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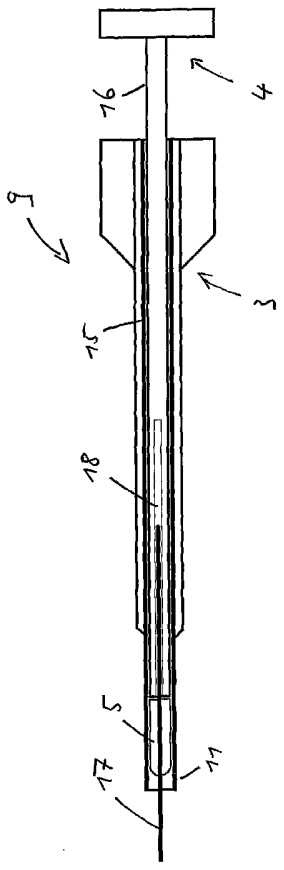
(54) Title: SYSTEM AND IMPLANT FOR LIGAMENT RECONSTRCTION OR BONE RECONSTRUCTION



(57) Abstract: The present application relates to an implant for ligament reconstruction and/orbone reconstruction. According to the application, the implant (5) comprises a biodegradable material which is suitable to be remodeled into vital bone, wherein the biodegradable material has a mechanical strength for securely fixinga ligament in a bore or hole of a bone by means of press fit or form fit and/or a mechanical strength for reshaping a collapsed surface of a bone into its original shape. The present application further relates to a surgical instrument (9) for ligament reconstruction and/or bone reconstruction which can be used to insert the present implant (5) into a bone. The surgical instrument (9) comprises a shaft member (3) having a first end (11), a second end and a longitudinal bore (15), wherein the longitudinal bore (15) has an inner diameter, and a pushing member (4) having a first end, a second end and a piston (16), wherein the piston (16) has an outer diameter, wherein the outer diameter of the piston (16) is smaller or equal than the inner diameter of the longitudinal bore (10) so that the piston (16) of the pushing member (4) can be slidably arranged within the longitudinal bore (10).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

System and implant for ligament reconstruction or bone reconstruction

Field and background of the invention:

This invention relates to systems and implants for ligament reconstruction or bone reconstruction.

Reconstructions of the cruciate ligaments are among the most frequently performed procedures in knee surgery nowadays. The most common method for reconstructing a torn cruciate ligament involves a bone-patellar tendon graft or a semitendinosus graft, which is frequently fixed with metal (e.g. titanium or stainless steel) interference screws. The metal interference screws offer the advantage of a permanent implant with adequate mechanical strength. Sharp threads of the metallic interference screws may harm the transplant. In addition, years after the cruciate ligament reconstruction a revision is difficult to realize due to a bony sheating of the metal implants and often is associated with iatrogen damage.

Alternatively, resorbable interference screws made from PLLA, PDLLA, PLLA/TCP (e.g. 70%/30%) have been used with specially designed threads in order not to cut the tendon transplant. However, drawbacks such as loosening fixation, bone resorption and inflammatory reactions have been reported in literature.

In a different common method, the semitendinous tendon is used as a transplant for the reconstruction of the cruciate ligaments. It is often attached with an interconnection cord using a fixation distant to the articular. Due to the length and the polynominality of the reconstruction, the fixation may result in deterioration of stiffness and micro movements in the bone channel. Proximal articular fixation systems for semitendinous plasty are performed by inserting a transcondylar pin made of metal or PLLA. Beside the drawbacks of the used materials tunnel

enlargement of the drilling tunnel (tunnel enlargement) can be observed in some cases.

The present invention also relates to systems and implants for bone reconstruction which may be necessary if a vital bone structure has collapsed due to too high loads. According to the prior art, a collapsed joint is reconstruced by drilling a bore from a side of the bone which is opposite to the collapsed surface. The collapsed surface is then reduced into the correct anatomical position by introducing a pestle into the bore and by pushing this pestle against the collapsed surface. After the original shape of the collapsed surface has been reestablished, the remaining void under the reshaped surface is filled by a bone replacement material. An example for such a bone replacement material is a cement material as for example described in US 6,733,582 B1. The advantage of this material is that it is biodegradable and is replaced by vital bone structure over the time. However, the replacement material is restricted to applications with minor loadings, because it has a high porosity and contains macro holes in the size of 100 to 500 micrometers which are necessary in order to achieve a fast ingrowth of the vital bone structure.

Objects and summary of the invention:

It is the primary object of the present invention to provide a surgical instrument, a system and an implant for ligament reconstruction in order to achieve an improved mechanical strength of the ligament bone connection over the healing period. Further, an early rehabilitation should be achieved.

This object and other objects are achieved by an implant according to claim 1, by a surgical instrument according to claim 25 and by a system according to claim 31. The dependent claims depict advantageous embodiments of the invention.

The inventive implant is a biodegradable material which is suitable to be remodeled into vital bone, and which has a mechanical strength for securely fixing a ligament in a bore or hole of a bone by means of press fit or form fit. In this patent

application, the property of the biodegradable material to be remodeled into vital bone means that new vital bone is formed simultaneously as the implant material degrades by cellular activity. Osteoblasts fill the lacunae, thus synthesizing extracellular matrix which is subsequently calcified.

For reconstructing a ligament according to the present invention, the practitioner drills a bore into the bone. A natural ligament plasty (autograft, allograft or xenograft) with optional small bone blocks at one or both ends or a synthetic ligament is then inserted into the bore. The ligament is pressed to the side walls of the bore by means of a pestle or trocar so that the ligament which has viscoelastic properties, as well as the surrounding bone structure expand in radial direction. The inventive implant is then pressed into the bore in order to securely fix the ligament to the bone by press fit or form fit. The other end of the ligament may finally be fixed to another bone by means of the inventive implant or by means of conventional methods.

The implantation of the inventive implant is simple and can easily be reproduced also by practitioners with little experience in this field. The implant achieves a tensile force to failure of the ligament bone connection which is comparable or equal to a conventional fixation with interference screws. The mechanical properties of the ligament bone connection are sufficient during the complete healing phase and allow early rehabilitation. The risk of a critical loss of mechanical strength over healing period is reduced.

For pressing the implant into the bore for securely fixing the ligament, the inventive implant is designed to have a sufficient mechanical strength. The mechanical strength is sufficient to resist the pressure of a surgical instrument for pressing the implant into the bore. Therefore, the implant preferably has a compression strength of at least 50 N/mm^2, in particular at least 80 N/mm^2. Therefore, in case of a diameter of the implant of 7 mm, a force of up to 1900 N or 3000 N, respectively, may be applied to the implant for inserting the implant into the bore and for securely fixing the ligament by press fit or form fit. In view of theses forces, the

inventive implant is also designed to resist shear stress of preferably at least 50 N/mm^2 so that the side walls of the implant are not sheared off during insertion into the bore.

The biodegradable material of the inventive implant may have a micro pore structure with an average diameter ranging from 1 to 50 micrometers, in particular from 2 to 10 micrometers. The micro porosity accelerates the remodeling process by increasing the surface area an allowing for circulation of body fluids. Therefore, the porosity of the biodegradable material should be tailored to the desired period of biodegradation within a vital bone. On the other hand, the porosity of the biodegradable material is tailored to the mechanical strength required for securely fixing a ligament in a bore or hole by means of press fit or form fit. In order to achieve this mechanical strength, a porosity ranging from 25 % to 50 % by volume is preferred, in particular a porosity of about 40 % by volume. Preferably, at least part or all of the biodegradable material has no macro pores, which are defined in this patent application as having a diameter ranging from 100 to 500 micrometers.

The micro pore structure is also advantageous in view of the mechanical properties of the implant. The maximum tension stress at the end of a micro crack is reduced, because the radius of a micro pore is larger than the radius at the end of a crack in case of a material without micro pores. As a result, the tendency of a propagation of micro cracks is significantly reduced, in particular during the insertion of the implant. Since the preferred biodegradable material of the present invention is a ceramic material which is highly fragile per se, the micro pore structure is a measure to reduce the risk that the implant breaks during implantation due to the high compression force in order to press the implant into the bore of the bone.

In order to optimize the mechanical properties and the remodeling characteristics, the biodegradable material may have a gradient porosity, e.g. lower porosity and a higher mechanical strength at the outer surface of the implant, and a higher poros-

ity at the center of the implant. With that, a quicker remodeling of vital bone at the end of the healing process and a quicker rehabilitation is achieved.

According to the present invention, the implant materials are comprised of sintered or not sintered microporous ceramics such as hydroxyapatite, tricalcium phosphate, brushite, calcium sulfates, bioglass and combinations thereof. The preferred biodegradable material is β-tricalcium phosphate (β-$Ca_3(PO_4)_2$). This ceramic material already has been suggested as material for filling voids in bones. However, since this material is optimized for fast biodegradation, it contains macro pores resulting in a low strength material. The use of β-tricalcium phosphate has been restricted according to the prior art to applications with minor loadings.

The implant preferably consists only or at least 60 % by weight, in particular at least 75 % by weight of said biodegradable material which is suitable for remodeling into bone. The biodegradable material for remodeling into bone may be mixed or coated with other degradable materials such as polysaccharides, dextran, starch, alginate, chitosan, proteins, albumin, collagen, gelatin, polyesters, different types of lactid acid, poly(glycolide) (PGA), poly(ε-caprolactone) (PCL), poly(β-hydroxyalkanoates) such as poly(β-hydroxybutyrate) (PHB) and poly(β-hydroxyvalerate) (PHV), polyether-ester, poly(p-dioxanone) (PDO), polycarbonates, poly(trimethylene carbonate) (PTMC), poly (desaminotyrosyl tyrosine [ethyl ester] carbonate) (PDTE), poly(amino acids), tyrosine-derived polycarbonates and polyarylates, poly(anhydrides), poly(SA-HAD anhydride), where SA is sebacic acid and HAD is hexadecandioic acid, poly(orthoesters), polyphosphoesters, polyphosphazenes, polyurethanes, polyesteramides, polyalkylenoxalates and polyalkylcyanoacrylates. Such a composition of materials can be designed to further improve the mechanical properties of the implant for specific applications. In particular, a composition with polymers reduces the fragility of the biodegradable material which is suitable for remodeling into bone.

The material of the implant may further contain one or more agents for facilitating osteogenesis. For this purpose, peptides, proteins, hormones, oligonucleotides, nucleic acids, steroids, antibiotics, antiseptics and vaccines are particularly suitable. The agent may be contained in or on the surface of the micro pore structure of the biodegradable material or in or on a polymer as a carrier for the agent in order to achieve a controlled release characteristic due to the degradation of the polymer and/or of the ceramic.

The implant of the present invention has preferably a cylindrical shape. With that, a maximum friction at the side walls of the implant is achieved so that pulling out of the ligament form the bore is avoided. However, also a conical shape is possible, in particular in case of a retrograde fixation of a ligament, i.e. at a side of the bone which is opposite to the joint. For that, an angle of the side walls with respect to the center axis of the implant of 2° to 15° is preferred, in particular about 7° to 8°.

The implant may further have circumferential or longitudinal grooves or be designed in shape of a screw or of a fir tree in order to locally have an increased pressure between the implant and the surrounding vital bone structure. Such a locally increased pressure promotes the ingrowth of vital bone into the implant.

In view of the mechanical properties of the implant, it is preferred that the implant has no internal bores having a length exceeding 500 micrometers, and no bores as, for example, necessary with conventional implants in the shape of a dowel for fixing screws. On the other side, the implant of the present invention may be provided with an internal bore extending through the entire implant at its center axis in order to cooperate with a guide wire during implantation. This internal bore should have a small diameter in order not to reduce the mechanical properties of the implant, but to sufficiently support the implant over the guide wire in order to avoid a misalignment of the implant within the bore of the bone.

According to the present invention, the implant is preferably performed by means of a surgical instrument comprising a shaft member having a first end, a second end and a longitudinal bore, wherein the longitudinal bore has an inner diameter, and a pushing member having a first end, a second end and a piston, wherein the piston has an outer diameter which is smaller or equal than the inner diameter of the longitudinal bore so that the piston of the pushing member can be slidably arranged within the longitudinal bore.

With this surgical instrument, the implant can be inserted into the longitudinal bore of the shaft member. The piston of the pushing member can be introduced into the longitudinal bore from the second end of the shaft member in order to push to implant out of the longitudinal bore. During implantation, the first end of the shaft member is brought into contact with the bone surface over the bore. The shaft member can not be inserted into the bore, because its diameter is slightly greater. Therefore, the shaft member serves to support the implant at its side walls during implantation whereas the pushing member presses the implant into the bore within the bone. As a result, the surgical instrument enables a proper and well aligned insertion of the implant, because the practitioner can easily control the insertion direction of the implant by means of the shaft member.

In order to further improve the support of the implant and its alignment during implantation, it is also possible to use a guide wire which extends through an internal bore of the implant and through an internal bore of the pushing member. With that, the implant is even supported when it is pushed out of the shaft member, because the guide wire may extend into the bore in the bone.

Alternatively, the guide wire can be fixed within the shaft member which extends at least partially at its center axis, and which extends through the first end of the shaft member so as to project by a length corresponding to the length of the implant. In this case, the pushing member has an internal slit so that it can be slided over the guide wire. The implant is sufficiently supported by the guide wire in

order to avoid a misalignment of the implant within the bore of the bone during implantation.

With the surgical instrument according to the present invention, high forces can be applied to the implant during implantation, however, without damaging the implant due to a guided insertion into the bore of the bone. It is advantageous to provide the second end of the implant and the first end of the pushing member with flat surfaces so that the pressure is evenly distributed.

As a result, a ligament fixation near joint surface is achieved with a high mechanical strength of the ligament bone connection and with a good in vivo behavior. Further, since the implant is biodegradable, a removal is not necessary in case of revision surgery.

It is another primary object of the present invention to provide a system and an implant for bone reconstruction which enables a simplified procedure, and which can also be used for applications with medium and high loadings. Further, an early rehabilitation should be achieved.

The inventive implant and the inventive surgical instrument may also be used for bone reconstruction. In case of a collapsed bone structure, a bore is drilled from a side of the bone which is opposite to the collapsed surface. The collapsed surface is then pushed outwardly by directly introducing the implant into the bore. Therefore, the collapsed surface is reshaped by the pressure of the implant itself. As a result, the step of filling a void within the bone which was necessary for inserting a pestle, has been reduced to the insertion of the implant only. According to the invention, it is not necessary to fill a void after reshaping of the collapsed surface, because the implant remains in the bore.

Brief description of the drawings:

Fig. 1 shows the situation of a knee joint in which a rupture of an anterior cruciate ligament may occur;

Fig. 2 shows a pestle of trocar of a system according to the present invention;

Fig. 3 shows a shaft member of a surgical instrument according to an embodiment of the present invention;

Fig. 4 shows a pushing member of a surgical instrument according to an embodiment of the present invention;

Fig. 5 shows an implant according to a first embodiment of the present invention;

Fig. 6 shows an implant according to a second embodiment of the present invention;

Fig. 7 shows an implant according to a third embodiment of the present invention;

Fig. 8 shows a surgical instrument with an implant according to another embodiment of the present invention;

Figs. 9 to 12 show the micro pore structure of a biodegradable material for an implant according to an embodiment of the present invention in various magnifications;

Figs. 13 and 14 show a structure having macro pores and micro pores of a biodegradable material according to the prior art.

Detailed description of the invention:

Fig. 1 shows the situation of a knee joint in which a rupture of an anterior cruciate ligament **1** may occur e.g. in case of forcible external rotation and abduction of the knee or by increased contraction of the quadriceps muscle induced by forcible flection of the knee. For restoring the ruptured anterior cruciate ligament **1**, a ligament plasty is necessary in which a ligament is connected to the bone structure. The present invention provides an implant, a surgical instrument and a system for reconstructing the anterior cruciate ligament. However, the present invention is not limited to this application; the present invention is also directed to the reconstruction of other ligament bone connections.

For reconstructing a ligament according to the present invention, the practitioner drills a bore into the bone. A natural ligament plasty (autograft, allograft or xeno-

graft) with an optional small bone blocks at one or both ends or a synthetic ligament is then inserted into the bore. The ligament is pressed to the side walls of the bore by means of a pestle or trocar **2** so that the ligament which has viscoelastic properties, as well as the surrounding bone structure expand in radial direction. The inventive implant **4, 5, 6** - as shown, for example, in **Figs. 5 to 7** - is then pressed into the bore in order to securely fix the ligament to the bone by press fit or form fit. The other end of the ligament may finally be fixed to another bone by means of the inventive implant or by means of conventional methods.

A pestle or trocar **2** according to a system of the present invention is shown in **Fig. 2**. The pestle **2** has a first end **8** with an outer diameter which is equal or slightly smaller than the outer diameter of the implant **4, 5, 6** so that the implant has to be inserted into the bore with a relatively high force in the order of for example greater than 500 N up to 3000 N.

For pressing the implant **4, 5, 6** into the bore for securely fixing the ligament, the inventive implant is designed to have a sufficient mechanical strength. The mechanical strength is sufficient to resist the pressure of a surgical instrument **9** for pressing the implant into the bore. Therefore, the implant preferably has a compression strength of at least 50 N/mm^2, in particular at least 80 N/mm^2. Therefore, in case of a diameter of the implant of 7 mm, a force of up to 1900 N or 3000 N, respectively, may be applied to the implant **4, 5, 6** for inserting the implant into the bore and for securely fixing the ligament by press fit or form fit. In view of theses forces, the inventive implant is also designed to resist shear stress of preferably at least 50 N/mm^2 so that the side walls of the implant are not sheared off during insertion into the bore.

Figs. 9 to 12 show the micro pore structure of a biodegradable material for an implant according to an embodiment of the present invention in various magnifications. The shown biodegradable material is β-tricalcium phosphate (β-$Ca_3(PO_4)_2$) having a micro pore structure with an average diameter ranging from 1

to 50 micrometers, in particular from 2 to 10 micrometers as shown in **Figs. 11 and 12**. The microporosity accelerates the remodeling process by increasing the surface area an allowing for circulation of body fluids. Therefore, the porosity of the biodegradable material should be tailored to the desired period of biodegradation within a vital bone. On the other hand, the porosity of the biodegradable material is tailored to the mechanical strength required for securely fixing a ligament in a bore or hole by means of press fit or form fit. In order to achieve this mechanical strength, a porosity ranging from 25 % to 50 % by volume is preferred, in particular a porosity of about 40 % by volume.

Preferably, at least part or all of the biodegradable material has no macro pores, which are defined in this patent application as having a diameter ranging from 100 to 500 micrometers. A biodegradable material such as β-tricalcium phosphate having macro pores and micro pores is shown in **Figs. 13 and 14**. This ceramic material already has been suggested as material for filling voids in bones. However, since this material is highly fragile, and since the macro pores result in a porosity of the material of 60 % to 70 %, the use of β-tricalcium phosphate has been restricted according to the prior art to applications with minor loadings.

The micro pore structure is also advantageous in view of the mechanical properties of the inventive implant. The maximum tension stress at the end of a micro crack is reduced, because the radius of a micro pore is larger than the radius at the end of a crack in case of a material without micro pores. As a result, the tendency of a propagation of micro cracks is significantly reduced, in particular during the insertion of the implant.

In order to optimize the mechanical properties and the remodeling characteristics, the biodegradable material may have a gradient porosity, e.g. a lower porosity and a higher mechanical strength at the outer surface of the implant, and a higher porosity at the center of the implant. With that, a quicker remodeling of vital bone at the end of the healing process and a quicker rehabilitation is achieved.

The implant preferaby consists only or at least 60 % by weight, in particular at least 75 % by weight of said biodegradable material which is suitable for remodeling into bone. The biodegradable material for remodeling into bone may be mixed with other biodegradable materials such as polysaccharides, dextran, starch, alginate, chitosan, proteins, albumin, collagen, gelatin, polyesters, different types of lactid acid, poly(glycolide) (PGA), poly(ε-caprolactone) (PCL), poly(β-hydroxyalkanoates) such as poly(β-hydroxybutyrate) (PHB) and poly(β-hydroxyvalerate) (PHV), polyether-ester, poly(p-dioxanone) (PDO), polycarbonates, poly(trimethylene carbonate) (PTMC), poly (desaminotyrosyl tyrosine [ethyl ester] carbonate) (PDTE), poly(amino acids), tyrosine-derived polycarbonates and polyarylates, poly(anhydrides), poly(SA-HAD anhydride), where SA is sebacic acid and HAD is hexadecandioic acid, poly(orthoesters), polyphosphoesters, polyphosphazenes, polyurethanes, polyesteramides, polyalkylenoxalates and polyalkylcyanoacrylates. Such a composition of materials can be designed to further improve the mechanical properties of the implant for specific applications. In particular, a composition with polymers reduces the fragility of the biodegradable material which is suitable for remodeling into bone.

The material of the implant may further contain one or more agents for facilitating osteogenesis. For this purpose, peptides, proteins, hormones, oligonucleotides, nucleic acids, steroids, antibiotics, antiseptics and vaccines are particularly suitable. The agent may be contained in the micro pore structure of the biodegradable material or in a polymer as a carrier for the agent in order to achieve a controlled release characteristic due to the degradation of the polymer.

Fig. 5 shows an implant **5** according to a preferred embodiment of the present invention which has a cylindrical shape. The outer diameter of the shown implant **5** is 7 mm and the length is 25 mm. A maximum friction is achieved with a cylindrical shape at the side walls of the implant so that pulling out of the ligament form the bore is avoided. However, also a conical shape of an inventive implant **6** is possible as shown in **Fig. 6**, in particular in case of a retrograde fixation of a

ligament, i.e. at a side of the bone which is opposite to the joint. For that, an angle of the side walls with respect to the center axis of the implant of 2° to 15° is preferred, in particular about 7° to 8°.

The implant may further have circumferential or longitudinal grooves **10**, as this is the case with the implant **7** having the fir tree structure shown in **Fig. 7**. The portions of the implant **7** having a larger diameter cause an increased pressure between the implant **7** and the surrounding vital bone structure. Such a locally increased pressure promotes the ingrowth of vital bone into the implant.

In view of the mechanical properties of the implant, it is preferred that the implant has no internal bores having a length exceeding 500 micrometers, and no bores as, for example, necessary with conventional implants in the shape of a dowel for fixing screws. On the other side, the implant of the present invention may be provided with an internal bore extending through the entire implant at its center axis in order to cooperate with a guide wire during implantation. This internal bore should have a small diameter in order not to reduce the mechanical properties of the implant, but to sufficiently support the implant over the guide wire in order to avoid a misalignment of the implant within the bore of the bone.

Fig. 3 shows a shaft member **3** of a surgical instrument according to a preferred embodiment of the present invention. The shaft member **3** has a first end **11**, a second end **12** and a longitudinal bore **15**, wherein the longitudinal bore **15** has an inner diameter. The surgical instrument of this embodiment further comprises a pushing member **4** - shown in **Fig. 4** - having a first end **13**, a second end **14** and a piston **16**, wherein the piston **16** has an outer diameter which is smaller or equal than the inner diameter of the longitudinal bore **15** so that the piston **16** of the pushing member **4** can be slidably arranged within the longitudinal bore **15**.

With the surgical instrument of this embodiment, an implant **5, 6, 7** can be inserted into the longitudinal bore **15** of the shaft member **3**. The piston **16** of the pushing member **4** can be introduced into the longitudinal bore **15** from the sec-

ond end **12** of the shaft member **3** in order to push to implant out of the longitudinal bore **15**. During implantation, the first end **11** of the shaft member **3** is brought into contact with the bone surface over the bore. The shaft member can not be inserted into the bore, because its diameter is slightly greater. Therefore, the shaft member **3** serves to support the implant at its side walls during implantation whereas the pushing member **4** presses the implant into the bore within the bone. As a result, the surgical instrument enables a proper and well aligned insertion of the implant, because the practitioner can easily control the insertion direction of the implant **5, 6, 7** by means of the shaft member **3**.

In order to further improve the support of the implant and its alignment during implantation, it is also possible to use a guide wire which extends through an internal bore of the implant and through an internal bore of the pushing member. With that, the implant is even supported when it is pushed out of the shaft member, because the guide wire may extend into the bore in the bone.

Fig. 8 shows a surgical instrument **9** with an implant according to another embodiment of the present invention. In this surgical instrument **9**, a guide wire **17** is fixed within the shaft member **3** which extends at least partially at its center axis, and which extends through the first end **11** of the shaft member **3** so as to project by a length corresponding to the length of the implant **5**. In this case, the pushing member **4** has an internal slit **18** so that it can be slided over the guide wire **17**. The implant **5** having an internal bore is sufficiently supported by the guide wire in order to avoid a misalignment of the implant within the bore of the bone during implantation.

With the surgical instrument according to the present invention, high forces can be applied to the implant during implantation, however, without damaging the implant due to a guided insertion into the bore of the bone. It is advantageous to provide the second end **20** of the implant and the first end **13** of the pushing member with flat surfaces so that the pressure is evenly distributed. The first end **19** of

the implant is preferably rounded in order to facilitate the insertion into the bore of the bone.

As a result, a ligament fixation near joint surface is achieved with the present invention with a high mechanical strength of the ligament bone connection and with a good in vivo behavior. Further, since the implant is biodegradable, a removal is not necessary in case of revision surgery.

The inventive implant and the inventive surgical instrument may also be used for bone reconstruction. In case of a collapsed bone structure, a bore is drilled from a side of the bone which is opposite to the collapsed surface. The collapsed surface is then pushed outwardly by directly introducing the implant into the bore. Therefore, the collapsed surface is reshaped by the pressure of the implant itself. As a result, the step of filling a void within the bone which was necessary for inserting a pestle, has been reduced to the insertion of the implant only. According to the invention, it is not necessary to fill a void after reshaping of the collapsed surface, because the implant remains in the bore.

Claims

1. Implant for ligament reconstruction and/or bone reconstruction characterized in that the implant comprises a biodegradable material which is suitable to be remodeled into vital bone, wherein the biodegradable material has a mechanical strength for securely fixing a ligament in a bore or hole of a bone by means of press fit or form fit and/or a mechanical strength for reshaping a collapsed surface of a bone into its original shape.

2. Implant according to claim 1, characterized in that said biodegradable material has a compression strength of at least 50 N/mm^2, in particular at least 80 N/mm^2.

3. Implant according to claim 1 or 2, characterized in that said biodegradable material has a shear stress strength of at least 50 N/mm^2.

4. Implant according to one of the preceding claims, characterized in that said biodegradable material comprises a micro pore structure.

5. Implant according to claim 4, characterized in that the micro pores have an average diameter ranging from 1 to 50 micrometers.

6. Implant according to claim 4, characterized in that the micro pores have an average diameter ranging from 2 to 10 micrometers.

7. Implant according to one of the preceding claims, characterized in that said resorbable material has a porosity ranging from 25 % to 50 % by volume.

8. Implant according to one of the preceding claims, characterized in that said resorbable material has a porosity of about 40 % by volume.

9. Implant according to one of the preceding claims, characterized in that the porosity of said biodegradable material is tailored to the mechanical strength required for securely fixing a ligament in a bore or hole by means of press fit or form fit.

10. Implant according to one of the preceding claims, characterized in that the porosity of said biodegradable material is tailored to the desired period of biodegradation within a vital bone.

11. Implant according to one of the preceding claims, characterized in that said biodegradable material has a gradient porosity, in particular a lower porosity and a higher mechanical strength at the outer surface of the implant, and a higher porosity at the center of the implant.

12. Implant according to one of the preceding claims, characterized in that at least part of said biodegradable material or all of said biodegradable material has no macro pores with a diameter ranging from 100 to 500 micrometers.

13. Implant according to one of the preceding claims, characterized in that said biodegradable material is selected from the group consisting of sintered or not sintered microporous ceramics such as hydroxyapatite, tricalcium phosphate, β-tricalcium phosphate (β-$Ca_3(PO_4)_2$), brushite, calcium sulfates, bioglass and combinations thereof.

14. Implant according to one of the preceding claims, characterized in that the implant consists of a composition of said degradable material and of a material selected from the group of: polysaccharides, dextran, starch, alginate, chitosan, proteins, albumin, collagen, gelatin, polyesters, different types of

lactid acid, poly(glycolide) (PGA), poly(ε-caprolactone) (PCL), poly(β-hydroxyalkanoates) such as poly(β-hydroxybutyrate) (PHB) and poly(β-hydroxyvalerate) (PHV), polyether-ester, poly(p-dioxanone) (PDO), poly-carbonates, poly(trimethylene carbonate) (PTMC), poly (desaminotyrosyl tyrosine [ethyl ester] carbonate) (PDTE), poly(amino acids), tyrosine-derived polycarbonates and polyarylates, poly(anhydrides), poly(SA-HAD anhydride), where SA is sebacic acid and HAD is hexadecandioic acid, poly(orthoesters), polyphosphoesters, polyphosphazenes, polyurethanes, polyesteramides, polyalkylenoxalates and polyalkylcyanoacrylates.

15. Implant according to one of the preceding claims, characterized in that the implant consists at least 60% by weight, in particular at least 75 % by weight of said biodegradable material.

16. Implant according to one of the preceding claims, characterized in that the implant comprises one or more agents selected from the group of: osteo-genesis facilitating agents, peptides, proteins, hormones, oligonucleotides, nucleic acids, steroids, antibiotics, antiseptics and vaccines.

17. Implant according to one of claims 1 to 13, characterized in that the implant only consists of said biodegradable material.

18. Implant according to one of the preceding claims, characterized in that the implant has a cylindrical shape.

19. Implant according to one of claims 1 to 17, characterized in that the implant has a conical shape.

20. Implant according to claim 18 or 19, characterized in that the implant has circumferential or longitudinal grooves.

21. Implant according to one of claims 1 to 17, characterized in that the implant has the shape of a screw or of a fir tree.

22. Implant according to one of claims 1 to 17, characterized in that the implant has an internal bore extending through the entire implant at its center axis for cooperating with a guide wire.

23. Implant according to claim 18 to 21, characterized in that the implant has no internal holes or bores.

24. Implant according to claim 18 to 23, characterized in that the implant has a rounded first end and a flat second end.

25. Surgical instrument for ligament reconstruction and/or bone reconstruction, characterized by
a shaft member having a first end, a second end and a longitudinal bore, wherein the longitudinal bore has an inner diameter, and
a pushing member having a first end, a second end and a piston, wherein the piston has an outer diameter,
wherein the outer diameter of the piston is smaller or equal than the inner diameter of the longitudinal bore so that the piston of the pushing member can be slidably arranged within the longitudinal bore.

26. Surgical instrument according to claim 25, characterized in that the length of the piston is equal to or longer than the longitudinal bore of the shaft member.

27. Surgical instrument according to claim 25 or 26, characterized in that the second end of the shaft member and the second end of the pushing member are both provided with a handle.

28. Surgical instrument according to one of claims 25 to 27, characterized in that the pushing member has an internal bore for slidably supporting a guide wire within the internal bore so that an implant with an internal bore can be sufficiently supported by the guide wire in order to avoid a misalignment of the implant within the bore of the bone during implantation.

29. Surgical instrument according to one of claims 25 to 27, characterized in that a guide wire is fixed within the shaft member which extends at least partially at its center axis, and which extends through the first end of the shaft member so as to project by a length corresponding to the length of the implant.

30. Surgical instrument according to claim 29, characterized in that the pushing member has an internal slit so that the pushing member can be slided over the guide wire so that an implant with an internal bore can be sufficiently supported by the guide wire in order to avoid a misalignment of the implant within the bore of the bone during implantation.

31. System for ligament reconstruction and/or bone reconstruction comprising a pestle having a first end and a second end, characterized by an implant according to one of claims 1 to 24.

32. System according to claim 31, characterized in that the outer diameter of the first end of the pestle is equal or slightly smaller than the outer diameter of the implant.

33. System for ligament reconstruction and/or bone reconstruction characterized by a surgical instrument according to one of claims 25 to 30, and by an implant according to one of claims 1 to 24.

34. System according to claim 33, characterized in that the implant is adapted to slide within the longitudinal bore of the shaft member, and in that the

pushing member is adapted to push the implant out of the longitudinal bore.

5

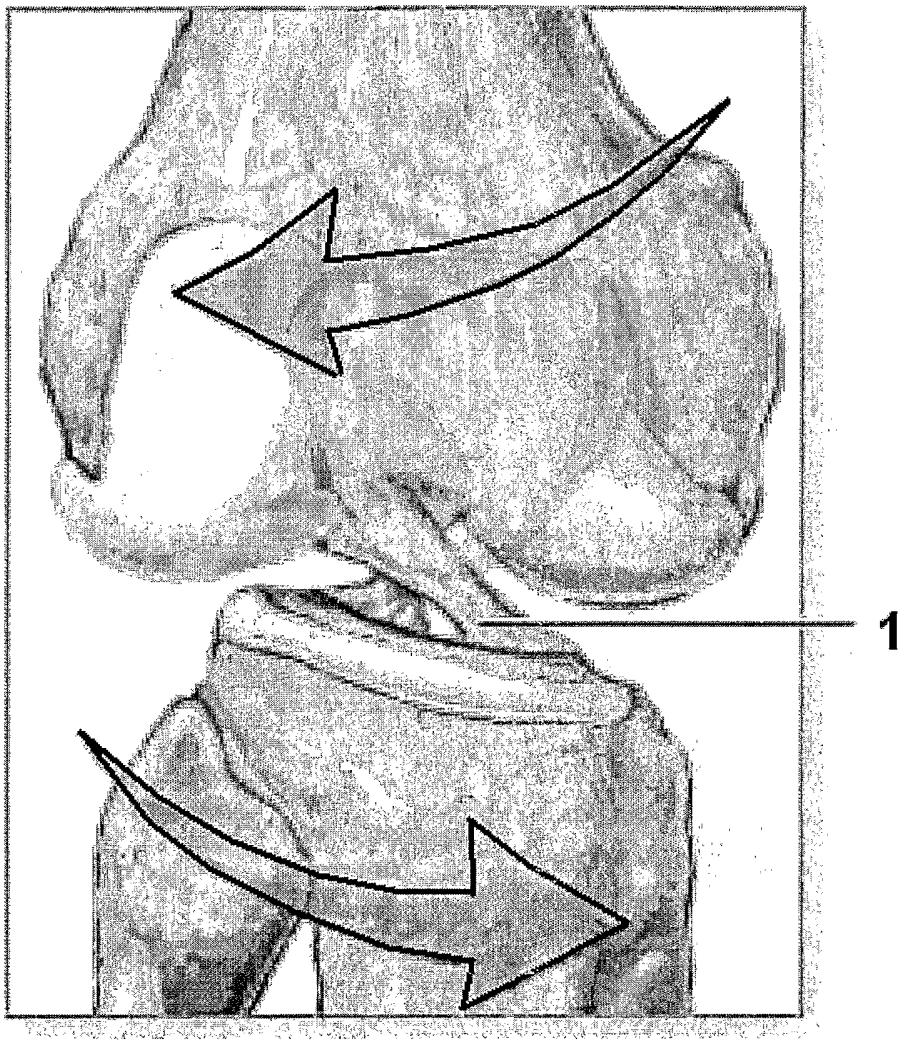


Fig. 1

Fig. 2

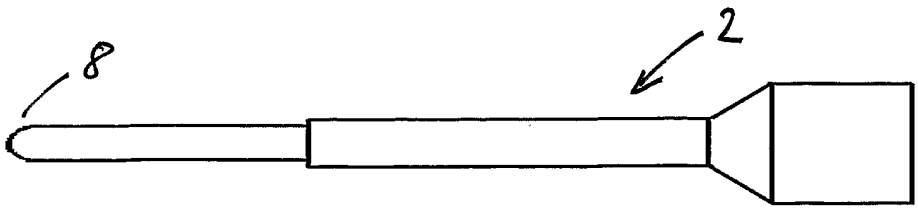


Fig. 3

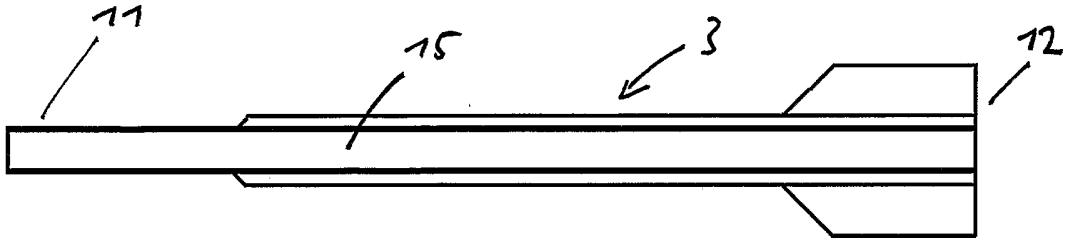


Fig. 4

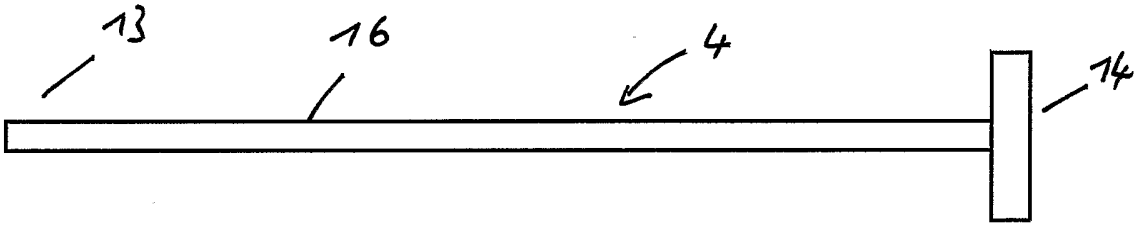


Fig. 5

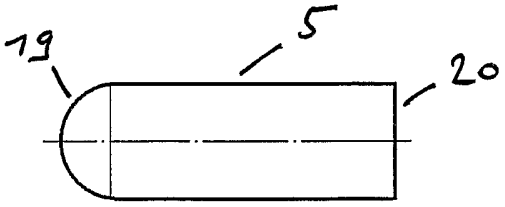


Fig. 6

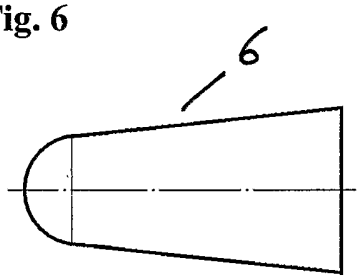
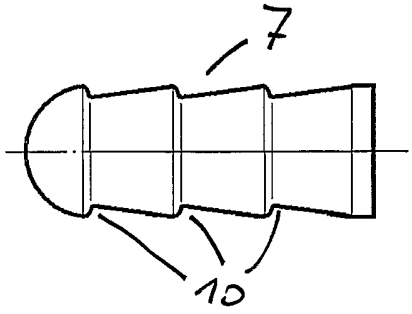


Fig. 7



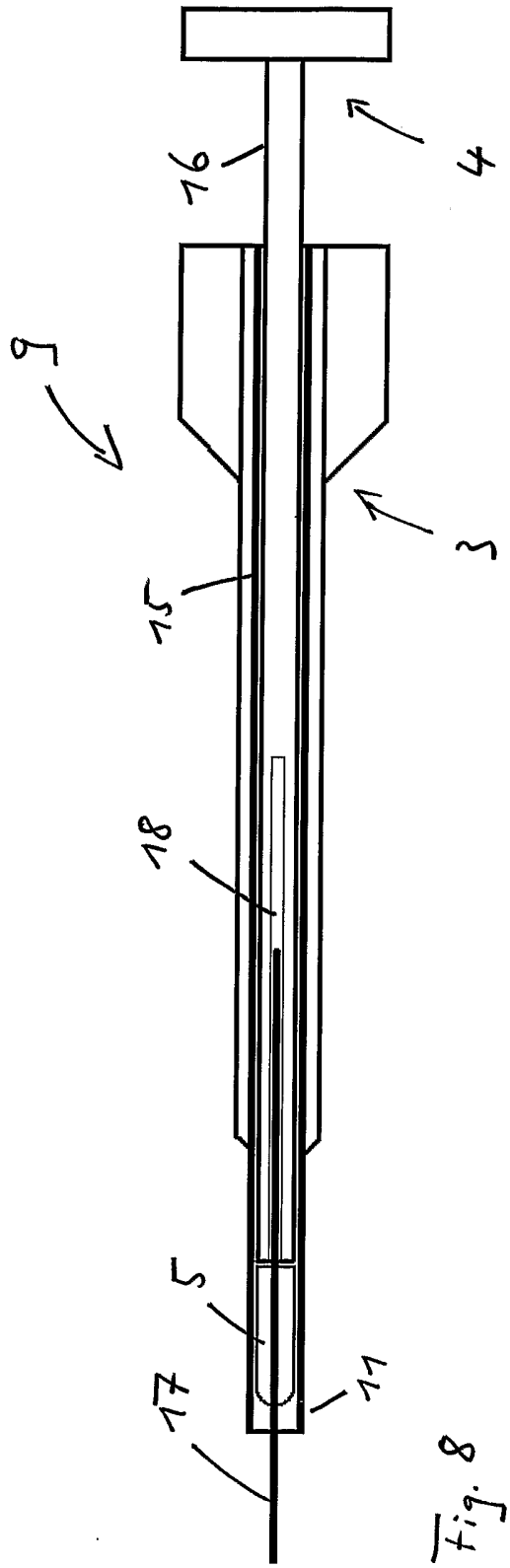


Fig. 8

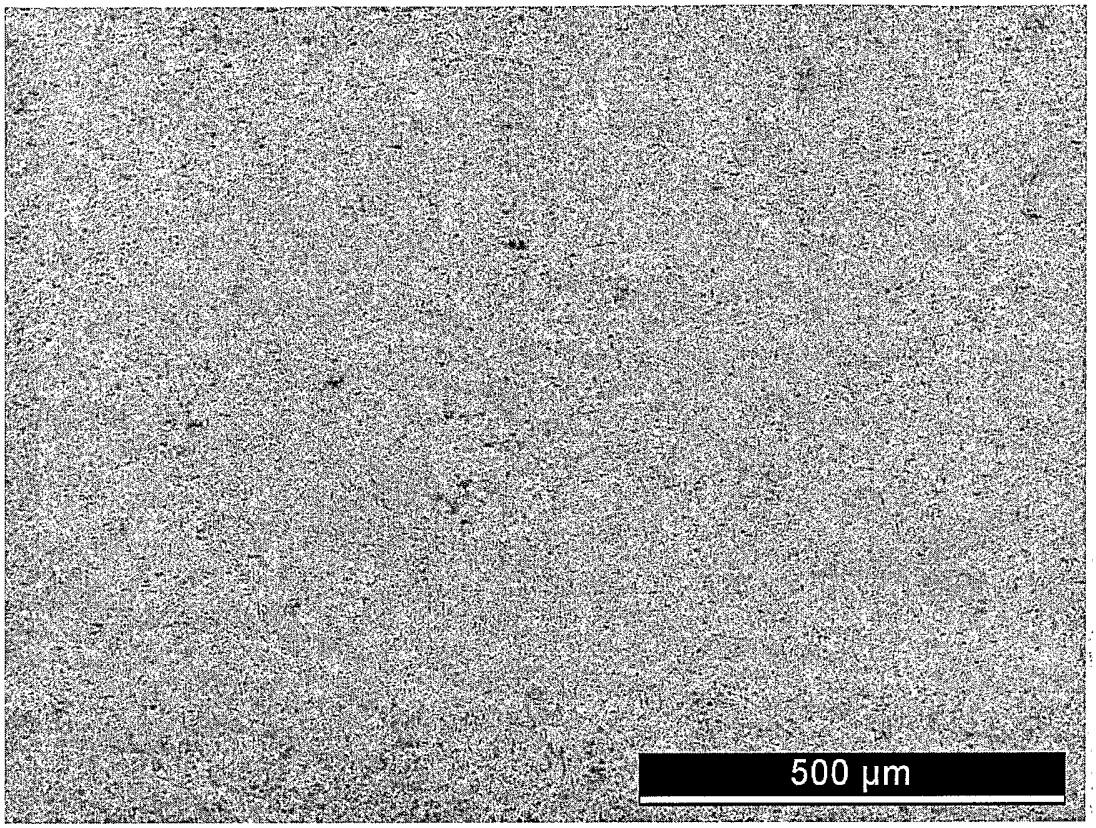


Fig. 9

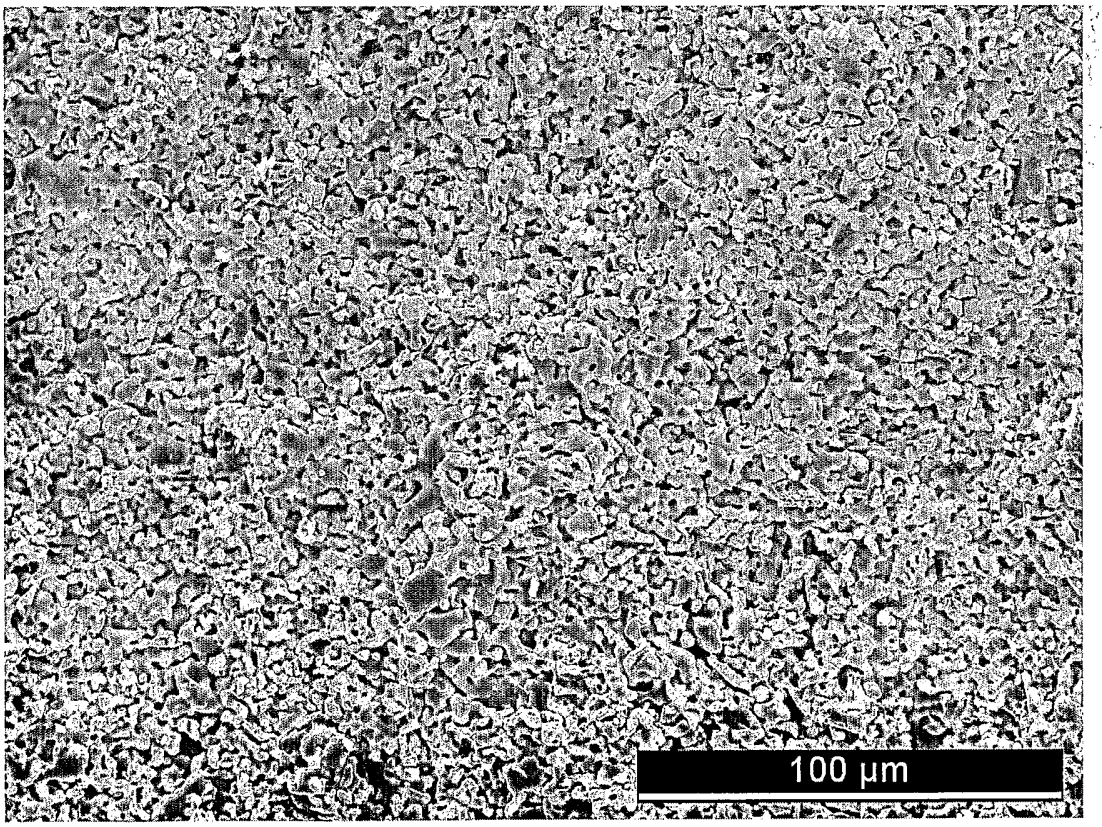


Fig. 10

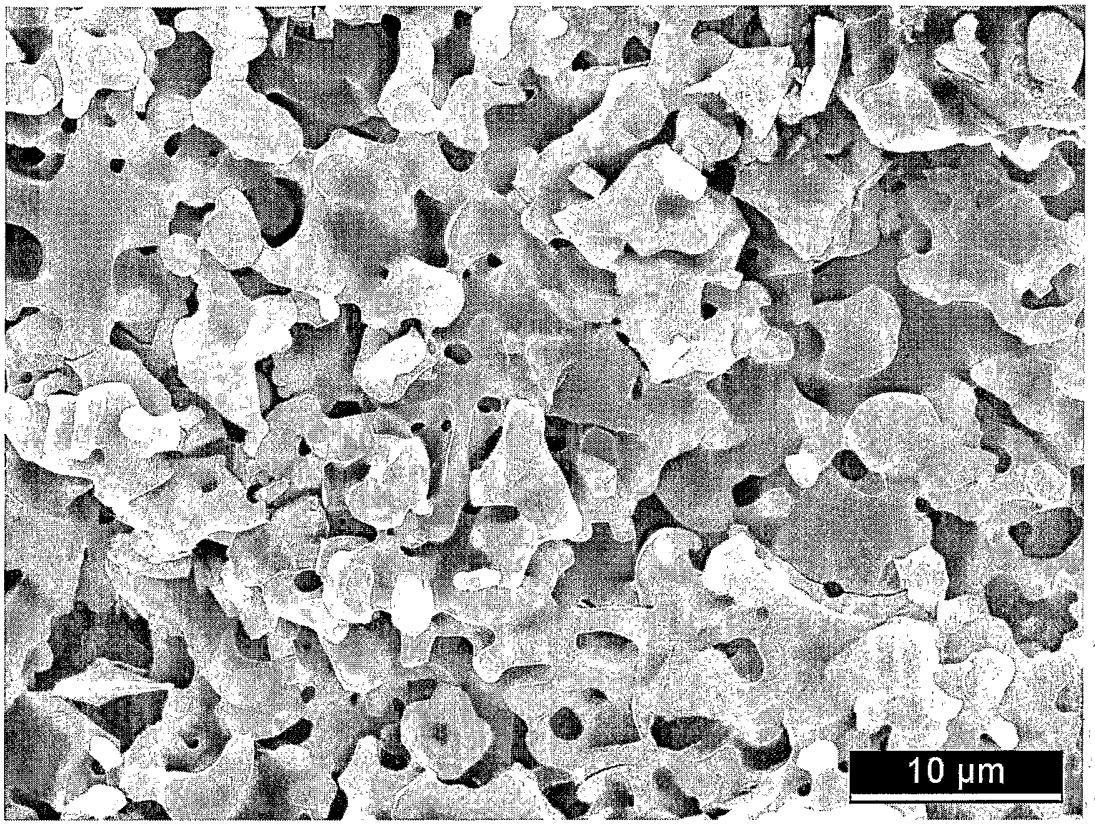


Fig. 11

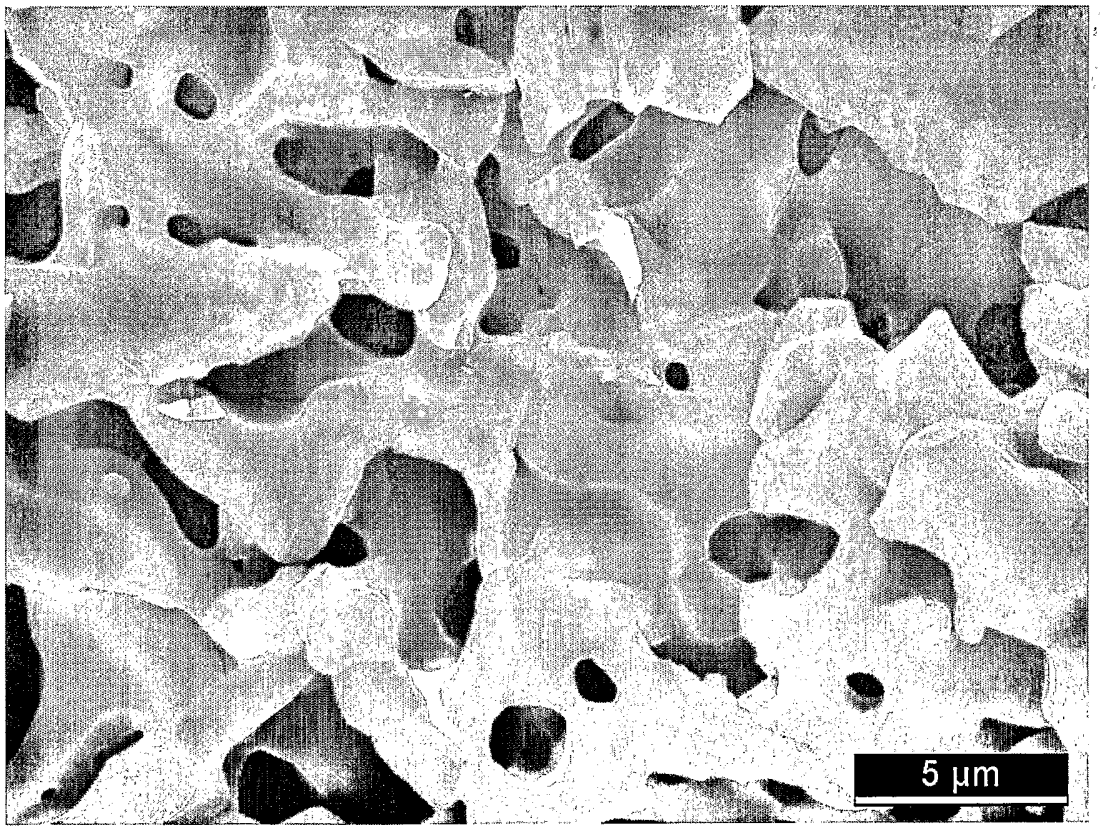


Fig. 12

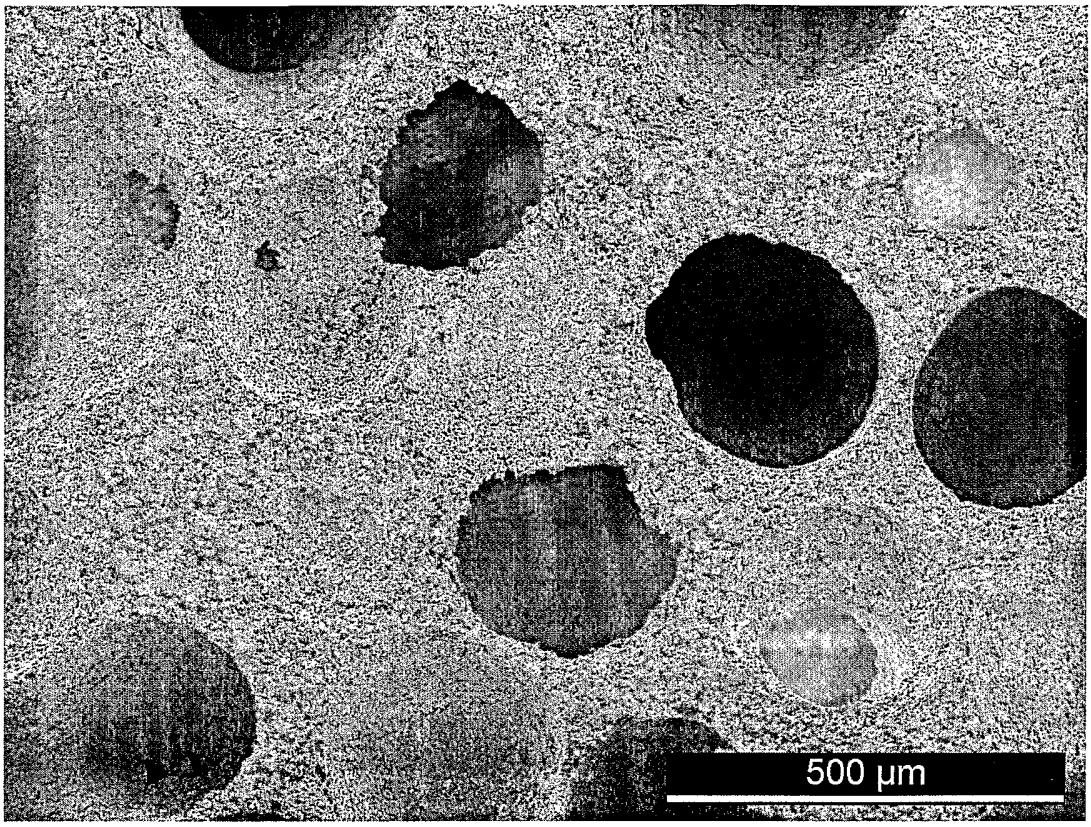


Fig. 13

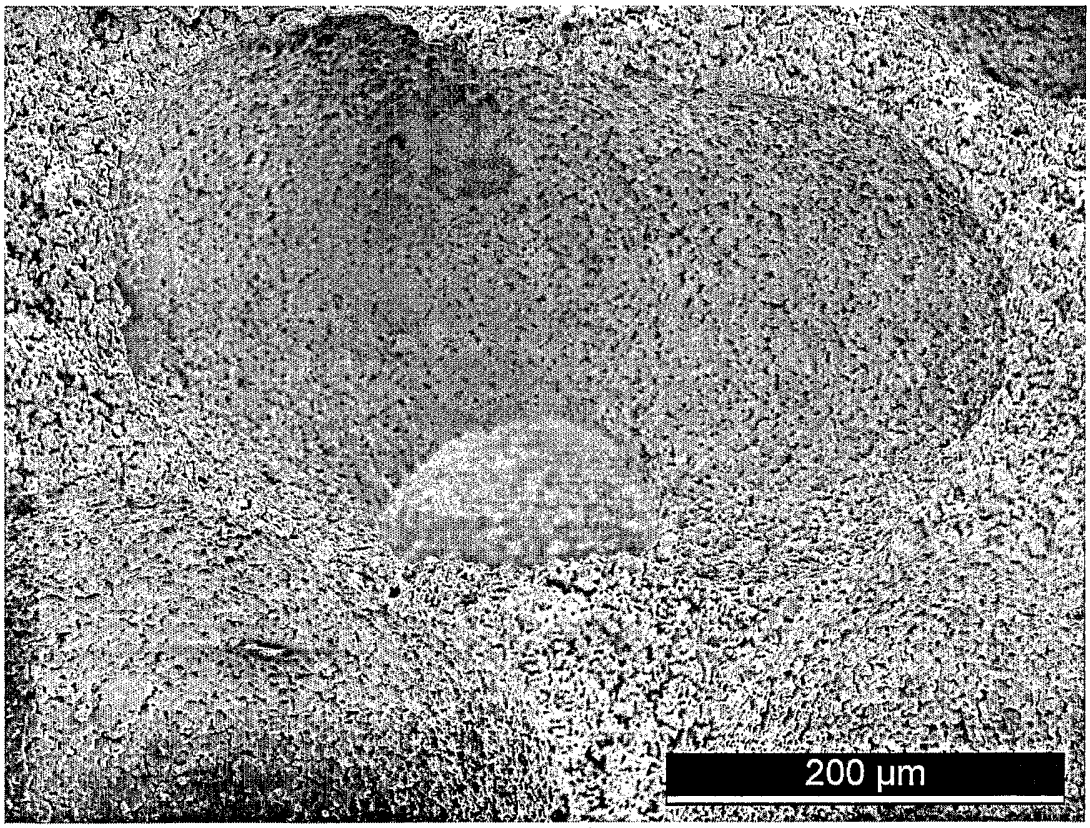


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2005/005089

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/08 A61F2/28 A61F2/30 A61L31/14 A61F2/46

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)
A61F A61L

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 346 123 B1 (MCKAY WILLIAM F) 12 February 2002 (2002-02-12) column 4, line 9 - column 9, line 24; claims; figures 1,5 -----	1,10,13, 16-18,23
X	US 5 084 050 A (DRAENERT ET AL) 28 January 1992 (1992-01-28) column 2, line 53 - column 9, line 45 claims; figures -----	1,7-10, 12-22,24
X	US 5 152 791 A (HAKAMATSUKA ET AL) 6 October 1992 (1992-10-06) column 1, line 45 - column 2, line 54 claims; figure; examples ----- -/--	1,4, 7-10,13, 15,17,18

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 March 2006	22. 06. 2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kuehne, H-C

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/68004 A (SDGI HOLDINGS INC ET AL) 20 September 2001 (2001-09-20) page 10, lines 7-27 page 18, line 2 - page 20, line 4 claims; figures	1,13,14, 16-18, 20-22,24

X	US 5 522 895 A (MIKOS ET AL) 4 June 1996 (1996-06-04) column 2, line 12 - column 4, line 19; claims; examples	1,2,7, 10,14, 15,17

X	US 2004/193270 A1 (DIMAURO THOMAS M ET AL) 30 September 2004 (2004-09-30) paragraphs [0009] - [0017], [0025]; claims; figure	1,2,4,5, 7,8,10, 11,13-17

A	US 4 629 464 A (TAKATA ET AL) 16 December 1986 (1986-12-16) column 2, lines 25-68; claims; figures; examples	1-24

A	US 6 013 853 A (ATHANASIOU ET AL) 11 January 2000 (2000-01-11) claims; figures; example 4	1

A	US 2002/106393 A1 (BIANCHI JOHN R ET AL) 8 August 2002 (2002-08-08) claims; figures	1-24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2005/005089

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-24

Implant for ligament reconstruction and/or bone reconstruction characterized in that the implant comprises a biodegradable material which is suitable to be remodeled into vital bone, wherein the biodegradable material has a mechanical strength for securely fixing a ligament in a bore or hole of a bone by means of press fit or form fit and/or a mechanical strength for reshaping a collapsed surface of a bone into its original shape.

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2. claims: 25-34

Surgical instrument for ligament reconstruction and/or bone reconstruction, characterized by a shaft member having a first end, a second end and a longitudinal bore, wherein the longitudinal bore has an inner diameter, and a pushing member having a first end, a second end and a piston, wherein the piston has an outer diameter, wherein the outer diameter of the piston is smaller or equal than the inner diameter of the longitudinal bore so that the piston of the pushing member can be slidably arranged within the longitudinal bore.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2005/005089

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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