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[Continued on next page]

(54) Title: DRUG DELIVERY IMPLANTS

(57) Abstract: An orthopaedic screw having a plurality of regions, at least one of which may be porous. The orthopaedic screw includes a head, a tip and at least one thread. The porosity of the screw of the present invention can vary within the part or region, including changes in pore shape, size and density. These characteristics can vary along the length of the screw axis and/or radially (from the outer diameter to the axis). The orthopaedic screw may further include at least one solid region formed of any implantable polymer, reinforced polymer or metal.

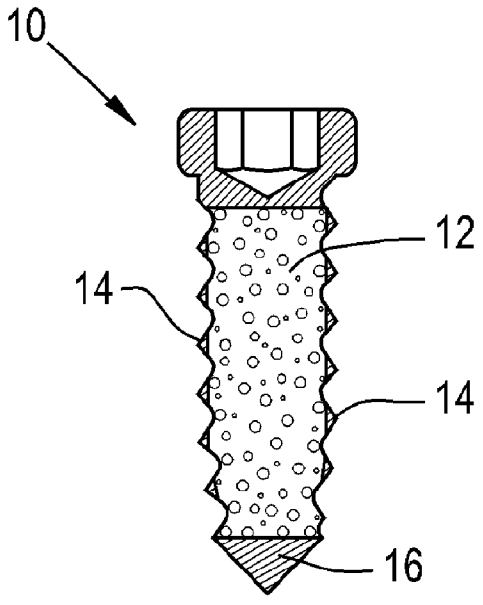

Fig. 1

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ORTHOPAEDIC SCREWS

Cross Reference To Related Applications

[0001] This is a non-provisional application based upon U.S. provisional patent application serial no. 61/088,383, entitled "ORTHOPAEDIC SCREWS", filed August 13, 2008, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to orthopaedic devices, and, more particularly, to orthopedic screws.

2. Description of the Related Art

[0003] A number of solid metal and resorbable polymer (e.g. PLLA, PGA) screws are known. These screws are generally meant to provide short term (9 months or less) attachment of the soft tissue to the bone until healing and integration can occur.

[0004] There are a number of problems associated with the known metal and resorbable screws. Due to the density of the metals that are used in the solid metal screws, it is difficult to examine bone or soft tissue that is near the screw via x-ray, CT, or MRI scan. The screw causes a significant 'white-out' in the region of the screw. Tissue healing and integration around the screw is critical to the success of the surgery, thus the ability to evaluate the tissue near the screw is valuable. In addition, the solid metal screws have issues with poor initial fixation and later pull-out of the soft tissue (e.g. pull out of an ACL from the bone) does occur. These are painful and can require follow-up surgery. Certainly any improvements to reduce the rate of pull-out and additional surgery would be desirable.

[0005] With respect to the known resorbable screws, issues with poor initial fixation and pull-out also exist. The rate of resorbtion of the polymer can be difficult to control and can occur too quickly for a given patient, increasing the risk of soft tissue pull-out. Further, resorbable materials have been shown to induce fibrous tissue formation between the resorbable implant and the bone, increasing the risk of soft tissue pull-out. This may be due

to the local chemistry created as the polymer dissolves.

[0006] What is needed in the art is an orthopaedic screw that allows for more effective fixation of the tissue and visualization with known imaging devices of the tissue near and surrounding the screw.

SUMMARY OF THE INVENTION

[0007] The present invention provides porous screws and screws that can deliver therapeutic agents. Further, the present invention provides a porous screw for attaching various soft tissues to bone, and/or for attaching bone to bone, and/or for delivering therapeutic agents (for example biologics or drugs) to soft tissue and/or bone. Potential uses include, but are not limited to, ACL and PCL reconstruction, medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, iliotibial band tenodesis reconstruction, patellar ligament and tendon repair, pedicle screws for spine repair, bone fracture fixation screw, and drug eluting implant (non-load bearing) for delivery of therapeutics.

[0008] One embodiment of the present invention provides an orthopaedic screw having a plurality of regions, at least one of which may be porous. The orthopaedic screw includes a head, a tip and at least one thread. The porosity of the screw of the present invention can vary within the part or region, including changes in pore shape, size and density. These characteristics can vary along the length of the screw axis and/or radially (from the outer diameter to the axis).

[0009] The orthopaedic screw of the present invention may further include at least one solid region formed of any implantable polymer, reinforced polymer or metal. The solid region of material may be, for example, at the outer portion of the threads and the leading tip of the screw due to the high stresses present during insertion. The solid region may further include the head of the orthopaedic screw of the present invention.

[0010] The materials to create the orthopaedic screw of the present invention can be any

implantable polymer, metal or ceramic, or any combination thereof. Possible polymers include polyetheretherketone (PEEK), polyetherketone (PEK), polyaryletherketone (PAEK), polyethylene, and resorbable polymers such as polylactic acid (PLA) and polyglycolic acid (PGA).

[0011] The thread of the orthopaedic screw of the present invention may be continuous or discontinuous and be a single or multiple lead thread. The inventive screw may further be cannulated or non-cannulated.

[0012] The orthopaedic screw of the present invention may further be used to locally deliver therapeutic agents that promote positive tissue response (e.g. increased growth rate, decreased inflammatory response). Such therapeutic agents include, but are not limited to, hydroxyapatite, drugs and biologics.

[0013] A second embodiment of the orthopaedic screw of the present invention provides for immediate delivery of a therapeutic agent through channels and/or holes and reservoirs for long-term delivery of a therapeutic agent. Access to the delivery channels, holes and/or reservoirs may be gained by provision of a self-sealing polymer diaphragm which can allow for direct interface with a needle at the time of surgery of post-surgery. Alternatively, a removable cap made of PEEK or other implantable material may provide access to and seal the medicine delivery features of the inventive screw.

[0014] A third embodiment of the inventive orthopaedic screw composed of radiolucent material includes a radiopaque marker to indicate position and orientation of the implant on an x-ray, fluoroscope, or similar diagnostic tool. The markers can be made of any number of more dense implantable materials. Options include, but are not limited to implantable metals (stainless steel, titanium, or titanium alloys for example), barium sulfate filled PEEK, carbon filled PEEK, and other polymers with radiopaque material (such as barium sulfate or zirconium dioxide). Examples of the marker structure include one or more of the following: a pin filling some or all of the cannula of a cannulated screw, one of material layers of the

inventive screw if manufactured by layering, all or some of the threads, a cross pin, or the head or tip of the screw. The opacity and/or amount of radiopaque material can be controlled so that the marker does not prevent evaluation of the tissue near the screw by x-ray or other diagnostic methods.

[0015] An advantage of the present invention is that the porous nature of the inventive orthopaedic screw and the ability to deliver therapeutic agents to the surrounding tissue promotes successful tissue integration. Such local delivery of therapeutic agents can aid in such issues as improving the attachment strength of soft tissue to bone in reconstructive surgeries, improving the attachment strength of bone to screw, and strengthen bone in osteoarthritic or osteoporotic patients.

[0016] Another advantage is that the orthopaedic screw of the present invention can effectively be utilized for long term or short term delivery of therapeutic agents. Another advantage is that the therapeutic agent can be pre-loaded into the device at the factory or loaded by the surgeon before, during or after surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0018] Fig. 1 is a section view of a porous screw with solid outer threads and tip according to the present invention;

[0019] Fig. 2A shows a view of a screw having a continuous thread;

[0020] Fig. 2B shows a view of a screw having a discontinuous thread;

[0021] Fig. 3 illustrates an implant according to the present invention for immediate delivery of a therapeutic agent;

[0022] Fig. 4 illustrates an implant according to the present invention for immediate or sustained delivery of a therapeutic agent;

[0023] Fig. 5 illustrates a therapeutic agent delivery implant according to the present invention with sealing cap;

[0024] Fig. 6 illustrates an implant according to the present invention with port attachment features;

[0025] Fig. 7A illustrates an implant according to the present invention including a radiopaque marker;

[0026] Fig. 7B illustrates an implant according to the present invention including a radiopaque marker; and

[0027] Fig. 7C illustrates an implant according to the present invention including a radiopaque marker.

[0028] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the invention and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0029] The present invention provides a device which can have a porous nature and which has the ability to deliver therapeutic agents. The porous nature of the device of the present invention and the ability of the device of the present invention to deliver therapeutic agents therethrough addresses existing deficiencies in the known art by promoting successful tissue integration.

[0030] The present invention provides a screw that is porous and/or can deliver therapeutic agents to the surrounding tissue. The materials to create this screw can be any implantable polymer, metal or ceramic or combinations of these. Possible polymers include PEEK

(Poly(etheretherketone)), PEK (Poly(etherketone)), PAEK (poly(aryletherketone)), polyethylene, and resorbable polymers such as PLA (Poly(lactic acid)) and PGA (poly(glycolic acid)). Likely first candidates are PEEK, reinforced PEEK (reinforcing materials include but are not limited to carbon fiber/particles/nanotubes, barium sulfate, zirconia) and titanium/titanium alloys. The screw of the present invention can include, but does not need to include, the ability to deliver therapeutic agents (such as drugs or biologics) to the surrounding tissue. The therapeutic agent can be selected by the surgeon before the surgery, at the time of surgery, or at any point in time thereafter. In addition, the therapeutic agent can be pre-loaded into the device at the factory through currently acceptable practices or loaded by the surgeon before, during, or after surgery (as a follow-up procedure).

[0031] The screw of the present invention can be porous but does not need to be porous.

[0032] **I. Porous Structure – Design Options According to the Present Invention**

[0033] Screw 10 of the present invention can be fully porous or have select regions of solid material. For example, screw 10 may include porous region 12 and a solid region of material at the outer portion of threads 14 and leading tip 16 of screw 10. The solid region of material at the outer portion of threads 14 and leading tip 16 of screw 10 may be desired due to the high stresses these regions can see during screw insertion (see Fig. 1). In addition, a very rough porous structure on the outer portion of the threads can cause insertion of the screw to be difficult due to its potential to grab versus slide past or cut through bone/soft tissue. In another example, the head (not shown) of screw 10 may be solid. This solid material can be formed of any implantable polymer, reinforced polymer, or metal.

[0034] Thread 14 can be continuous (see Fig. 2A) or discontinuous (see Fig. 2B) and be a single or multiple lead thread.

[0035] The porosity of the screw can vary within the region(s), including changes in pore shape, size, and density. These characteristics can vary along the length of the screw axis and/or radially (from the outer diameter to the axis).

[0036] *Delivery of Therapeutic Agents*

Another way of improving integration of the surrounding tissue is to deliver therapeutic agents that promote positive tissue response (e.g. increased growth rate, decreased inflammatory response). The orthopaedic screw of the present invention can be used to locally deliver such therapeutic agents to the tissue surrounding the device. Such local delivery of therapeutic agents can aid in such issues as improving the attachment strength of soft tissue to bone in reconstructive surgeries, improving the attachment strength of bone to the screw, and strengthen bone in osteoarthritic or osteoporotic patients. Therapeutic agents include, but are not limited to, hydroxyapatite, drugs, and biologics.

[0037] Screws allowing for localized delivery of therapeutic agents, according to the present invention, can be, but need not be, porous. Porous screws according to the present invention can, but need not, allow for localized delivery of therapeutic agents.

[0038] Screw 10 can contain reservoirs 18 for the long-term delivery of the therapeutic agents, as illustrated in Fig. 4 and/or channels/holes 20, as illustrated in Fig. 3, for immediate, local delivery of therapeutic agents. Screw 10 can further include a plurality of interconnected pores (22) allowing for local delivery of a therapeutic agent to the surrounding tissue, as shown in Fig. 4. These options are described as follows:

1. Long term delivery.
    a. *Reservoirs*. One or more reservoirs 18 can allow for the long term (hours to weeks) delivery of the therapeutic agents. Access to delivery channels 20, reservoir 18, etc. of screw 10 is gained by several ways including:
        i. Self-sealing polymer diaphragm 24 can allow for direct interface with a needle at the time of surgery or post-surgery (see Fig. 4).
        ii. A removable cap 26 made of PEEK or another implantable material can also provide access to the therapeutic agent delivery features and seal these features after delivery of the therapeutic agent (Fig. 5). A

tool that facilitates insertion of the screw could also aide in assembling cap 26 to the screw.

b. *Connect to another device*. Access to the therapeutic agent delivery features of the screw can be provided by interfacing screw 10 with a device designed to deliver therapeutic agents from subcutaneous to elsewhere in the body (e.g. a port that is frequently used to deliver therapeutic agents from sub-skin to a vein deeper in the chest cavity). The last option can include attachment feature 28 on screw 10 that directly interfaces with port 30, interfaces with catheter 32 (which interfaces with the port 30) or interfaces with an additional component, which can be attached to screw 10 to interface with port 30 or catheter 32 – See Fig. 6).

2. Immediate delivery. No reservoir is required for this approach. The access means of the reservoir design above (self-healing polymer diaphragm 24 and removable cap 26) can also be used to access delivery channels 20 in this design. This design can also include a simple interface with a delivery tool. An example of this is a simple slip fit between a delivery needle and the screw's cannula.

A given screw can contain any or all of these options.

[0039] *Cannulation*

The screws can be cannulated or non-cannulated.

[0040] *Radiopaque markers – Polymer implants*

If the implant according to the present invention is made of a radiolucent material (for example polymers such as PEEK), radiopaque markers 34 can be included to indicate position and orientation of the implant on an x-ray, fluoroscope, or similar diagnostic tool. Markers can be made of any number of more dense implantable materials. Options include, but are not limited to, implantable metals (stainless steel, titanium, or titanium alloys for example), barium sulfate filled PEEK, carbon filled PEEK, or other polymers with

radiopaque material (such as barium sulfate or zirconium dioxide). Examples of the marker design include one or more of the following: pin 36 filling some or all of cannula 38 of a cannulated screw, one of the material layers if the manufacturing method involves material layering (discussed below), all or some of threads 14, cross pin 40, or head 42 or tip 16 of the screw (see Figs. 7A-C). The opacity and/or amount of radiopaque material can be controlled so that the marker does not prevent evaluation of the tissue near the screw by x-ray or other diagnostic ways (as occurs with current solid metal screws).

[0041] II. Porous Structure – Manufacturing Options According to the Present Invention

[0042] The porous structure of the present invention can be manufactured using a variety of methods. These manufacturing options according to the present invention include seven options as follows:

1. Rolled. A porous sheet can be, for example, rolled into a screw. This is essentially the reverse of making a radial, spiral cut that is parallel to the axis of the screw. Layers of different materials can be combined in this process. This process involves the following:
    a. Make a porous sheet with holes in a pattern so that they line up when rolled.
    b. Roll sheet. This step can be performed with or without the aid of a center mandrel or rod.
        1. The sheet can be rolled without the aid of any center mandrels. This can create a cannulated screw. A biocompatible pin/rod can be inserted in any center hole and bonded to the screw to create a non-cannulated screw.
        2. The sheet can be rolled around a removable mandrel. This can create a cannulated screw. A biocompatible pin/rod can be inserted in any

center hole and bonded to the screw to create a non-cannulated screw.

3. Alternately the sheet can be rolled around and bonded to a biocompatible rod, creating a non-cannulated screw.

c. Bond the rolled material.

2. Spiraled layers. This method is similar to the rolled approach, but this method involves bands of material that are wrapped around one another. The main difference between this method and that of rolling is that in this method, the bands of material translate along the axis while they are wrapped. Bands of several materials can be combined and intertwined. All bands can have the same direction and pitch of winding or different directions and pitches. These bands can be wrapped around a mandrel that is later removed to aid in bonding and to create a cannula. They can also be wrapped around a pin which they are then bonded to, creating a non-cannulated screw. An alternate option for creating a non-cannulated screw is to create the screw with or without the aid of a mandrel, then insert and bond a pin within the center hole of the screw.

3. Layered/stacked. Make a number of layers that are stacked and bonded to create the screw. These layers can be parallel to one another. The faces of the layers are perpendicular to the axis of the screw, parallel to it, or any other angle of orientation. To reduce secondary operations, alignment of one layer to another may be desirable. Alignment of layer to layer can be achieved by such ways as alignment fixtures that line up the center cannula (if the screw is cannulated) of each layer to one another (by way of a pin for example), fixtures or implant components/features that align pore or thread features to one another, or fixtures or implant components/features that align

features on the outer diameter of each layer to one another. Features can also be created within a given layer to aid in alignment and/or assembly (such as grooves and mating protrusions).

Note: The holes in options 1-3 can be created by, for example, laser cutting, punching, etching, electrical discharge machining, plasma etching, electroforming, electron beam machining, water jet cutting, stamping, or machining. For polymer based materials, they can be created as the sheets are created by, for example, extruding, injection molding, or hot stamping.

4. Dissolvable material.
    a. One method involves creating a mixture of powdered implantable material (e.g. PEEK) and a powder (e.g. salt) that is soluble in something in which the implantable material is not soluble (such as water, isopropyl alcohol for the PEEK example). The mixture is then heated to bond the implantable particles together. Pressure can also be applied to aid in the bonding of particle to particle. Heat can be created by convection or other ways (such as coating the powder with a material that absorbs a given range of energy waves – such as laser waves – and causes heating. (e.g. Clearweld coating by Gentex® Corporation)). Finally, dissolve away the filler to create the porous implantable material. This method can create net shape parts or raw material shapes from which individual parts can be created.
    b. Another method involves mixing an implantable polymer with a dissolvable material such as described above. The mixture is then pelletized and then injection molded to an intermediary or the final part shape. The filler is dissolved away to create the porous implantable polymer.
5. Stereolithography.
6. Laser or electron beam sintering of powdered material.

7. A combination of the above methods: for example, using the dissolvable method to create microporous sheets of PEEK, then stamping larger pores and stacking to create a screw.

[0043] III. How to bond parts containing polymer(s)

[0044] *Options for bonding processes*

1. Heat. Heat can be generated in several ways:
    a. Ultrasonic welding – use ultrasonic waves to create heat at the interface of layers.
    b. Heat staking – use a heated tool to cause melting between the layers.
    c. Vibratory welding.
    d. Laser welding.
    e. Convection – use an oven to create heat to cause bonding.
    f. Intermediary layer – for example, use a material that can absorb energy waves that pass through the polymer (for example PEEK) without causing damage. The absorbed energy will cause localized heating. An example of such a coating is Clearweld by Gentex® Corporation. The laser waves that Clearweld absorbs pass through the PEEK without causing damage, allowing the layers to be melted together without large scale damage to the PEEK.
2. Chemical.
    a. Adhesives – a secondary material (such as adhesive) can be used to bond the material.
    b. Solvent bonding – a material in which the polymer or reinforced polymer is soluble can be applied to the sheet surfaces allowing multiple surfaces to be bonded to one another.
    c. Overmolding – overmolding of the polymer or reinforced polymer can provide a chemical bonding

3. Mechanical.
    a. Overmolding – overmolding of a polymer or reinforced polymer can create a mechanical lock between components on a micro or macro scale (microscale – the molded material locks with surface asperities of the existing material. Macroscale – features such as tongue-groove connections or undercuts). The overmolded material can be a separate component from the layers or one layer can be overmolded onto another layer.
    b. Features are provided within the layers or by a separate component which provides a mechanical lock – e.g. a pin, snap lock connection, dove-tail, tongue-groove, rivet, melting tabs to create a mechanical lock, etc.
    c. Some adhesives provide a mechanical bond in addition to or instead of a chemical bond.
4. Combinations of any/all of the above methods.

[0045] *Order of processes*

1. Bond all layers together at once – especially attractive for methods utilizing energy waves to trigger bonding (e.g. Clearweld coating by Gentex® Corporation or ultraviolet light curable adhesives).
2. Simultaneously bond and roll/stack layers at once – again, may be especially attractive for methods utilizing energy waves to trigger bonding (e.g. if light cannot penetrate all layers of a rolled design in order to activate an adhesive, the rolling operation could take place in a light box allowing for a continuous rolling and adhesive curing operation.
3. Roll/stack layers and bond in increments. This could add a single layer at a time or multiple layers.

[0046] **IV. How to bond metal/metal alloy parts**

[0047] *Options for bonding processes*

1. Heat.
    a. Laser welding – layers can be laser welded in a number of locations. Two or more layers or wraps of material can be welded together at once depending on the size of the part and alignment of the pores (the laser can access several layers to be bonded through the porosity).
    b. Spot welding – traditional spot welding can be used to bond two or more layers/wraps of material.
    c. Diffusion bonding/sintering.
    d. Vibratory welding.
    e. Ultrasonic welding.
2. Adhesives.
3. Mechanical ways. Features are provided within the layers or by a separate component which provides a mechanical lock – e.g. a pin, snap lock connection, dove-tail, tongue-groove, rivet, melting tabs to create a mechanical lock etc.
4. Overmolding with an implantable polymer. Overmolding of PEEK or another implantable polymer can create a mechanical lock between components on a micro or macro scale (microscale – the molded material locks with surface asperities of the existing material. Macroscale – features such as tongue-groove connections or undercuts). The overmolded material can be a separate component from the layers or one layer can be overmolded onto another layer.

[0048] *Order of processes*

As with the polymer materials discussed above, two or more layers of metal can be bonded during increments or as a continuous stacking/bonding process.

[0049] V. Making threads – Manufacturing Options According to the Present Invention

1. Form the threads after the layers have been bonded to create a screw blank (see Fig. 13)
    a. Machine the threads
    b. Hot form the threads with a mold
2. Form threads in the sheets prior to bonding.
    a. Rolling method: The material will not actually create the complete thread shape until the sheets are formed into the final shape. Continuous or discontinuous threads can be created. Design options for this method include creating raised material that forms the threads or removing material to leave the thread material. The raised material in the first method can be created by way of machining, laser ablation, hot stamping, hot or cold forming, chemical etching, electro-discharge machining and similar methods. The material of the second method can be removed by way of machining, laser cutting, stamping, etching, punching, electro-discharge machining, water jet cutting, electron beam machining or other means.
    b. Stacking method: Continuous or discontinuous threads can also be created by this method. The 'ears' of material in each layer form the threads when the layers are stacked. These can be created by way of machining, hot stamping, hot or cold forming, dies/punches, chemical etching, electro-discharge machining and similar methods.
3. Add separate threads – Threads can be formed separately and attached to the screw blank. The material for these threads can include: biocompatible polymers, reinforced biocompatible polymers and/or biocompatible metals. The attachment ways for these threads include:
    a. Mechanical attachment – press/interference fit, tabs.

b. Overmolding – mold the solid, porous, or reinforced polymer screw inside of the solid threads or mold the porous, solid or reinforced polymer threads onto the already formed screw.

c. Adhesive or solvent bonding.

[0050] **VI. Cannulation – Manufacturing Options According to the Present Invention**

With any of the manufacturing methods, screws can be created with or without a cannula.

1. Cannulated.
    a. Rolling method. In this method, it can be desirable to wind the material around a mandrel that is at the center of the screw, running along its axis. This mandrel can be removed to leave an open cannula.
    b. Layered method. A center hole at the axis of each layer is created to form the cannula when they are stacked together.
2. Non-cannulated.
    a. Rolled method.
        i. The sheet can also be bonded to the mandrel, with the mandrel forming a portion of the implant. This mandrel can be solid or porous and of any implantable material such as PEEK or titanium.
        ii. In addition, the material can be formed around a removable mandrel, creating a cannula. This cannula can be then be filled with a biocompatible material that is attached/bonded to the screw.
    b. Layered method. The layers that are stacked to create the screw can have solid material in place of the holes that would create the cannula. Alternately, they can have cut-outs creating the cannula and this cannula can be filled with a biocompatible material that is attached/bonded to the screw.

[0051] While this invention has been described with respect to at least one embodiment, the present invention can be further modified within the spirit and scope of this disclosure. This

application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

WHAT IS CLAIMED IS:

1. An orthopaedic device comprising:

a screw including a head, a tip and at least one thread, said screw including a plurality of regions, at least one of said plurality of regions being porous.

2. The orthopaedic device of claim 1, wherein said screw is at least one of an implantable polymer, metal and ceramic.

3. The orthopaedic device of claim 2, wherein said implantable polymer is one of polyetheretherketone (PEEK), Polyetherketone (PEK), polyaryletherketone (PAEK), polyethylene, polylactic acide (PLA) and polyglycolic acid (PGA).

4. The orthopaedic device of claim 1, wherein said plurality of regions includes at least one solid region.

5. The orthopaedic device of claim 4, wherein said at least one solid region is at least one of said head, said tip and an outer portion of said at least one thread.

6. The orthopaedic device of claim 4, wherein said solid region is one of implantable polymer, reinforced polymer and metal.

7. The orthopaedic device of claim 1, wherein said at least one thread is one of continuous and non-continuous.

8. The orthopaedic device of claim 1, wherein said at least one thread is one of a single lead thread and a multiple lead thread.

9. The orthopaedic device of claim 1, wherein said at least one porous region includes a plurality of pores, said plurality of pores being at least one of different sizes and different shapes.

10. The orthopaedic device of claim 1, further comprising at least one therapeutic agent.

11. The orthopaedic device of claim 10, wherein said therapeutic agent is one of hydroxyapetite, drugs and biologics.

12. An orthopaedic device comprising:

a therapeutic agent; and

a screw having at least one of channels, holes and a reservoir, said screw configured to deliver said therapeutic agent to a surrounding tissue when said screw is implanted in said tissue.

13. The orthopaedic device of claim 12, wherein said therapeutic agent is one of hydroxyapetite, drugs and biologics.

14. The orthopaedic device of claim 12, further comprising a self-sealing diaphragm configured for injection of said therapeutic agent into said screw.

15. The orthopaedic device of claim 12, further comprising a removable self-sealing cap configured for sealing said screw after delivery of said therapeutic agent.

16. The orthopaedic device of claim 12, further comprising a port and a catheter, wherein

said screw is configured to receive said therapeutic agent through said port.

17. The orthopaedic device of claim 12, wherein said screw is one of porous and non-porous.

18. The orthopaedic device of claim 12, wherein said screw is one of cannulated and non-cannulated.

19. The orthopaedic device of claim 12, wherein said screw has opposing sides and includes a plurality of pores.

20. The orthopaedic device of claim 19, wherein said plurality of pores are interconnected and configured to deliver said therapeutic agent from said screw to said surrounding tissue.

21. An orthopaedic device comprising:

a screw including a radiolucent marker, said screw having a head, a tip and at least one thread.

22. The orthopaedic device of claim 21, wherein said radiolucent marker is one of stainless steel, titanium, titanium alloy, barium sulfate filled polyetheretherketone (PEEK), carbon filled PEEK, and a polymer including one of barium sulfate and zirconium dioxide.

23. The orthopaedic device of claim 21, wherein said radiolucent marker is at least one of a pin, said head, said tip, and said at least one thread.

24. The orthopaedic device of claim 21, wherein said screw further comprises a plurality

of layers.

25. The orthopaedic device of claim 24, wherein at least one of said plurality of layers is said radiolucent marker.

26. Method of localized delivery of a therapeutic agent to surrounding tissue, the method comprising:

providing a therapeutic agent;

providing a screw having at least one of channels, holes and a reservoir for delivering a predetermined amount of said therapeutic agent to said surrounding soft tissue; and

positioning said screw at a predetermined location in the body of a patient.

27. The method according to claim 26, wherein said therapeutic agent is pre-loaded in said screw.

28. The method according to claim 26, wherein said therapeutic agent is loaded into said screw one of before, during and after a surgery.

29. The method according to claim 28, further comprising the step of providing one of a self-sealing polymer diaphragm and a removable cap for direct interface with a needle for loading said therapeutic agent into said screw.

30. The method according to claim 26, wherein said therapeutic agent is one of hydroxyapetit, drugs and biologics.

31. The method according to claim 26, further comprising the step of providing a marker for indicating position and orientation of said screw in said body of said patient.

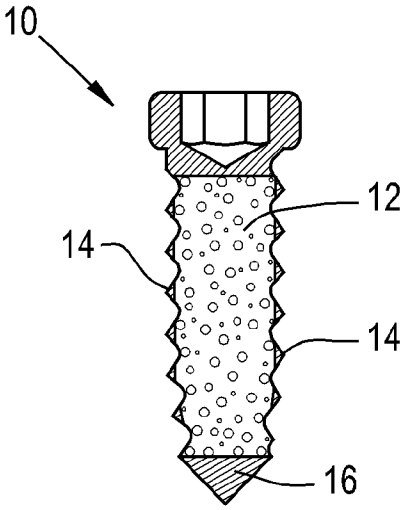

Fig. 1

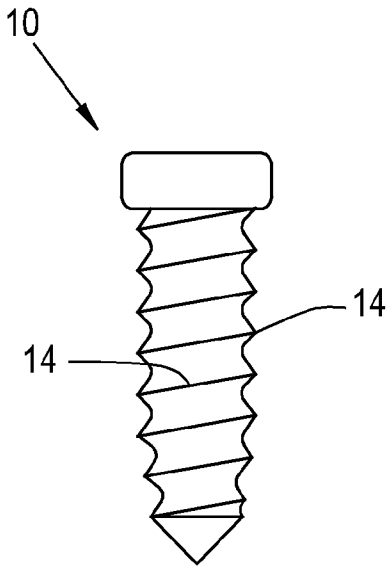

Fig. 2A

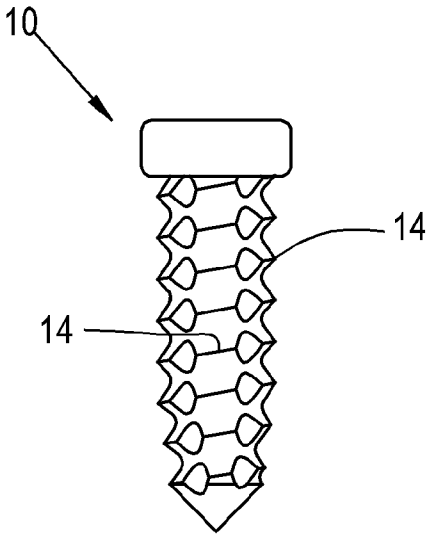

Fig. 2B

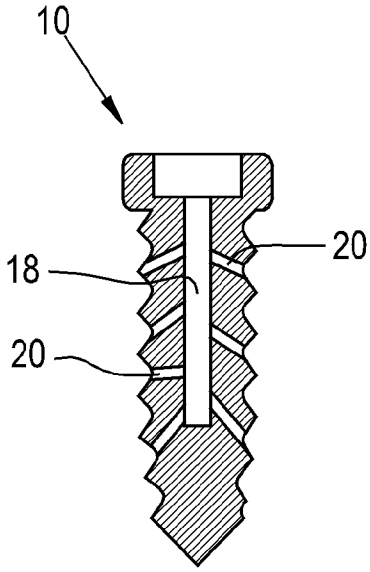

Fig. 3

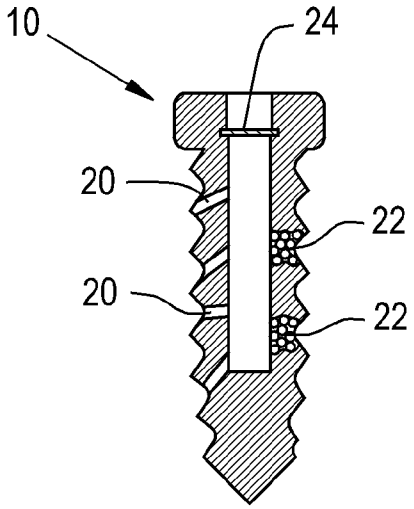

Fig. 4

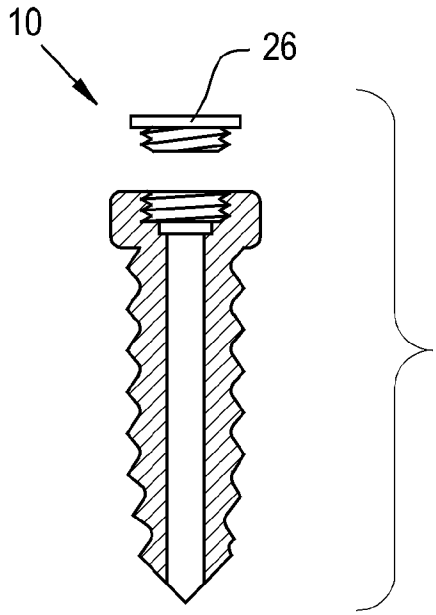

Fig. 5

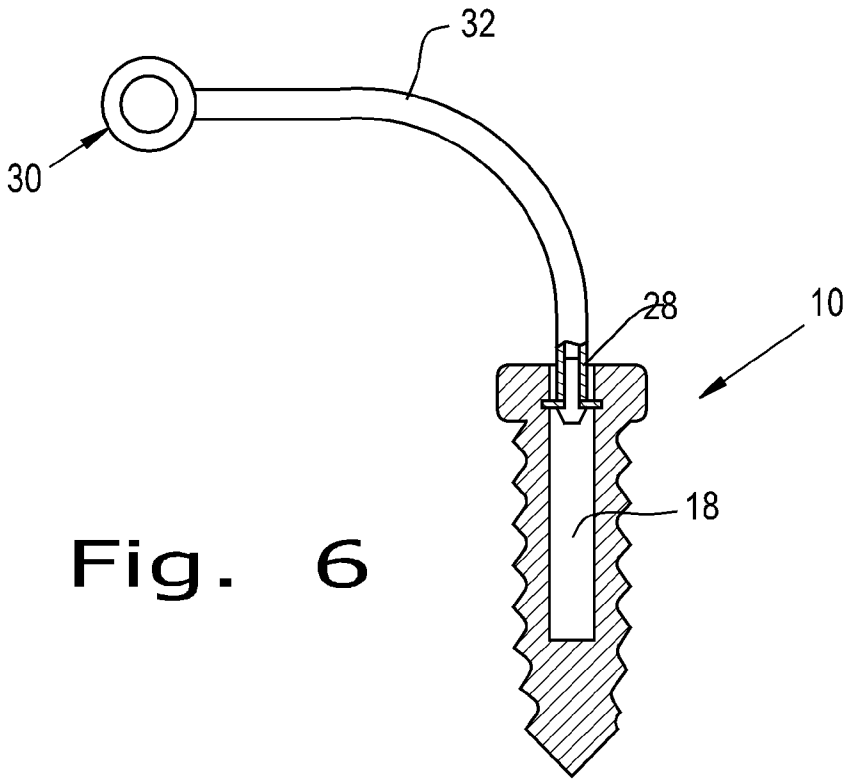

Fig. 6

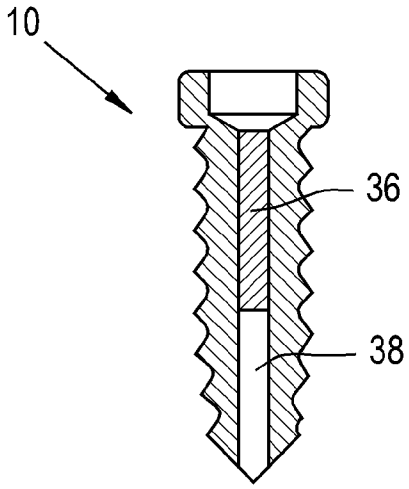

Fig. 7A

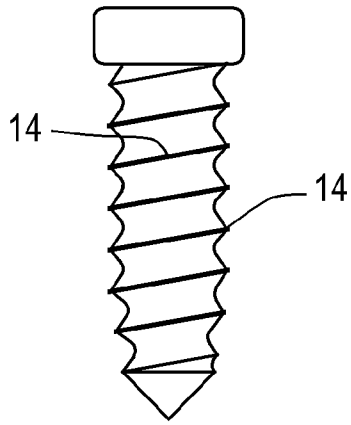

Fig. 7B

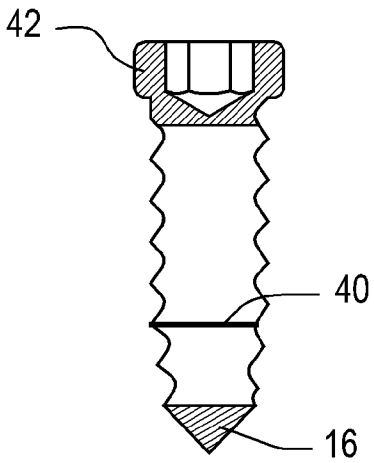

Fig. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/053735

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/58 (2009.01)
USPC - 606/300
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/58, 17/86, 17/88 (2009.01)
USPC - 604/93.01; 606/94, 218, 300, 304

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2004/0267263 A1 (MAY) 30 December 2004 (30.12.2004) entire document	12-13, 17, 19-20, 26, 30 --- 1-11, 14-16, 18, 21-25, 27-29, 31
Y	US 2005/0187555 A1 (BIEDERMANN et al) 25 August 2005 (25.08.2005) entire document	1-11, 18
Y	US 2005/0137707 A1 (MALEK) 23 June 2005 (23.06.2005) entire document	14, 29
Y	US 2005/0015059 A1 (SWEENEY) 20 January 2005 (20.01.2005) entire document	15-16, 27-29
Y	US 2006/0264950 A1 (NELSON et al) 23 November 2006 (23.11.2006) entire document	21-25, 31

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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
21 September 2009	28 SEP 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)