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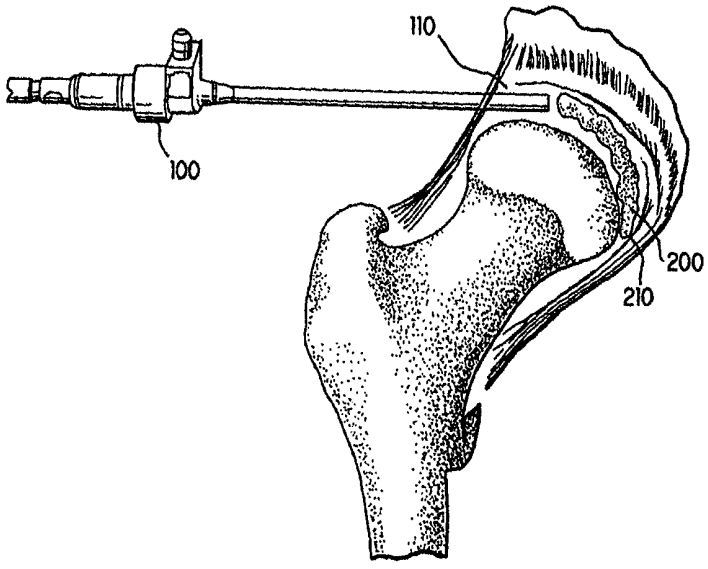

(57) Abstract

The current invention is a method and apparatus (300) for percutaneous interposition balloon arthroplasty. The method comprises the steps of entering a joint (10), introducing a deflated balloon (200) within the joint, and inflating the balloon (300) with a filler solution. The apparatus of this invention is a balloon (300) suitable for percutaneous interposition arthroplasty, comprising an outer shell (210) and a filler solution. The balloon (300) may further comprise a filling solution that comprises a condensed phase composition, a gas composition, and any mixtures thereof.

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APPARATUS FOR PERCUTANEOUS INTERPOSITION BALLOON ARTHROPLASTY

FIELD OF THE INVENTION

This invention relates to a method and apparatus for performing arthroplastic surgery for the interposition of balloons within joints. Specifically, this invention relates to a method and apparatus for performing percutaneous interposition balloon arthroplasty for the repair of movable and mixed articulating joints in the body.

BACKGROUND OF THE INVENTION

There are three basic classifications of joints of the human body: synarthroidal, amphiarthroidal, and diarthroidal. Synarthroidal joints provide immovable articulations; amphiarthroidal joints provide mixed articulations; and diarthroidal joints provide movable articulations. Healthy fibrocartilage and hyaline cartilage within the joint provide a weight bearing function and allow painless articulation of amphiarthroidal and diarthroidal joints.

Primary osteoarthritis is a debilitating disease that affects amphiarthroidal and diarthroidal joints. The changes that occur with primary osteoarthritis involve altered biomechanical, biochemical, histologic and metabolic characteristics of the cartilage, synovial fluid and bone. Initially, these changes affect the articular cartilage and eventually affect the surrounding perichondral tissues in a cascade of events. Articular cartilage comprises 70-80% water and functions as a weight bearing surface by its unique interaction between the water and cartilage matrix. There are many theories concerning how articular cartilage functions as a weight bearing surface which include hydrodynamic, boundary,

elastohydrodynamic and squeeze film lubrication. However, it is known that the viscoelastic properties contribute to the multiple functions of articular cartilage, including its weight bearing function. The viscoelastic properties of cartilage are due to an intricate tight meshwork of interlacing collagen fibers that physically ensnare the large macromolecules of proteoglycan.

For example, in a typical case of osteoarthritis of the hip joint, the femoral head remains covered with fibrocartilage over a third to two-thirds of its surface, but in the superior weight bearing region, the lining tissue becomes considerably thinner, although intact throughout. Where thin, the lining tissue is partly fibrocartilage, and partly fibrous, displaying focal areas of cystic degeneration. However, where fibrocartilage is present, the thickness of the membrane between the femoral cup, cacetabulum, and the bone does not generally exceed 2 mm.

To treat osteoarthritis effectively, procedures are needed for repairing amphiarhroidal and diarthroidal joints that prevent the disintegration of fibrocartilage and that restore the viscoelastic properties of articular cartilage for an indefinite period of time.

Historically, repair of the joint was conducted by disintegration of the diseased tissue followed by fibrous repair. However, this method has significant disadvantages, even when accompanied by conventional arthroplasty.

Orthopedic surgeons who specialize in total joint arthroplasties have been uncomfortable with performing resections of an entire joint. In the hip joint, for example, the entire acetabulum down to the intra-pelvic bone and the proximal femur would have to be resected. Sections of the proximal femur that are resected in this procedure include the femoral head, neck and intramedullary bone of the upper half of the femur. However, the

pathology in primary osteoarthritis is initially and primarily isolated to the articular cartilage. Thus, the resected tissue is many times greater than the surface area actually responsible for the patient's symptoms.

Traditionally, osteoarthritis of the hip has been treated in one of two ways: arthroplasty utilizing foreign substances of non-animal origin, and other methods that ameliorate pain and disability in osteoarthritis of the hip. Arthroplastic procedures that consist of interposing membranes, metallic cups, or other inserts to sustain the joint space until new joint spaces can regenerate have been extensively used in the prior art.

Cup or mould arthroplasty has commonly been used to treat degenerative arthritis of the hip joint. This procedure consists of denuding the femoral head and the acetabulum to bleeding bone, and reshaping them into a ball and socket joint with a metallic cup interposed between the two surfaces. The aim of mould arthroplasty is the formation of smooth glistening fibrocartilage around the periphery of the articular surface and hyaline cartilage in the central portion. Smith-Petersen concluded that, in response to physiologic stresses of friction and intermittent pressure of movement and supported weight-bearing, the repairing tissue will mold into smooth fibro-cartilage and in some instances to hyaline cartilage. M.N. Smith-Petersen, 21 J. Bone & Joint Surg. 269 (1939). Other inventors used mould arthroplasty with varying degrees of success. P'ean and Chlumsky were the first to utilize foreign materials in arthroplasty, the former in human joints, while the latter experimented with an array of metal plates and films of celluloid, rubber, and collodion; Sir Robert Jones successfully utilized a strip of gold foil to cover the reconstructed head of the femur; Pupovac used magnesium plates; and Rehn was the first to use cup arthroplasty when he inserted a previously molded cap-like appliance of steel into the acetabular side of the hip joint. Paul H.

Harmon, 76 Surg. Gyn. Obst. 347 (1943). Smith-Perterson utilized cups of various materials: glass, viscaloid, pyrex glass, bakelite, and vitallium. M.N. Smith-Peterson, J. M. J. Bone Surg., 18: 869 (1936). Vitallium was the most successful material used in cup arthroplasty.

However, cup arthroplasty caused severe trauma in patients and showed poor formation of hyaline cartilage.

Other approaches have been used to repair disease of joints in the human body. For instance, in the vertebral column, a collapsible plastic bladder-like prosthesis with the same shape as the nucleus pulposis of an intervertebral disc is delivered via a stem into the space between the vertebrae. U.S. Pat. No. 3,875,595 (Froning). A method and apparatus has been described for the repair of tissue in the vertebral column, such as fibrocartilage, using a bladder-like prosthesis device that can be inserted into the disc space and thereby infused with biomaterial to distract the space and provide a permanent replacement disc. However, this method addresses only prosthetic placement in the vertebral column. PCT Pat. App. No. WO 97/26847 (Felt, et al). In yet another case, an arthroscopically implantable prosthetic device consisting of a pair of multi-compartment rings shaped to fit into a joint and filled with a polymeric substance is used to restore function to a diseased joint. U.S. Pat. No. 5,344,459 (Swartz).

What is needed is a method and apparatus for restoring the function of movable and mixed articulating joints and for repairing fibrocartilaginous tissue and restoring the viscoelastic properties of articular cartilage in amphiarthroidal joints such as the hip for an indefinite period of time.

SUMMARY OF THE INVENTION

The current invention provides a method and related materials for percutaneous interposition arthroplasty, comprising the steps of entering the joint with a probing device, introducing a deflated balloon within the joint, and inflating the balloon. Moreover, this method may further comprise the step of distending and debriding the joint prior to introducing the deflated balloon, the step of keeping ligaments (*e.g.*, the ligamentum teres) intact, the step of resecting the ligaments, the step of closing the puncture wound, and the step of removing the balloon. Combinations of these steps are considered part of this invention.

In addition, this invention is a balloon suitable for percutaneous interposition arthroplasty and comprising an outer shell and a filler solution. The filler solution may be a condensed phase composition, a gas composition, or mixtures of gases and condensed phases. Condensed phase compositions include, but are not limited to, polymers, curable condensed compositions, gels, resins, liquids, and solutions. This group further includes, for example, silicone-gel, saline solution, and soybean oil. Gas phase compositions may include, but are not limited to, air, nitrogen, oxygen, argon, carbon dioxide, and mixtures thereof. The balloon may be any shape, may have multiple compartments, may be capable of withstanding significant pressures, and may be relatively impenetrable. Combinations of filler solution materials are considered part of this invention.

The interposition of a balloon may also facilitate the repair or reformation of the cartilage tissue on the surfaces of the bones of the joint.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows primary osteoarthritis of the hip joint.

Figure 2 shows hip joint distention and arthroscopic placement.

Figure 3 shows balloon introduction.

Figure 4 shows balloon inflation.

Figure 5 shows interposition balloon arthroplasty.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a method and related devices for repairing joints and surrounding tissues by minimally invasive means. In particular, the invention provides a method and related materials for using minimally invasive means to repair and reconstruct tissue such as fibrocartilage, particularly fibrocartilage associated with diarthroidal and amphiarthroidal joints. The method involves using minimally invasive means to prepare the site of pathology, and distending a joint site *in situ* in order repair the damaged joint.

The method comprises the steps of:

a. performing surgery to enter the joint;

b. using a minimally invasive means to remove damaged or diseased material from a narrowing joint space and nearby tissues;

c. introducing at least one deflated balloon to a cavity; and

d. inflating the balloon.

Arthroscopy has revolutionized knee surgery but has been of minimal use, for example, when it comes to hip pathology. However, arthroscopy is applicable to the hip joint. The hip joint is well suited for balloon arthroplasty because the hip is accessible

percutaneously without disturbing its blood supply. Furthermore, the joint can be significantly distended by releasing its inherent negative pressure, resulting in a relatively uncomplicated surgical process as the space between the acetabular fossa and the head of the femur can serve as a suitable cavity for the delivery and inflation of a balloon. The surfaces of the acetabular fossa, the femoral head and surrounding tissues can be treated or covered with a suitable material in order to enhance their integrity and use as a cavity. Moreover, the ligamentum teres may be preserved or resected to ensure a permanent replacement procedure.

The ligamentum teres is vital only in infancy and childhood. By adulthood, the primary blood supply to the femoral head is through the anterior and posterior femoral circumflex arteries. As a result, the ligamentum teres can be resected with balloon insertion while maintaining the blood supply through the circumflex arteries. The advantage of preserving the ligamentium teres is to add to the stability of the femur.

The procedure consists of, first, making an appropriate incision. Then, through a probing device such as an orthoscope, the hip joint is entered, distended and debrided. Depending on the circumstances, the ligamentum teres may be preserved. The debriding step is optional. Then, through a probing device, a deflated balloon may be introduced within the joint and distended similar to the fashion in which a breast implant is filled with saline. The arthroscopic introducer-inflator may be removed and the puncture wound(s) closed. Rehabilitation for such a procedure is relatively minimal. The advantages include joint space restoration with restoration of viscoelastic dynamics. Additionally, a total hip replacement would remain viable if the procedure should fail. Moreover, a surgeon could wait for a predetermined period of time and then remove the balloon implant if desired.

This procedure permits the femoral head to be resurfaced (with the balloon or, subsequently, by repair or reformation of the cartilage) without dislocating the hip which in some circumstances would disrupt the blood supply, thereby causing avascular necrosis. The procedure, therefore, allows full access to the femoral head for complete resurfacing while maintaining the primary blood supply.

Surgeons could reduce total hip arthroplasty with its inherent risks and complications to a brief, percutaneous, out-patient procedure with minimal risk plus maintenance of anatomy should a formal hip resection and replacement be required later on. Similar procedures could be used for balloon arthroplasty in other joints.

PREPARING THE JOINT SPACE AND INSERTING A BALLOON

The description of the preparation of the joint space and insertion of a balloon are described for the hip joint. Similar procedures can be used for balloon arthroplasty of other joints. Figure 1 shows primary osteoarthritis of the hip joint. This may be characterized, in part, by a narrowing joint space **10**, cartilage loss **20**, and thickening joint capsule **30**. The narrowing joint space **10** is the space between the head of the femur **40** and the acetabular fossa **50**. Other symptoms may exist and are well known to those in the art.

The procedure for balloon arthroplasty contains the following steps as appropriate.

(i) Assessment of the extent of osteoarthritis.

(ii) Distension of the joint.

(iii) Orthoscopy into the joint space.

(iv) Optional removal and/or cleaning of destroyed tissue.

(v) Delivery of a deflated balloon.

(vi) Inflation of the balloon.

(vii) Optional deflation/removal of the balloon.

Performing the surgery for entering the hip joint can be carried out using techniques well within the skill of those in the art. The narrowing joint space **10** may be viewed, for instance, by remote visualization techniques such as fiberoptic visualization. The integrity of the hip and femur can be assessed, and optionally, repaired, for example, by the application of a biocompatible patching material, such as a fibrin glue.

Figure 2 shows hip joint distention and arthroscopic placement. In some patients, joint distention is unnecessary. However, if a surgeon desires, distention may be achieved by mechanical displacement of the femur with respect to the acetabular fossa. The joint space **10** can be distended prior to and/or during either the preparation and/or delivery of the balloon. Distension can be accomplished by any suitable means, including by mechanical and/or hydrostatic means. A surgeon can employ external traction. An orthoscope **100** may be inserted into the cavity **110** formed by distending the narrowed joint space **10**. The deflated balloon may then be placed into the distended cavity.

If required, the destroyed pelvic and femur related tissue such as fibrocartilage may be removed and cleaned prior to inserting the deflated balloon. The remaining, repaired tissue and bone matter serve as a support for an inflated balloon. The head of the femur **40** engages a balloon **300** like a penile condom. The ligamentum teres may be preserved, so as to allow any balloon to occupy the cavity, **110**, except for the void around the ligamentum teres. See, for example, Figure 5. Once the damaged material has been removed and the remaining joint tissues repaired, the joint space **10** may be used as a cavity **110** to contain a delivered balloon. The joint space **10**, including any repaired portions is created to be of sufficient dimension to

allow a deflated balloon to be delivered and distended. By the use of distension, the joint space **10** can be sufficiently re-established to achieve any desired final dimension and position. The means used to accomplish distension (for example, another balloon or other mechanical devices) may also form at least one barrier (for example, a cavity **110**) for the balloon.

The narrowed joint space **10** may be easily distended by the use of one or more inflatable balloons. When inflated, a balloon provides rigid walls that are capable of expanding the joint space **10**. An inflatable balloon provides sufficient strength and dimensions and can be prepared using conventional materials. In use, the deflated balloon can be delivered to the narrowed joint space **10** and inflated to separate the space **10**. For example, a balloon may be inserted with an orthoscope. Under certain circumstances, distension prior to the insertion of the inflatable balloon is unnecessary.

Once positioned within the cavity **110**, Figure 4 shows that the orthroscope **100** may be used to inflate a balloon by injecting a suitable filler solution (not shown) to create an inflated balloon **300**. Depending on the application, the same or different orthoscope may be used for insertion of the deflated balloon **200**, and for inflating the deflated balloon **200.** For example, an orthroscope **100** may be inserted into the space **10** to deliver an deflated balloon and a second probing device used to inflate the deflated balloon.

A suitable gas (for example, nitrogen, carbon dioxide, oxygen, argon, *etc.*) may be delivered in order to inflate the balloon *in situ*. Positioning of the balloon may be facilitated by the use of ancillary means, such as using a C-arm cine , or by self-effecting means embodied within the balloon or the delivery apparatus.

Suitable materials for preparing balloons of the present invention, for example, are those that may be used for balloon angioplasty. Suitable materials provide an optimal combination of such properties as compliance, biostability and biocompatability, and mechanical characteristics such as elasticity and strength. Balloons can be in any suitable form, including those having at least one layer and having at least one compartment when expanded. A useful balloon device will include the balloon (optionally having a plurality of lumens), a delivery probing device, and fluid or gas pressure means. An orthoscope may be used as a probing device.

Examples of suitable balloon outer shell **210** materials include, but are not limited to, polyolefin copolymers, polyethylene, polycarbonate, and polyethylene terephthalate. Such polymeric materials can be used in either unsupported form, or in supported form, for example, by the integration of polyethylene terephthalates or other fibers.

Balloons can also take several forms, depending on how the balloon is to be delivered and inflated. A single, thin walled balloon can be used, for instance, to contact and form a barrier along the joint surface. A balloon can be provided that occupies less than the entire volume of the cavity **110**. The balloon may be, for instance, in the shape of a cylinder or a collapsed, bell tent.

Any portion, region or surface of the outer shell of the balloon **210** may be treated with friction modifying coatings or other materials to improve or otherwise alter the physical or chemical properties.

A balloon of the present invention can be inflatably attached (for example, provided in an releasable and deflated or inflated configuration) within or upon the end of a probing device, in order to be inserted into the space **10** or cavity **110**. Moreover, the balloon may be

inserted using minimally invasive means, and remote visualization methods including fiberoptic visualization.

Once within the space **10** or cavity **110**, the balloon can be finally positioned and delivered. The balloon may be self-venting, in that whatever volume of gas may be present within the balloon and shaft at the time of insertion can be displaced by the filler solution and vented through the balloon walls, for example, to the surrounding tissue. The balloon may be evacuated by the application of suction or vacuum to the shaft. Some or all of the gas present within the shaft and/or balloon may be vented through the balloon material by the deliver of a filler solution. As the filler solution fills the balloon and displaces the gas the filler solution also serves to inflate the balloon to a desired extent, and in a suitable position within the cavity **110** sufficiently distended, the filler solution may be cured, or permitted to fully cure, *in situ* in order to retain the balloon and filler solution permanently in place. This step is optional and depends upon the filler solution.

The balloon may be fabricated from natural or synthetic materials, including but not limited to, polymeric materials, such as films or membranes, and woven or nonwoven fabrics or meshes. Balloons that will not permit the effusion or diffusion of liquids, gels, solids, other condensed compositions and gases can be fabricated as one or more layers comprising such materials, and/or with one or more regions or portions of differing properties.

The materials used to fabricate balloons may provide an optimal combination of such properties as biocompatability, biodurability, strength, wall thickness, wettability with a filler solution, puncture resistance, compliance, flexibility, modulus of elasticity, stress/strain curve yield point, burst pressure, maximum inflation, Young's modulus, shear modulus, and the ability to be easily fabricated and sterilized.

Examples of suitable balloon materials include, but are not limited to, solid polymeric materials such as membranes. Polymeric materials may be provided with suitable venting holes. Suitable polymeric materials include, but are not limited to, elastomeric and other materials commonly used for angioplasty and related application, and include polyurethanes, polyolefins, polyamides, polyvinyl chlorides, and polyethylene terephthalates, as well as various copolymers, combinations and permutations thereof.

Balloon materials are available commercially for use in filtration and other applications, and include cloth and mesh formed of polymeric materials such as polyester, polypropylene and nylon threads. A material may be reinforced, for example, with woven glass or fine fibers of other materials, to provide added strength or other desirable properties. Such materials can be selected to provide an optimal combination of such properties as strength, mesh opening, thread diameter, mesh count, percent open area, and cost. Examples of suitable materials are commercially available and include, but are not limited to, nylon screen cloth, such a nylon mesh.

The balloons themselves may be fabricated by a variety of means. The balloon may be formed as a continuous (for example, unitary) and non-interrupted (for example, seamless) form. The balloon may be fabricated from a plurality of generally sheet-like portions, which can be assembled and sealed together. Sealing may be accomplished by any suitable means, including by the use of adhesives, sewing, RF bonding, heat sealing, impulse sealing, and any combination thereof. Once sealed, the balloon may be turned inside out in order to provide the sealed seam on the interior of the resultant balloon.

The balloon may be fabricated to assume any desired shape upon inflation, for example, a generally oval shape, or the shape of a kidney bean, in order to approximate the

natural anatomical shape of the space **10**. The balloon may provide major surfaces for contacting the principal surfaces of the joint, for example, the head of the femur **40** and acetabular fossa **50**. The balloon may further provide wall portions for contact with other tissue.

A balloon may be provided with one or more orientation markers, in order to permit the surgeon to determine the optimal orientation of the balloon *in situ*. Suitable orientation markers include, but are not limited to, the placement of detectable markers or indications within or upon the balloon material and/or probing device, the marking or indications themselves being detectable by minimally invasive means, for example, by fiberoptic visualization, interoperative magnetic resonance imaging (MRI), ultrasound, and laser radiation.

The deflated balloon may be positioned within the space **10** or cavity **110** following preparation. As described hereinabove, mechanical distension of the space can be used as well, for example, either while inserting and/or positioning a balloon and/or during inflation of a balloon with filler solution.

Once in place within the cavity **110**, the balloon may be filled by having the probing device connected to a filler solution delivery device capable of delivering filler solution through the probing device and into the balloon under sufficient pressure. When in the form of a curable polymer, the filler solution may begin to cure as it leaves the mixing chamber of the delivery device. Saline, as a filler solution, will never cure. If a curing filler is chosen, the cure rate of the biopolymer may be controlled, in combination with the dimensions and other conditions of the distension means, in order to provide sufficient time for the filler solution to expand the balloon before final curing occurs. Noncuring materials may change

viscosity upon entering the cavity **110**. Such changes may result from different pressures, temperatures or both. In some cases, the phase of filler solution may change, for example, from gas to liquid or solid to liquid or gel, *etc.* The progress of inflating may be monitored, for example, by C-arm cine or interoperative MRI.

"Cure" and inflections thereof, will refer to any change in the physical properties of a material by chemical reaction or vulcanization. Curing may occur with the aid of any combination of heat, chemicals, catalysts, and energy, such as, but not limited to, light and ultrasound. When used with regard to the method of the invention, for instance, "curable" can refer to uncured biomaterial, having the potential to be cured *in vivo* (as by the application of a suitable energy source), as well as to a biomaterial that is in the process of curing, as with a biomaterial formed at the time of delivery by the concurrent mixing of a plurality of biomaterial components.

Figure 5 shows interposition balloon arthroplasty upon completion. The balloon **300** becomes semi-circular shaped balloon **400**, which encompasses the head of the femur **40**. The balloon can be left in place for a fixed period of time, and then removed by a similar procedure, or the balloon may be permanent. The balloon was constructed so that it would form a semicircular shape and as it was distended would obtain stability by "locking" over the expanse of the head-neck angle. The balloon may leave the ligamentum teres undisturbed.

FILLER SOLUTIONS

Natural cartilage is a non-vascular structure found in various parts of the body. Articular cartilage tends to exist as a finely granular matrix forming a thin incrustation on the surfaces of joints. The natural elasticity of articular cartilage enables it to break the force of

concussions, while its smoothness affords ease and freedom of movement. Filler solutions are intended to mimic many of the physical-chemical characteristics of natural tissue.

Filler solutions can be provided as one component systems, or as two or more component systems that can be mixed prior to or during delivery, or at the site of repair. Generally, fillers are flowable, meaning they are of sufficient viscosity to allow their delivery into the balloon. The fillers may be heated or subject to pressure changes to aid flowing. Moreover, the fillers may be solvated in a liquid, gel, or other condensed phase composition to aid flowing into the balloon with or without temperature or pressure changes. Suitable fillers may comprise gas phase compositions which include, but are not limited to, air, nitrogen, oxygen, argon, carbon dioxide, other inert gases, and mixtures thereof.

Filler solutions may be homogeneous (*i.e.*, providing the same chemical-physical parameters throughout), or they can be heterogeneous. Filler solutions may be used that provide implants having varying regions of varying or different physical-chemical properties.

Common polymeric materials for use in medical devices include, but are not limited to, polyvinyl chlorides, polyethylenes, styrenic resins, polypropylene, thermoplastic polyesters, thermoplastic elastomers, polycarbonates, acrylonitrilebutadiene-styrene ("ABS") resins, acrylics, polyurethanes, nylons, styrene acrylonitriles, and cellulosic.

Suitable filler solutions are those polymeric materials that provide a suitable combination of properties relating to their device application and *in vivo* use. Such properties include, but are not limited to, processability and the ability to be stably sterilized and stored. In the course of applying such material, such properties include *in vivo* flowability and moldability.

The filler solution may comprise a thermosetting polyurethane polymer based on a suitable combination of isocyanates, long chain polyols, and short chain (low molecular weight) extenders and/or crosslinkers. Suitable components are available commercially and are each may be used in the highest possible grade, for example, reagent or analytical grade or higher. Examples of suitable isocyanates include, but are not limited to, 4,4'-diphenyl methane diisocyanate ("MDI"), and 4,2'-diphenylmethane diisocyanate, including mixtures thereof, as well as toluene diisocyanate ("TDI"). Examples of suitable long chain polyols include, but are not limited to, tetrahydrofuran polymers such as poly(tetramethylene oxide) ("PTMO"). Examples of suitable extenders/crosslinkers include, but are not limited to, 1,4-butanediol and trimethylol propane, and blends thereof.

Such performance may be evaluated using procedures commonly accepted for the evaluation of natural tissue and joints. Curing is unnecessary, for example, for oils (carbon or silicon based), water, saline solution, gels, resins and other condensed phases which may possess an optimal combination of physical chemical properties. Suitable gels, for example, include silicone gels. Suitable oils include, for example, soybean oils.

Filler solutions of the present invention may further include adjuvants and additives, such as stabilizers, fillers, antioxidants, catalysts, plasticizers, pigments, and lubricants, to the extent such ingredients do not diminish the utility of the composition for its intended purpose.

Filler solutions may be stable under conditions used for sterilization and stable on storage and in the course of delivery. They may be capable of flowing through a delivery device to an *in vivo* location, and/or being cured *in situ*, as by exposure to an energy source such as light or by chemical reaction. Thereafter, a cured filler solution may be amenable to

shaping and contouring. Uncured filler solutions may be shaped and contoured to the extent that the balloon and filler solution will allow.

One or more catalysts may be incorporated into one or more components of the curable filler solutions in order to cure the filler solution in the physiological environment within a desired length of time. Curable filler solutions may be able to cure within about 5 minutes or less.

Means may be employed to improve the biostability, for example, the oxidative and/or hydrolytic stability, of the filler solution, thereby extending the life of the implant. Suitable means for improving biostability include the use of aliphatic macrodiol such as hydrogenated polybutadiene (HPDI). By judicious choice of the corresponding diisocyanate (for example, MDI) and chain extender (for example, ethylenediamine), those skilled in the art will be able to achieve the desired packing density or crystallinity of the hard segments, thereby improving the hydrolytic stability of the cured polyurethane.

Filler solutions may be provided as a plurality of components, for example, a two-part polyurethane system, may be mixed at the time of use using suitable mixing techniques, such as those commonly used for the delivery of two-part adhesive formulations. A suitable mixing device involves, for instance, a static mixer having a hollow tube having a segmented, helical vein running through its lumen. A two-part polyurethane system can be mixed by forcing the respective components through the lumen under pressure.

The foregoing description is intended to be illustrative of the invention, but is not to be considered as comprehensive or limiting of its scope.

What is claimed is:

1. A method of treating joint disease using percutaneous interposition arthroplasty, comprising the steps of:

a. using minimally invasive means to enter a joint space;

b. introducing a deflated balloon within a joint space; and

c. inflating the balloon.

2. The method of claim 1, further comprising the step of distending a joint space prior to introducing a deflated balloon.

3. The method of claim 1, further comprising the steps of:

a. distending a joint space prior to introducing a deflated balloon; and

b. using minimally invasive means to remove damaged or diseased material from a joint space and nearby tissues.

4. The method of claim 1, further comprising the step of examining and determining the integrity of the damaged tissue.

5. The method of claim 1, wherein the inflated balloon facilitates the repair or reformation of cartilage on one or more surfaces of the joint.

6. The method of claim 1, wherein the inflated balloon helps restore the viscoelastic dynamics of a joint space.

7. The method of claim 1, further comprising the step of covering joint surfaces and surrounding tissue in order to enhance the integrity of the joint.

8. The method of claim 2, or 3 where the distending step is achieved by mechanical means.

9. The method of claim 2, or 3 where the distending step is achieved by hydrostatic means.

10. The method of claim 1, where the minimally invasive means to enter a joint space are orthoscopic.

11. The method of claim 3, where the minimally invasive means to remove damaged or diseased material from a joint space and nearby tissues are orthoscopic.

12. A method of treating joint disease of the hip using percutaneous interposition arthroplasty, comprising the steps of:

c. using minimally invasive means to enter a hip joint space;

d. introducing a deflated balloon within a hip joint space; and

e. inflating the balloon.

13. The method of claim 12, further comprising the step of distending a hip joint space prior to introducing a deflated balloon.

14. The method of claim 12, further comprising the steps of:

a. distending a hip joint space prior to introducing a deflated balloon; and

b. using minimally invasive means to remove damaged or diseased material from a hip joint space and nearby tissues.

15. The method of claim 12, further comprising the step of examining and determining the integrity of the damaged tissue.

16. The method of claim 12, wherein the inflated balloon facilitates the repair or reformation of cartilage on one or more surfaces of the hip joint.

17. The method of claim 12, wherein the inflated balloon helps restore the viscoelastic dynamics of a hip joint space.

18. The method of claim 12, further comprising the step of covering joint surfaces and surrounding tissue in order to enhance the integrity of the joint.

19. The method of claim 12, wherein the balloon covers the femoral head.

20. The method of claim 12, wherein the ligamentum teres remains undisturbed.

21. The method of claim 12, wherein the ligamentum teres is resected.

22. The method of claim 13, or 14 where the distending step is achieved by mechanical means.

23. The method of claim 13, or 14 where the distending step is achieved by hydrostatic means.

24. The method of claim 12, where the minimally invasive means to enter a joint space are orthoscopic.

25. The method of claim 14, where the minimally invasive means to remove damaged or diseased material from a joint space and nearby tissues are orthoscopic.

26. The method of claim 12, where the joint disease is osteoarthritis.

27. A method of repairing a hip joint without dislocating the hip using percutaneous interposition balloon arthroplasty, comprising the steps of:

c. using minimally invasive means to enter a hip joint space;

d. introducing a deflated balloon within a hip joint space; and

e. inflating the balloon.

28. The method of claim 1, or 12 wherein the balloon is semicircular.

29. The method of claim 1, or 12 wherein the balloon is inflated using orthoscopic means.

30. The method of claim 1, or 12 wherein the balloon is inflated with a filler solution.

31. The method of claim 30, wherein the filler solution is selected from at least one member of a group consisting of polyvinyl chlorides, polyethylenes, styrenic resins, polypropylene, thermoplastic polyesters, thermoplastic elastomers, polycarbonates, acrylonitrilebutadiene-styrene resins, acrylics, polyurethanes, nylons, and styrene acrylonitriles

32. The method of claim 30, wherein the filler solution comprises a thermosetting polyurethane polymer.

33. The method of claim 30, wherein the filler solution is selected from at least one member of a group consisting of gels and oils.

34. The method of claim 30, wherein the filler solution is selected from at least one member of a group consisting of carbon dioxide, oxygen, and nitrogen.

35. The method of claim 30, wherein the filler solution is selected from at least one member of a group consisting of inert gases.

36. The method of claim 30, wherein the filler solution is curable.

37. The method of claim 1, or 12 wherein the balloon comprises an outer shell.

38. The method of claim 37, wherein the outer shell comprises at least one member of a group consisting of PVC, polyurethane, polyethylene terephalate and polycarbonate.

39. A balloon suitable for percutaneous interposition arthroplasty, comprising an outer shell.

40. The balloon of claim 39, wherein the outer shell comprises one member selected from a group consisting of PVC, polyurethane, polyethylene terephalate, and polycarbonate.

41. The balloon of claim 39, wherein the balloon is semicircular.

42. The balloon of claim 39, wherein the balloon is capable of withstanding pressures of at least 500 pounds per square inch.

43. The balloon of claim 39, wherein the balloon is capable of withstanding pressures of at least 500 pounds per square inch.

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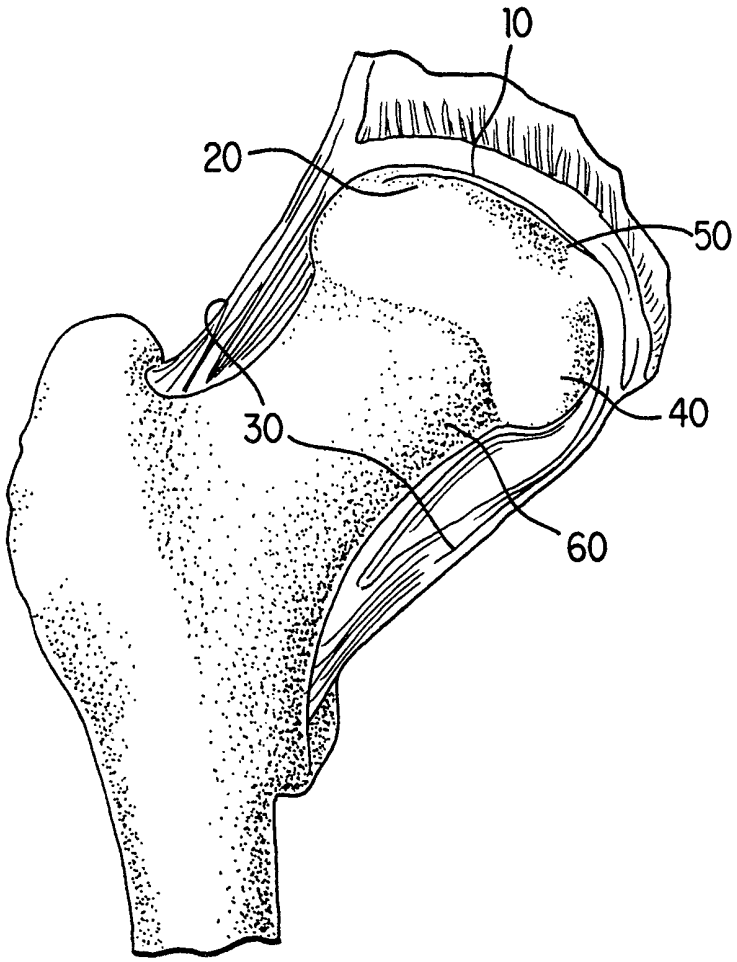

FIG. 1

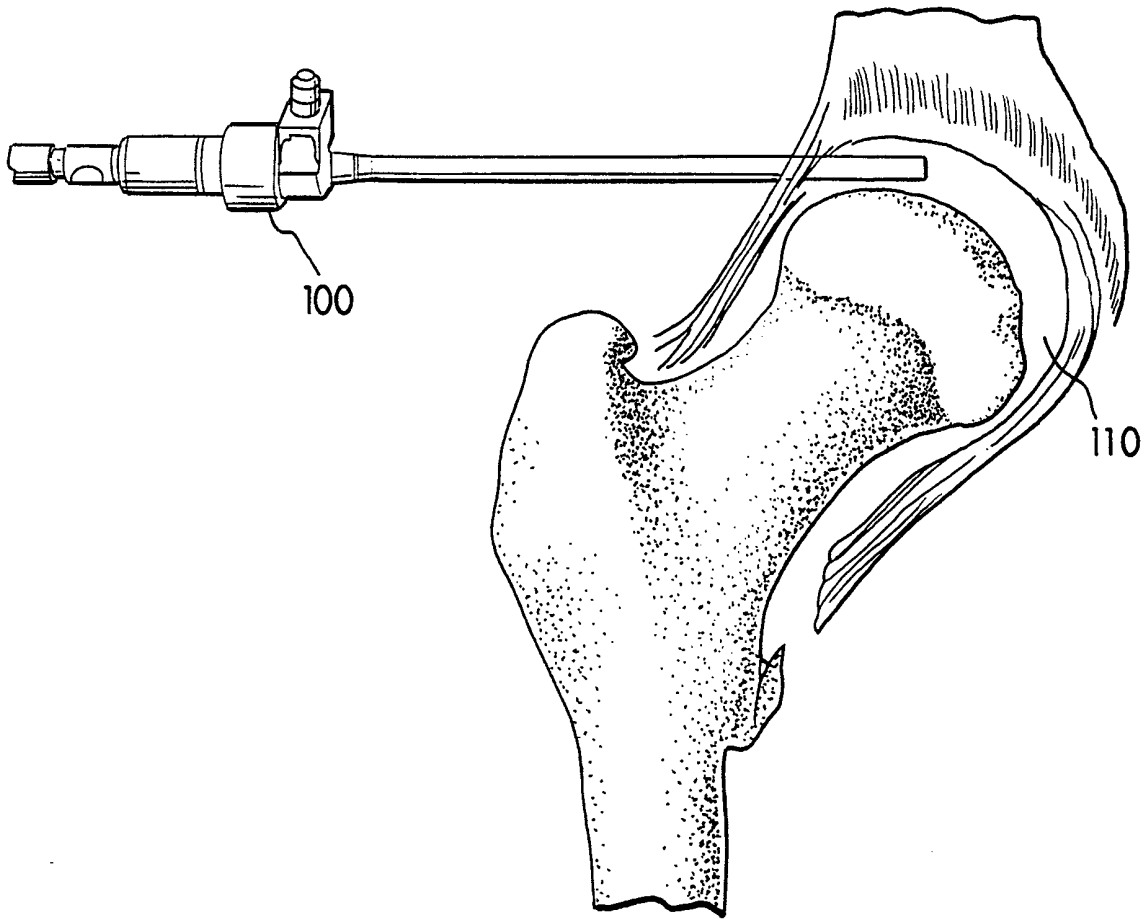

FIG. 2

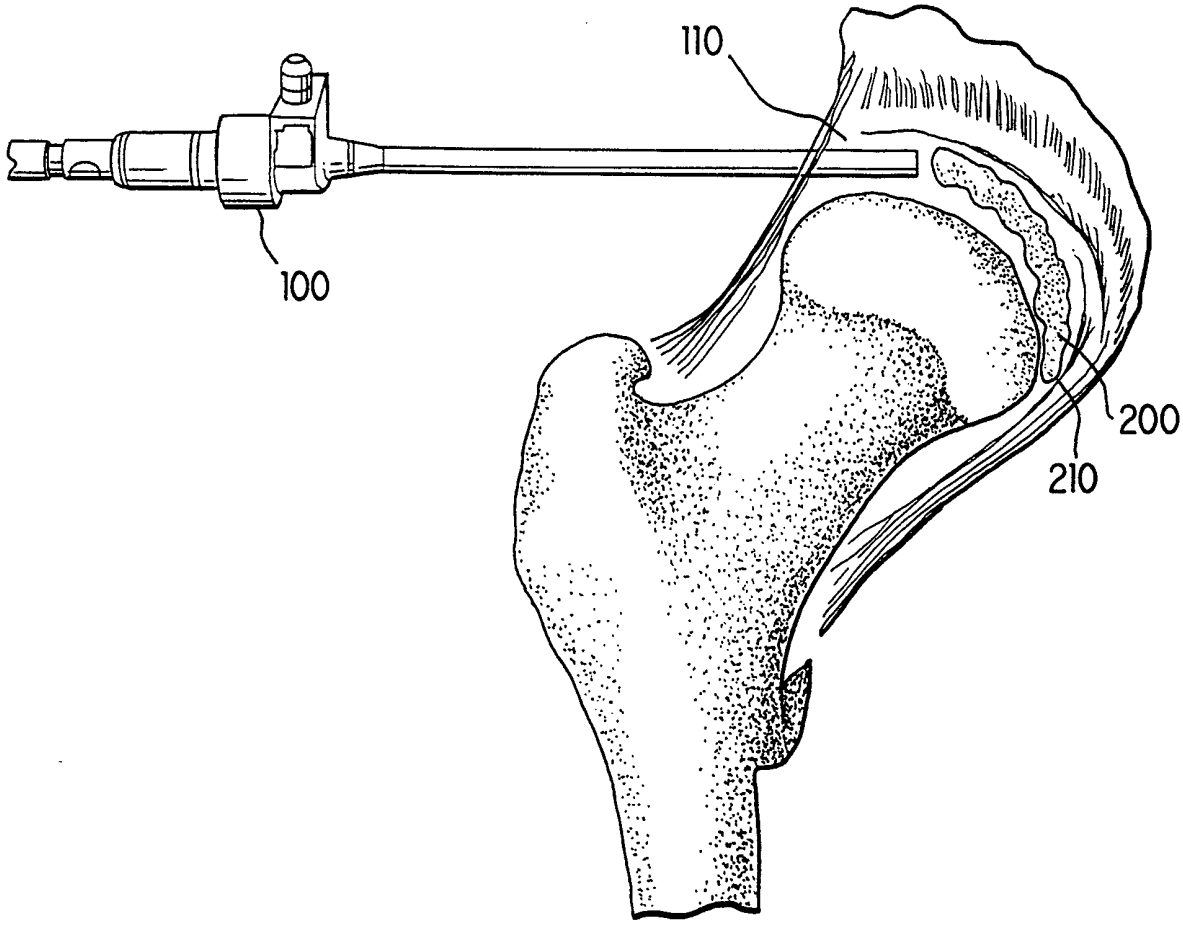

FIG. 3

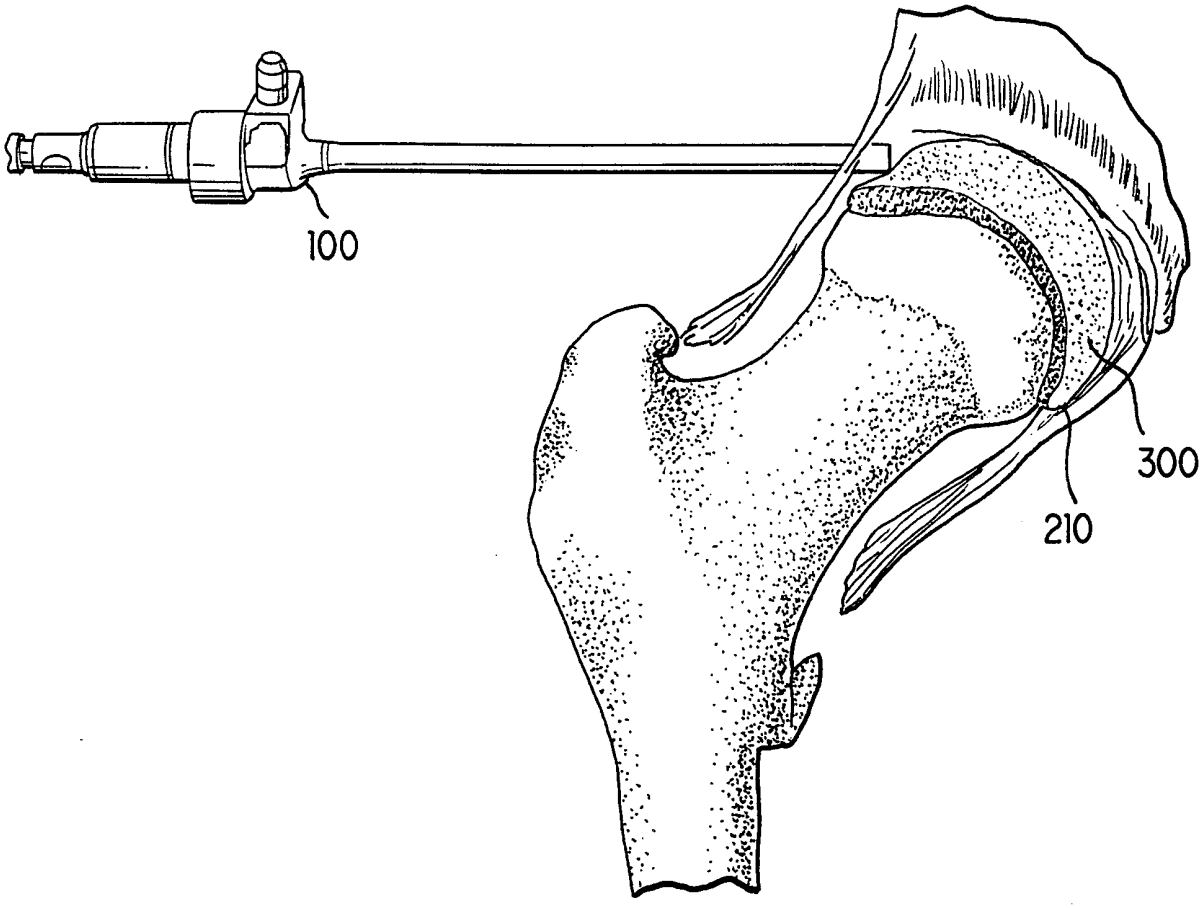

FIG. 4

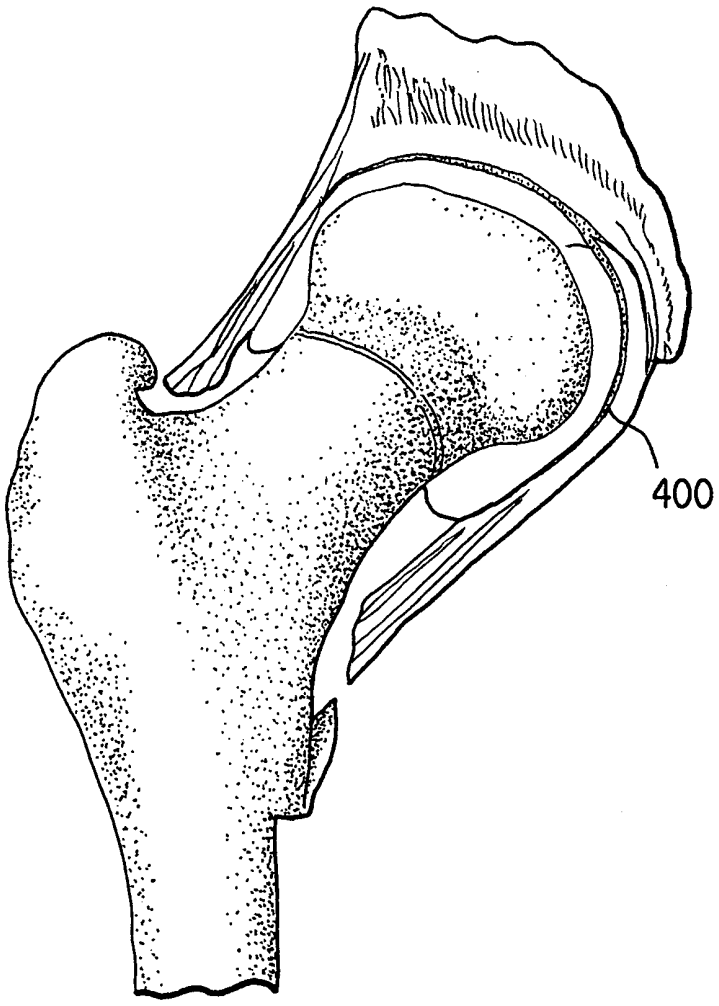

FIG. 5

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 99/24467

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/30 A61F2/46 A61L27/18

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 7 A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 507 645 A (BOUVET) 7 October 1992 (1992-10-07) the whole document	39-41
X	US 4 467 479 A (BRODY) 28 August 1984 (1984-08-28)	39,41
Y	abstract; figures 6-8	40
A		42
Y	US 5 344 459 A (SWARTZ) 6 September 1994 (1994-09-06) cited in the application claim 9	40
X	FR 2 734 146 A (HECHARD) 22 November 1996 (1996-11-22) the whole document	39,41

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in 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
15 March 2000	21/03/2000

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	Klein, C

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Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 25 01 080 A (PATZER) 15 July 1976 (1976-07-15) the whole document	39,41
A	FR 1 061 009 A (COUTURE) 8 April 1954 (1954-04-08)	
A	WO 97 26847 A (ADVANCED BIO SURFACES) 31 July 1997 (1997-07-31) cited in the application	
A	US 3 875 595 A (FRONING) 8 April 1975 (1975-04-08) cited in the application	

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 24467

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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

1. [X] Claims Nos.: 1-38
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers 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.:

Remark on Protest

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

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

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 99/24467

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