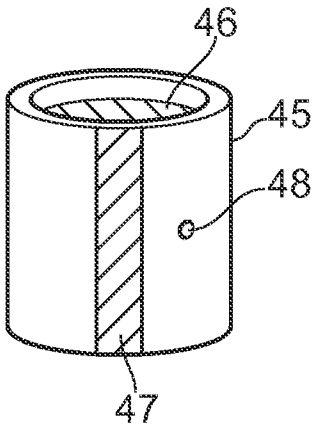


FIG. 19a

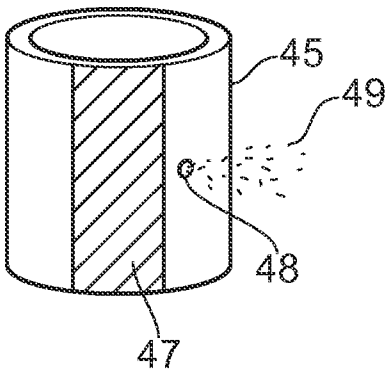


FIG. 19b

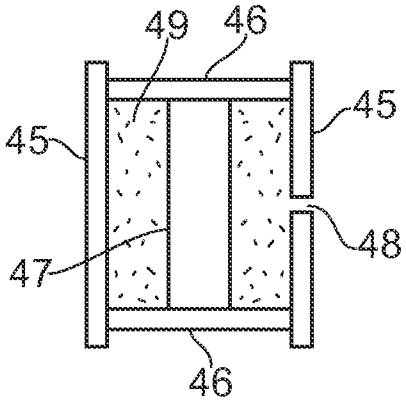


FIG. 20a

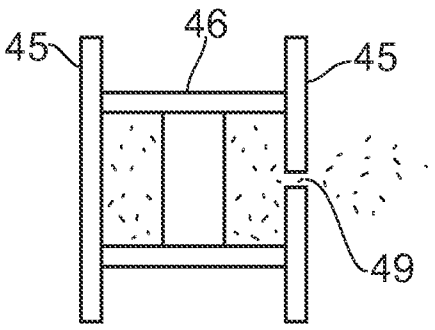


FIG. 20b

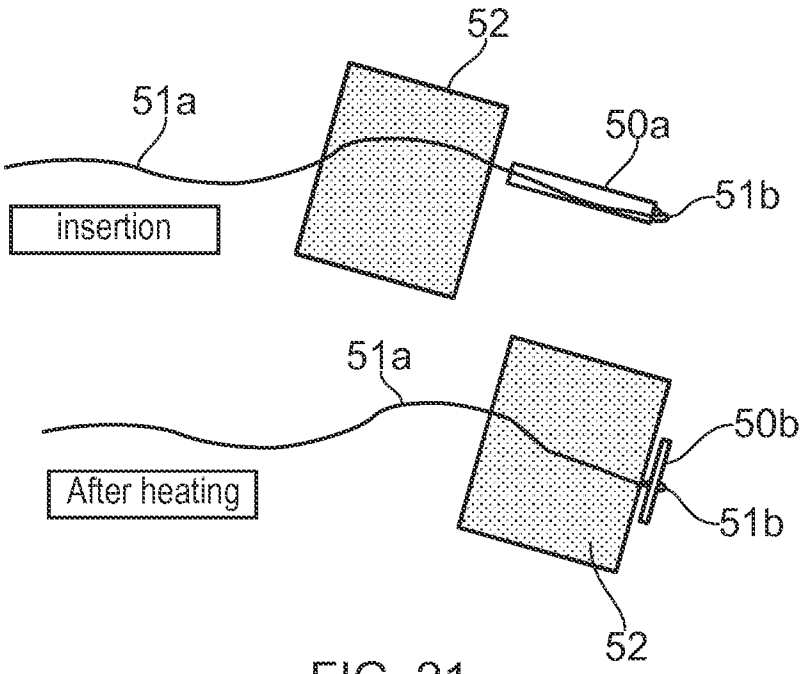

52
51a
50a
51b
insertion
51a
50b
After heating
51b
52

FIG. 21

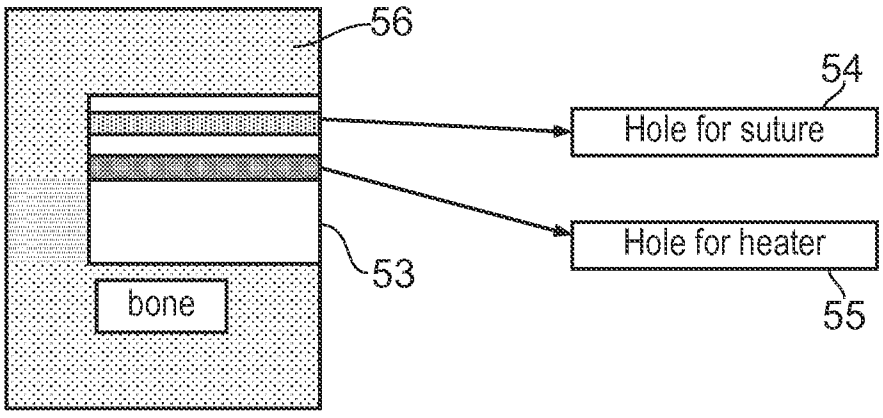

56
54
Hole for suture
Hole for heater
53
55
bone

FIG. 22

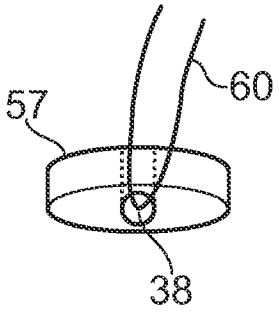


FIG. 23a

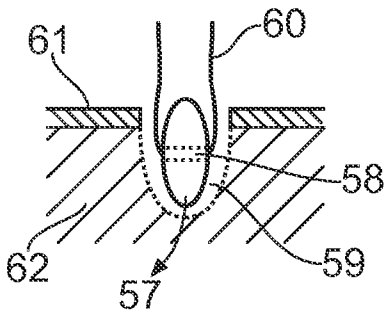


FIG. 23b

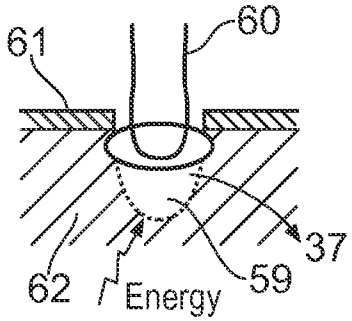


FIG. 23c

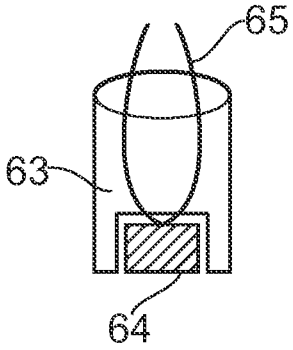


FIG. 24a

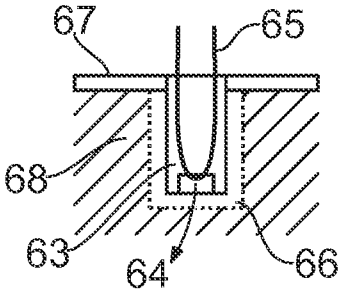


FIG. 24b

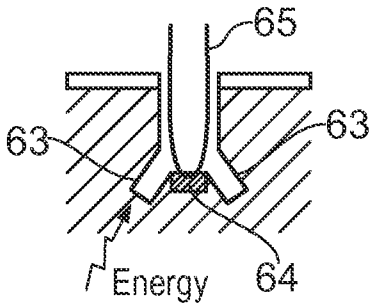


FIG. 24c

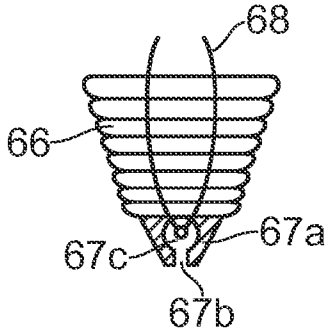


FIG. 25

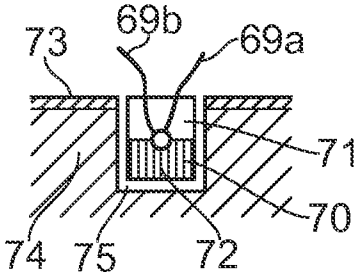


FIG. 26a

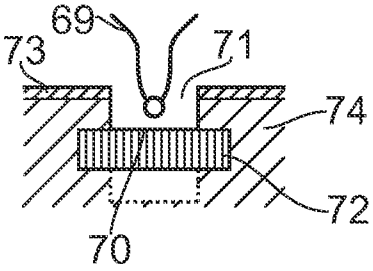


FIG. 26b

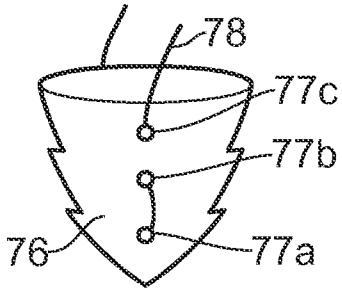


FIG. 27a

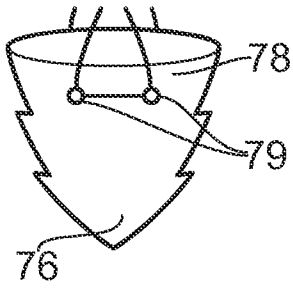


FIG. 27b

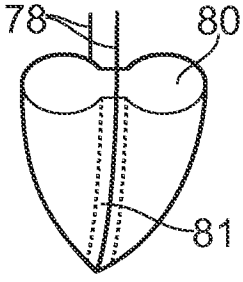


FIG. 27c

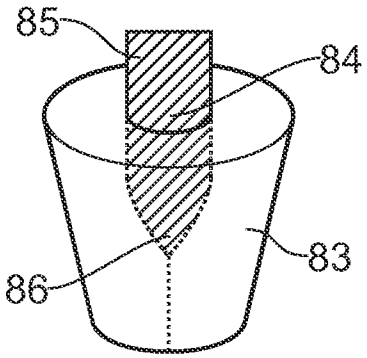


FIG. 28a

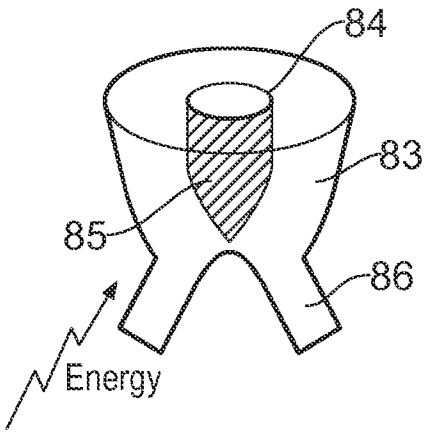


FIG. 28b

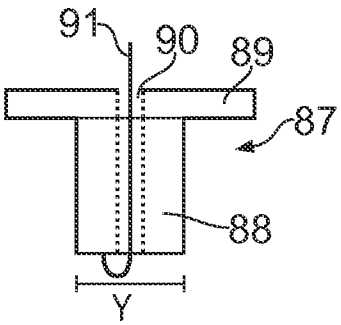


FIG. 29a

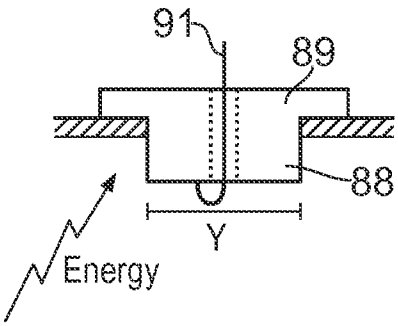


FIG. 29b

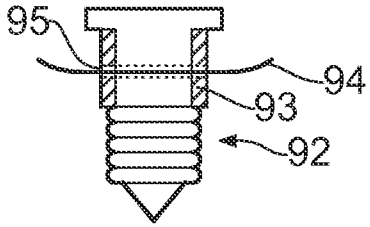


FIG. 30a

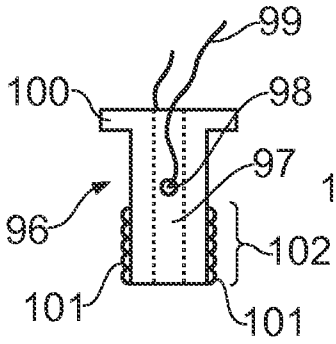


FIG. 30b

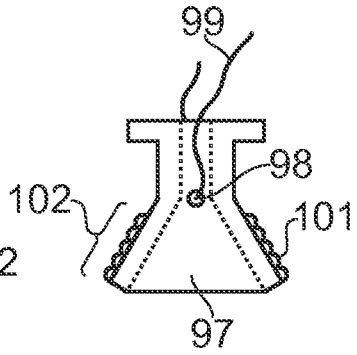


FIG. 30c

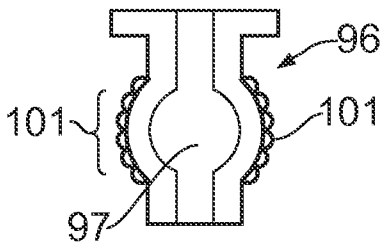


FIG. 30d

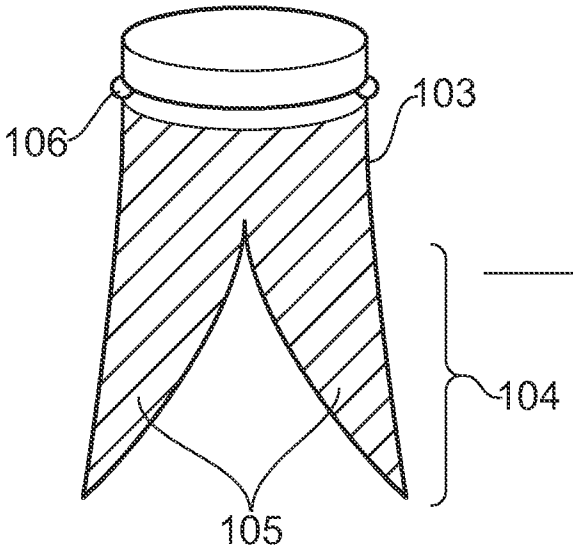


FIG. 31a

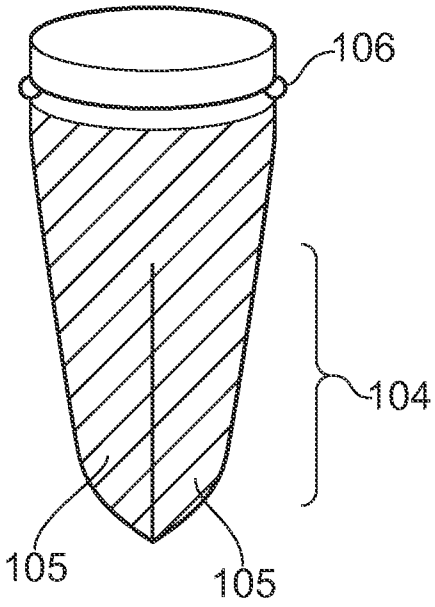


FIG. 31b

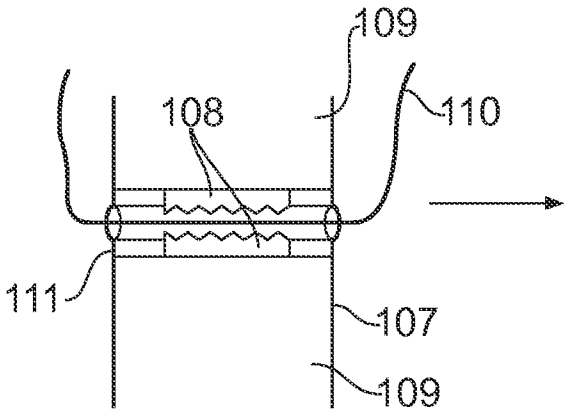


FIG. 32a

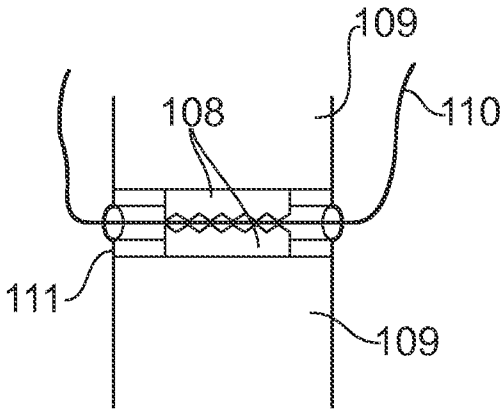


FIG. 32b

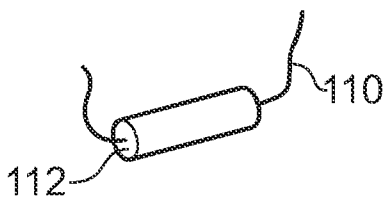


FIG. 32c

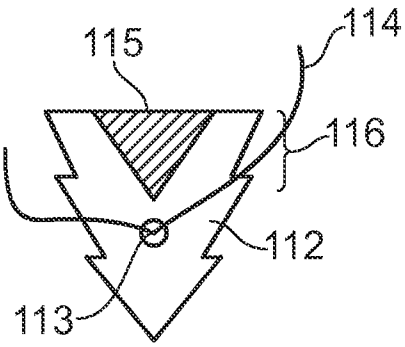


FIG. 33a

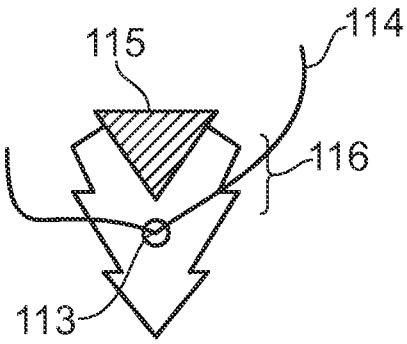


FIG. 33b

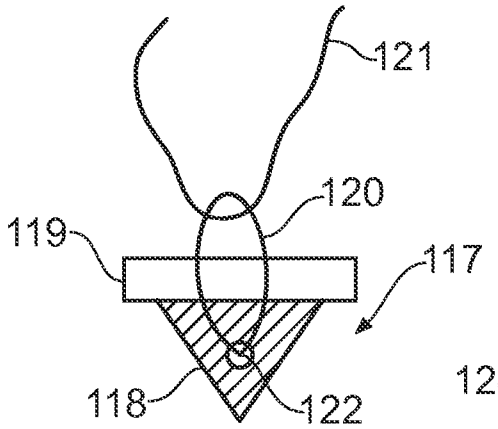


FIG. 34a

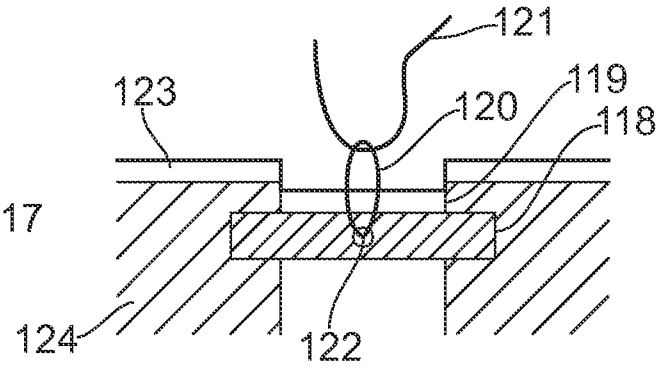


FIG. 34b

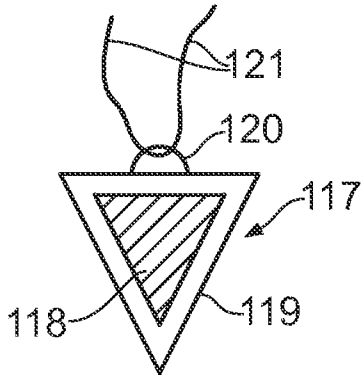


FIG. 34c

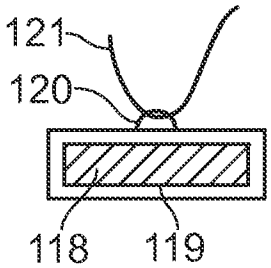


FIG. 34d

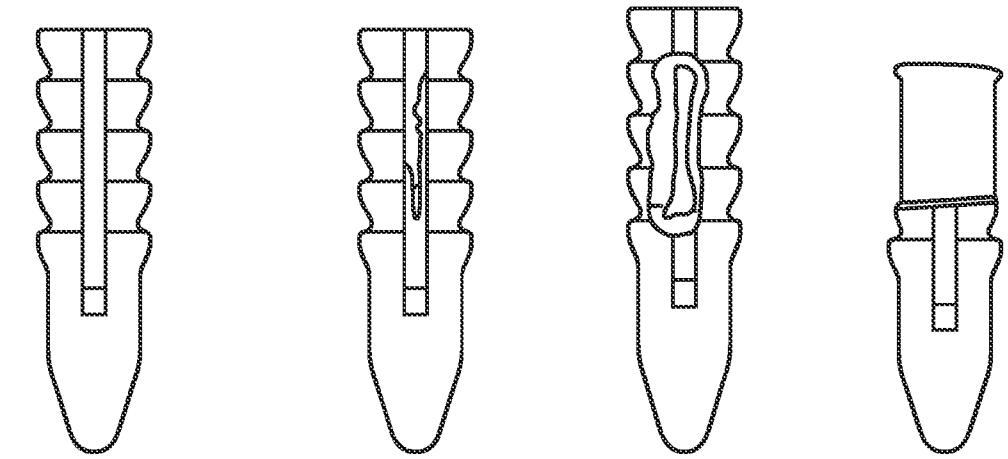


FIG. 35

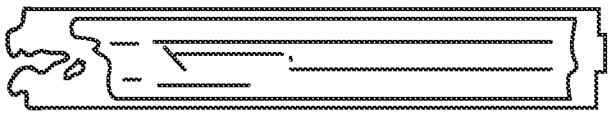


FIG. 36

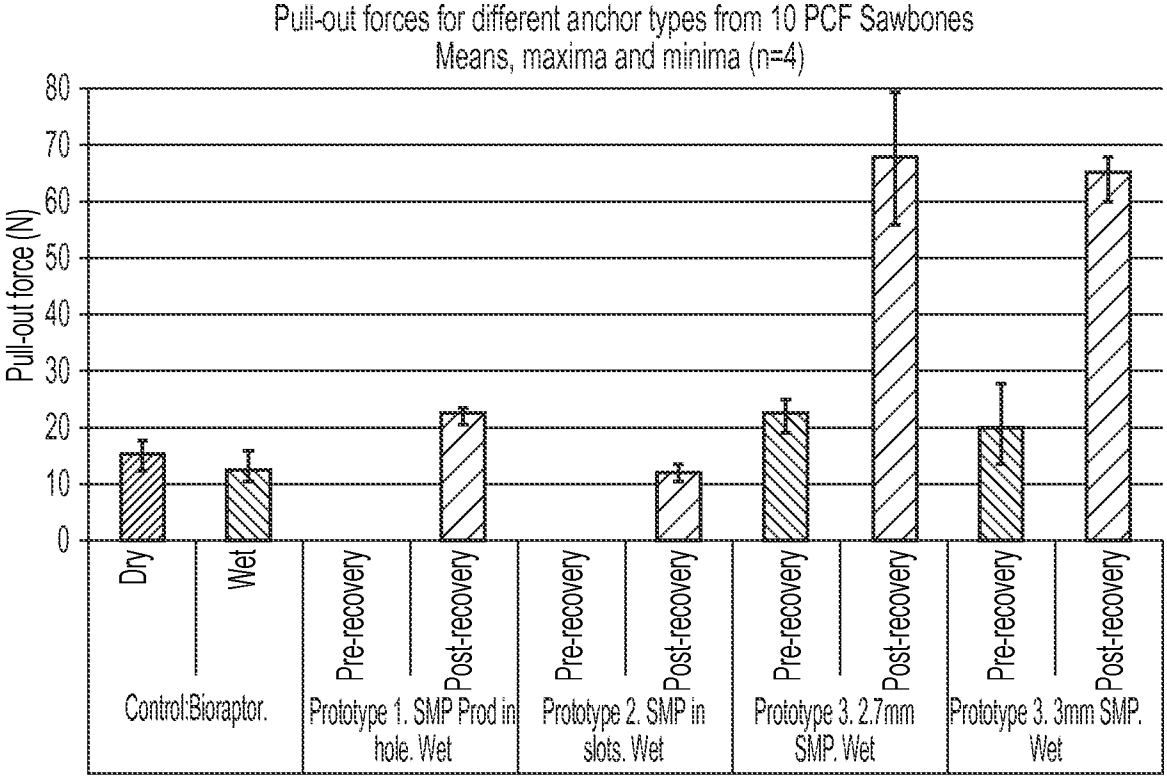

Pull-out forces for different anchor types from 10 PCF Sawbones
Means, maxima and minima (n=4)
Pull-out force (N)
80
70
60
50
40
30
20
10
0
Dry
Wet
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Control:Bioraptor.
Prototype 1. SMP Prod in hole. Wet
Prototype 2. SMP in slots. Wet
Prototype 3. 2.7mm SMP. Wet
Prototype 3. 3mm SMP. Wet

FIG. 37

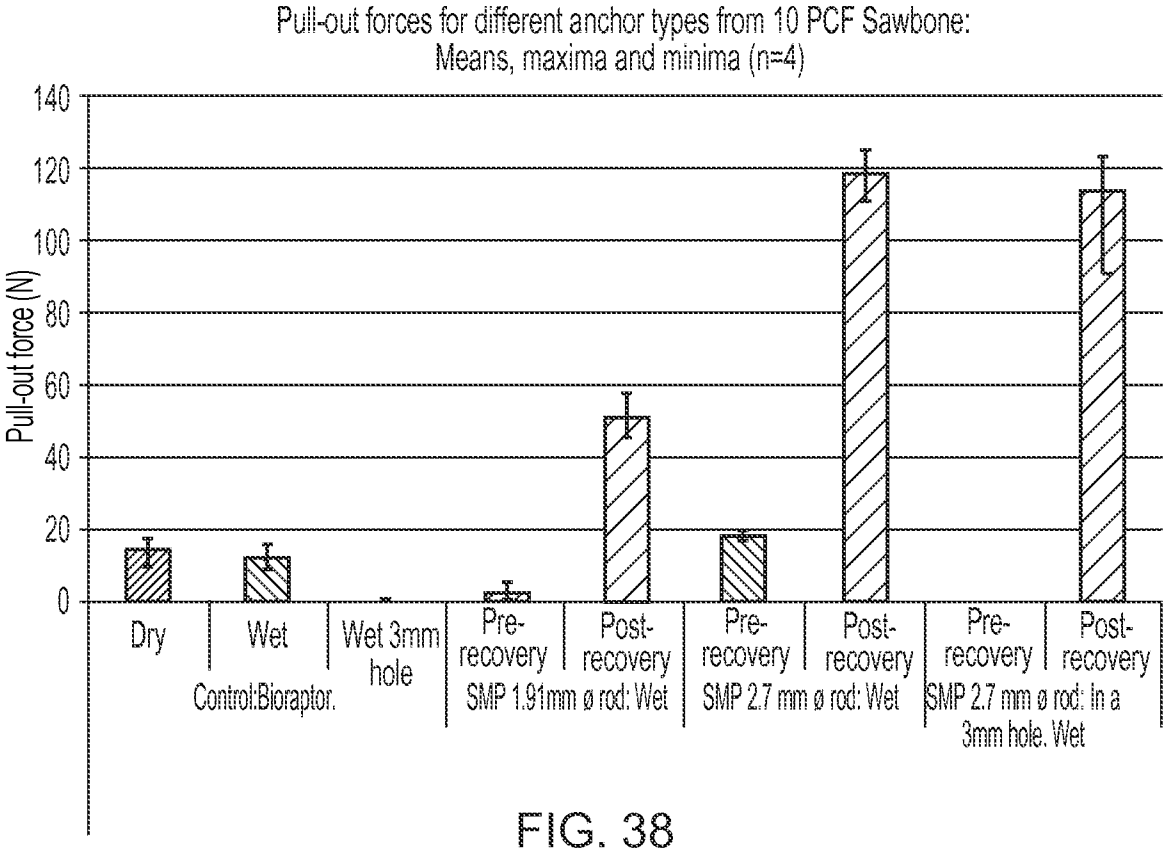

Pull-out forces for different anchor types from 10 PCF Sawbone:
Means, maxima and minima (n=4)
Pull-out force (N)
140
120
100
80
60
40
20
0
Dry
Wet
Wet 3mm hole
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Control:Bioraptor.
SMP 1.91mm ø rod: Wet
SMP 2.7 mm ø rod: Wet
SMP 2.7 mm ø rod: In a 3mm hole. Wet

FIG. 38

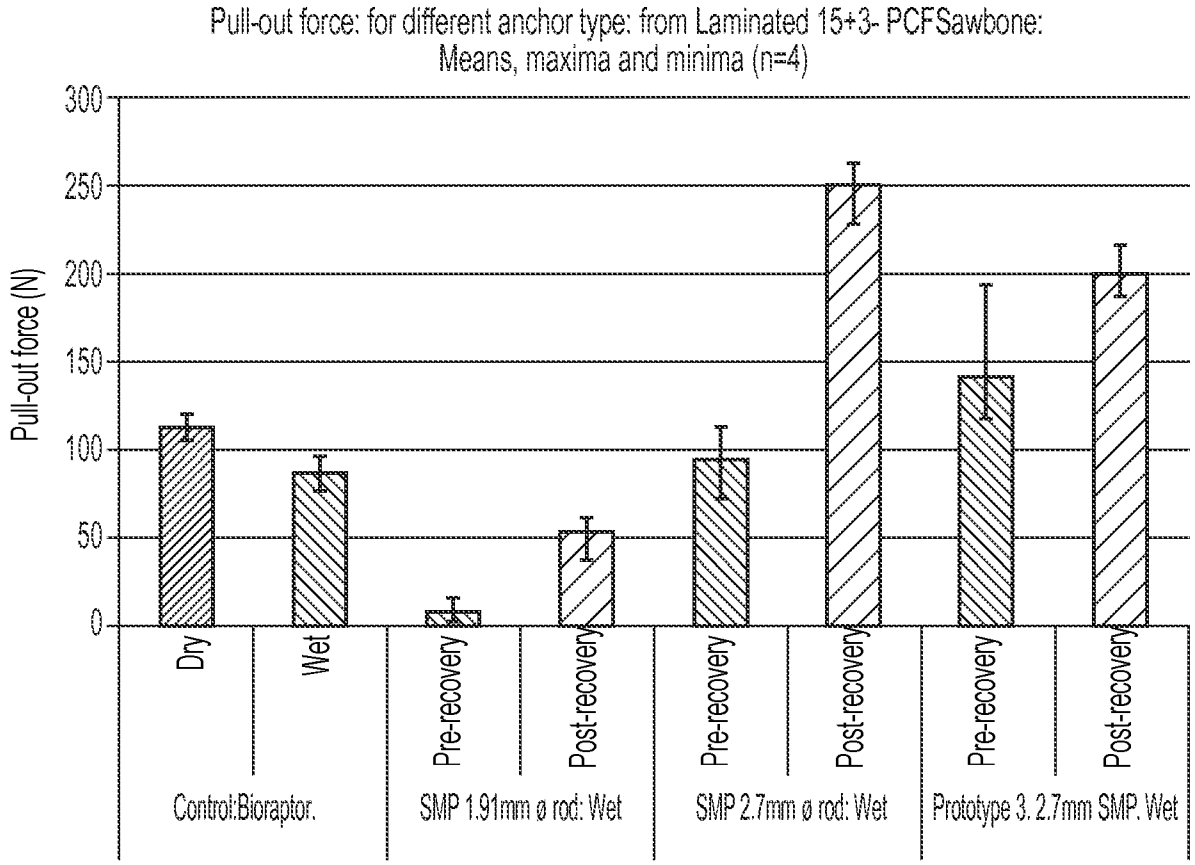

Pull-out force: for different anchor type: from Laminated 15+3- PCFSawbone:
Means, maxima and minima (n=4)
Pull-out force (N)
300
250
200
150
100
50
0
Dry
Wet
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Pre-recovery
Post-recovery
Control:Bioraptor.
SMP 1.91mm ø rod: Wet
SMP 2.7mm ø rod: Wet
Prototype 3. 2.7mm SMP. Wet

FIG. 39

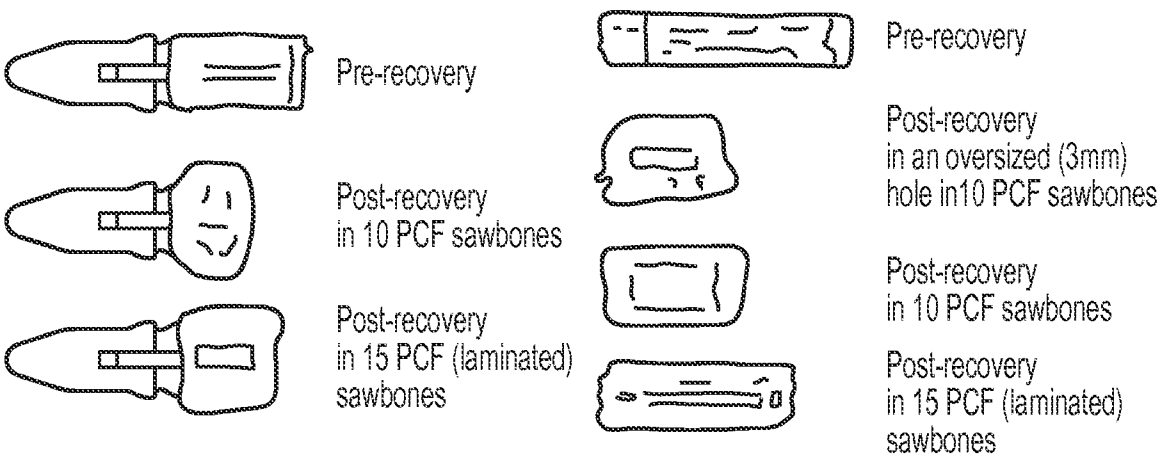

Pre-recovery
Post-recovery
in 10 PCF sawbones
Post-recovery
in 15 PCF (laminated)
sawbones
Pre-recovery
Post-recovery
in an oversized (3mm)
hole in10 PCF sawbones
Post-recovery
in 10 PCF sawbones
Post-recovery
in 15 PCF (laminated)
sawbones

FIG. 40

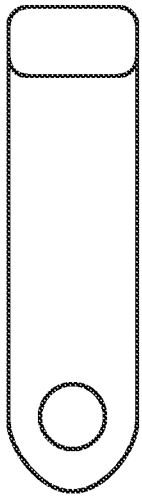


FIG. 41

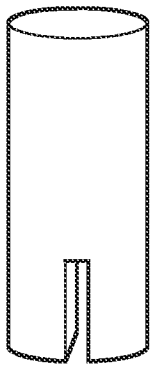


FIG. 42

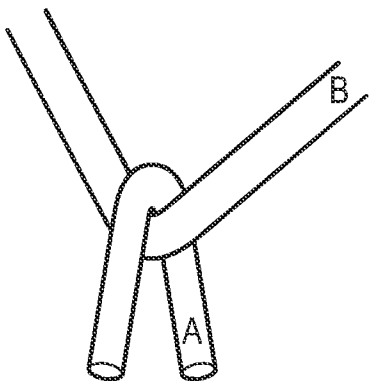


FIG. 43

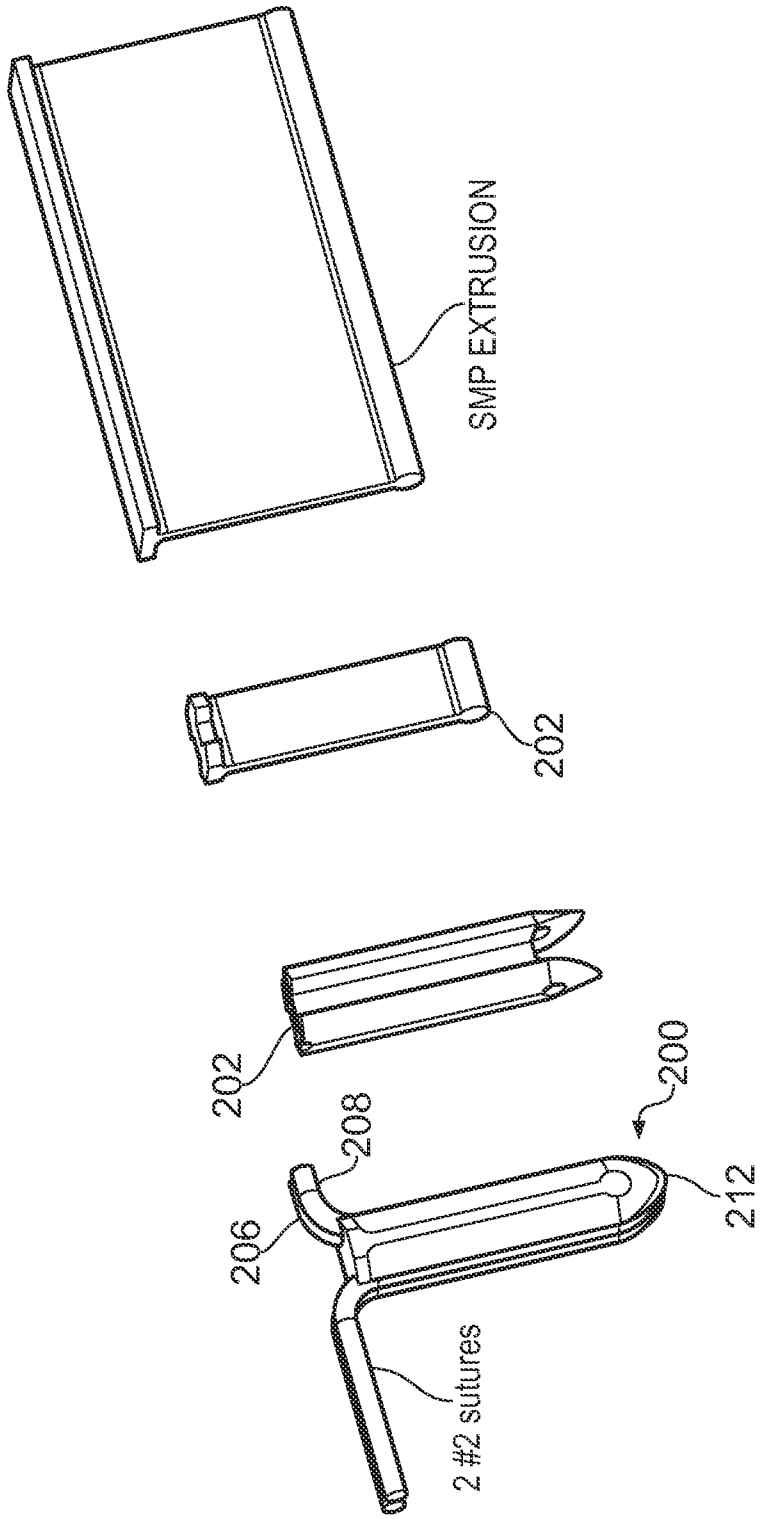


FIG. 44

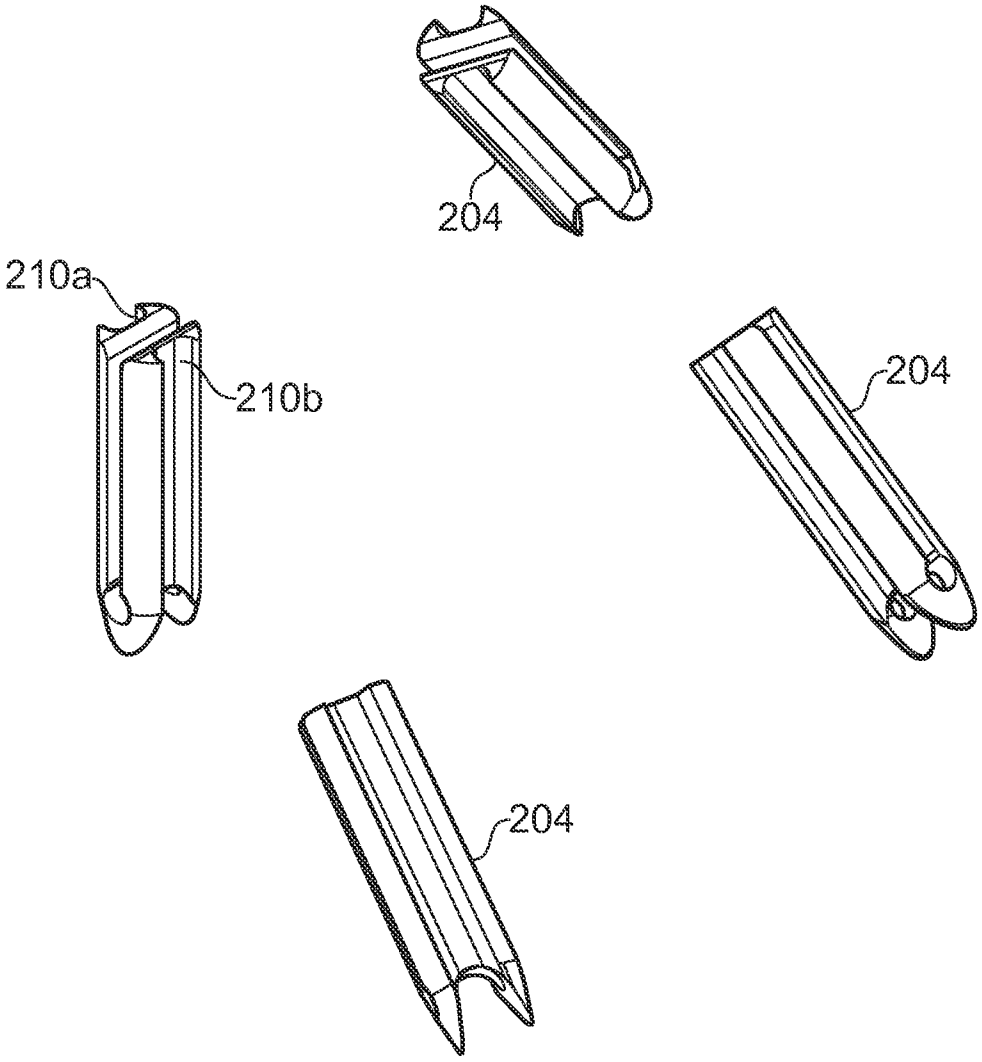


FIG. 45

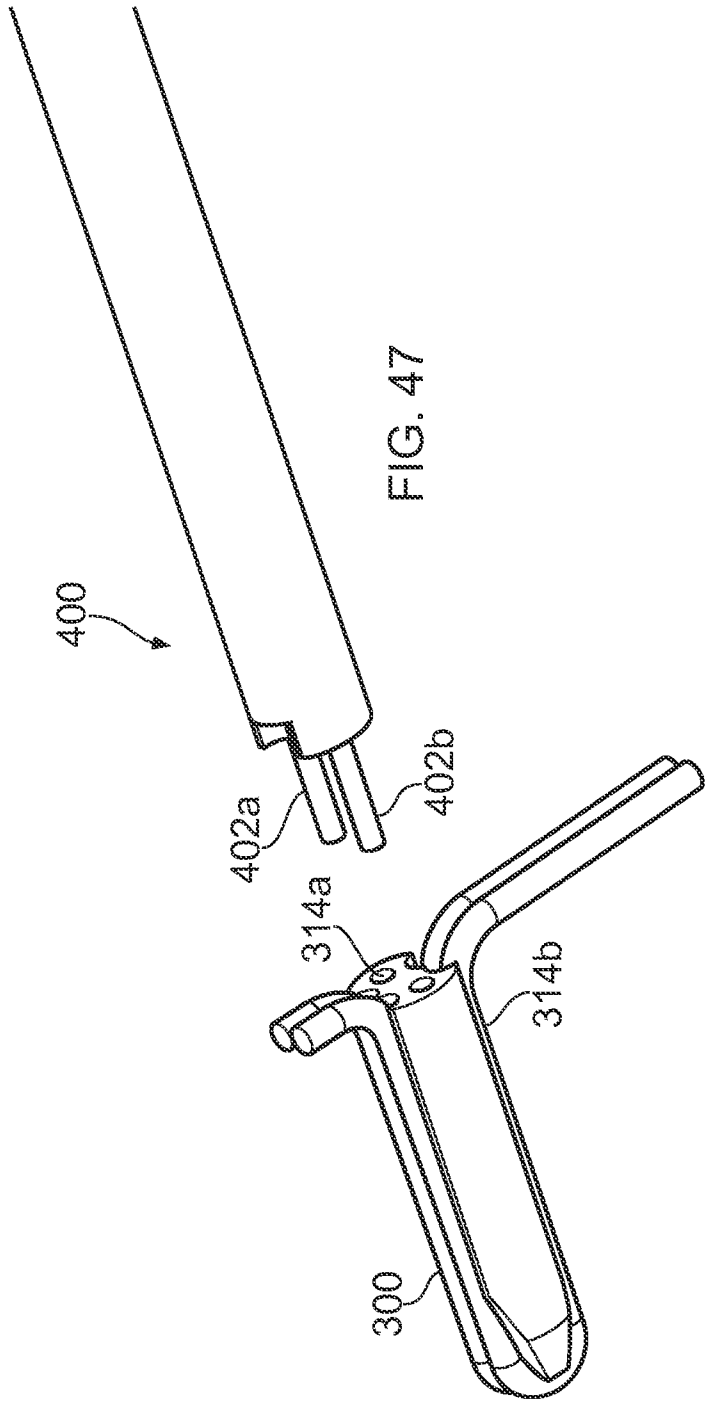


FIG. 46

FIG. 47

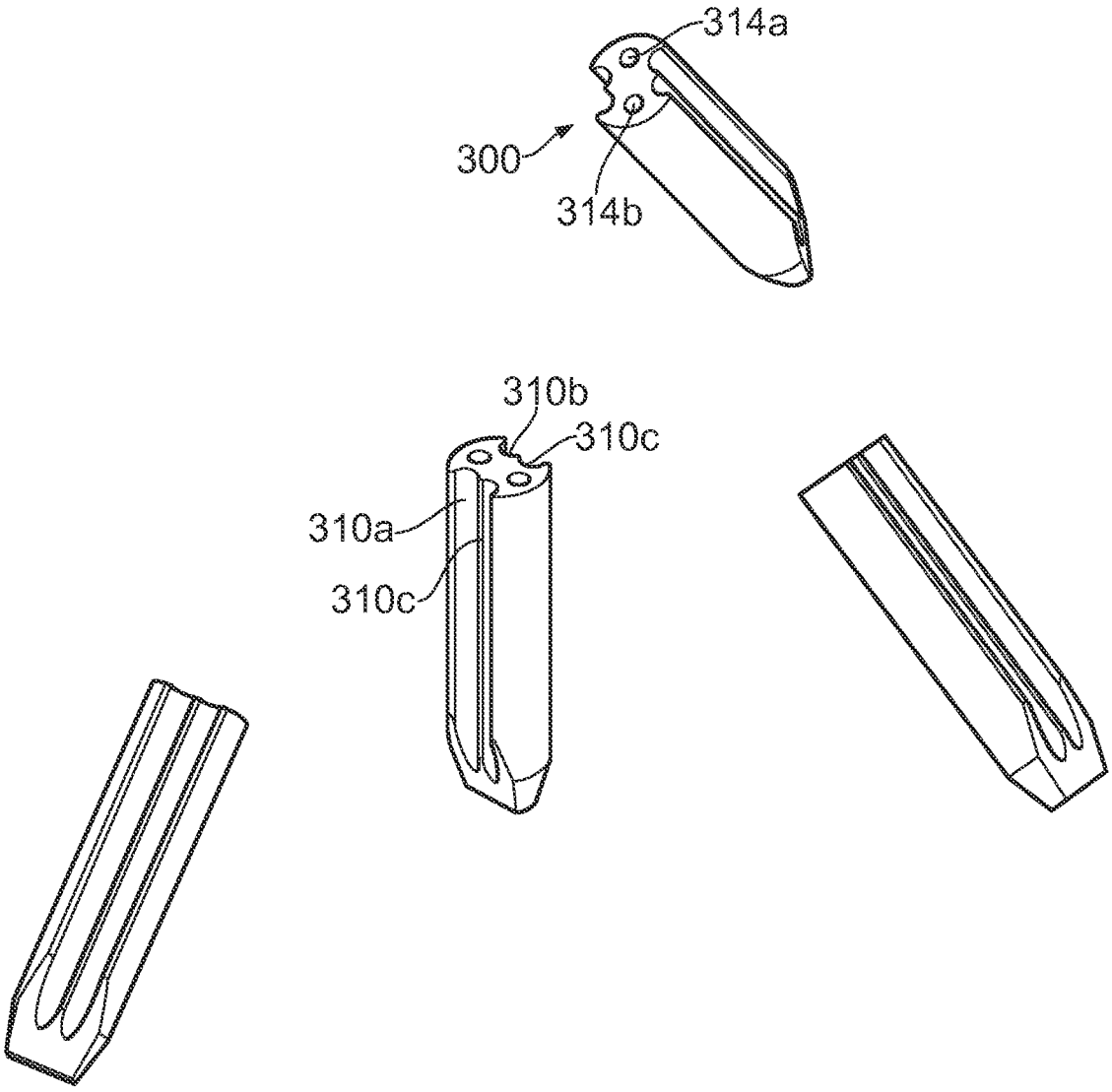


FIG. 48

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/052470

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L31/06 A61L31/12 A61L31/14 A61B17/04 A61B17/86
ADD.

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)
A61L 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 practicable, search terms used)
EPO-Internal, BIOSIS, EMBASE, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/112912 A2 (SMITH & NEPHEW INC [US]; AUSTIN GENE EDWARD [US]; BETTENGA MASON [US];) 18 September 2008 (2008-09-18) paragraphs [0002], [0137], [0144], [0147], [0198], [0199], [0203], [0217], [0222], [0223], [0240], [0240] - [0257] -----	1,2,8-42
X	US 2011/067712 A1 (GALL KENNETH A [US]) 24 March 2011 (2011-03-24) paragraphs [0058] - [0062]; figure 4 -----	1-7,12, 26,33-42

☐ Further documents are listed in the continuation of Box C.

☒ 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 application or patent 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
18 February 2013	22/02/2013

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, Fax: (+31-70) 340-3016	Cadamuro, Sergio

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2012/052470

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008112912 A2	18-09-2008	EP 2131879 A2	16-12-2009
		US 2010318085 A1	16-12-2010
		WO 2008112912 A2	18-09-2008
US 2011067712 A1	24-03-2011	NONE	