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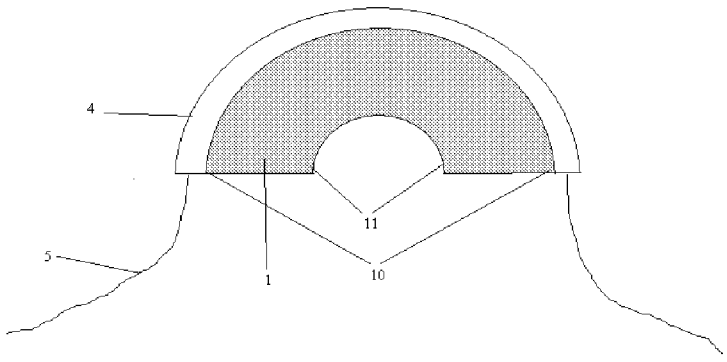
(54) **Title**: MENISCUS IMPLANT ASSEMBLY AND METHOD

Figure 2: Shows a schematic top view of a meniscus repair/replacement assembly according to the present invention with sleeve for the non-stretch material



(57) **Abstract**: The present invention provides an assembly for repairing or replacing a damaged meniscus in a patient, the assembly including a scaffold material, and methods using such an assembly in repairing and maintaining meniscal function.

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MENISCUS IMPLANT ASSEMBLY AND METHOD

FIELD

[0001] The present invention relates generally to an assembly and method for use in repairing or replacing a damaged meniscus in a patient during arthroscopic surgery.

BACKGROUND

[0002] The meniscus is a fibrocartilaginous structure in the knee joint which performs multiple critical functions, including contributing to normal knee biomechanics and the general well-being of the joint. Generally, the menisci are comprised of two C-shaped fibrocartilaginous structures residing on the tibial plateau. The peripheral rim of a meniscus is thick, tapering to a thin, free inner border. The superior surface is contact with the femoral condyles, while the inferior surface is in contact with the tibial plateau. The collagen fibers within the menisci are mainly oriented circumferentially throughout the meniscus, parallel to the peripheral border, to withstand hoop stresses placed upon the meniscus by the femoral condyles. Menisci may be torn by twisting injuries to the knee and the extent of the tear is variable.

[0003] The peripheral region or zone of the meniscus is generally referred to as the red zone that has good blood supply. This is usually the peripheral ⅓ of the meniscus. The inner region or zone of the meniscus (the remaining ⅔) is generally referred to as the white zone and is avascular. Nutrition for this zone is drawn from the joint fluid (synovial fluid). It is generally recognized that repair of meniscal lesions or tears is possible when the tear is within the red zone or at the junction of the red and white zones. Tears within the white zone are usually treated by excision of the torn fragment at arthroscopic key hole surgery. Repair of a tear, if possible, is preferable to excision so as to attempt to maintain the volume of the meniscus and have it continue to function as intended, protecting the joint surfaces from wear. In addition, it is important to maintain vascularity within the peripheral area of the meniscus to promote healing. When the

meniscus is removed, the risk of later joint surface degeneration (osteoarthritis) is increased.

[0004] Often, tears in the peripheral vascular red zone are repaired. However, in certain instances the tear may be more extensive and complex in nature so that repair of the existing damaged meniscus is not feasible. Therefore, in some cases it may be necessary to replace meniscus tissue in a patient including and up to the peripheral rim of the meniscus. The International Patent Application No. PCT/US11/25852 describes a method to repair a tear or lesion in a damaged meniscus. The method described therein however requires presence of the meniscal rim integrity, i.e., at least the peripheral portion including the peripheral rim of the meniscus to be repaired. This is necessary in the described method in order for vascularization and regrowth to occur in the scaffold material used therein. An example of a polyurethane-based biocompatible material useful as such scaffold material is described in WO 2009/141732. The scaffold alone is therefore not suitable for replacement of the entire meniscus.

[0005] When a meniscus in a patient requires replacement as a whole the peripheral rim which is responsible for the hoop stress resistance function of the meniscus is no longer present and any implant assembly needs to be able to provide for such hoop stress function. There is a growing need for an implant assembly and method of replacing meniscal tissue which provides for meniscus repair while preserving and/or providing meniscal function including absorbing hoop stresses. The alternative method of reconstructing the meniscus is to implant an allograft i.e., cadaveric donor meniscal tissue, an expensive and resource limited option. The assembly and method of the present invention provides for such meniscus reconstruction while preserving the meniscal hoop-stress resistance function. Accordingly, the assembly of the present invention is suitable for patients who have lost their whole meniscus out to the peripheral rim and provides hoop-stress resistance. The present invention will reduce the expense and morbidity associated with waiting for and undergoing meniscal transplantation.

SUMMARY

[0006] An assembly is provided for repairing or replacing a damaged meniscus of the knee comprising: a) a scaffold material substantially in the shape of a meniscus having a thick peripheral rim area tappering of to a thin inner border, b) a sleeve intimately connected to the scaffold material along the length of the thick peripheral rim, and c) a rectangular non-stretch material inside the length of the sleeve and extending outward at both ends of the sleeve, wherein the assembly provides support to retain at least the meniscal function of hoop-stress resistance. The assembly may also provide a mechanism for anchorage of the meniscal substitute to the bone.

[0007] An assembly is provided for repairing or replacing a damaged meniscus of the knee comprising: a) a scaffold material substantially in the shape of a meniscus having a thick peripheral rim area tappering of to a thin inner border, and b) a rectangular non-stretch material attached to the scaffold material along the entire length of the thick peripheral rim and extending in the same direction past the peripheral rim on both longitudinal edges, wherein the assembly provides support and retains at least the meniscal function of hoop-stress resistance. The assembly may also provide a mechanism for anchorage of the meniscal substitute to the bone.

[0008] According to various features, the scaffold material may be a porous structure such as for example comprising natural or synthetic fibers in a fabric or non-woven film material, or comprising polymer foam material. This scaffold material is preferably biocompatible and/or degradable. Preferably the scaffold material comprises a biocompatible and degradable polymer foam.

[0009] According to other features, the non-stretch material may be a natural or synthetic ligament, or any other biocompatible fiber or braided and/or woven structure. This natural ligament can be a tendon, such as a single hamstring tendon or the synthetic ligament can be any biocompatible ligament structure such as for example a polyester ligament. Preferably, the ligament is attached to the scaffold material in such a manner so as to ensure that the ligament-scaffold material assembly remains porous to blood supply and cell ingrowth.

[0010] A method is provided for repairing or replacing a damaged meniscus of the knee includes forming a passage in the knee to repair the tear or lesion, the passage defining an entrance and an exit. The assembly of the present invention is passed through the passage. The assembly is manipulated whereby the implant assembly is positioned so as to replace the damaged meniscus and providing all meniscal functions including hoop-stress resistance and cushioning of the joint surfaces. The assembly can then secured to the knee joint, preferably the tibia, using a securing means.

[0011] Further areas of applicability of the present disclosure will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and various examples, while indicating various embodiments of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the following claims.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1: Shows a schematic side view of a meniscus repair/replacement assembly according to the present invention comprising a scaffold material implant, a sleeve at the peripherial rim of the scaffold material, and a non-stretch material inside the sleeve.

Figure 2: Shows a schematic top view of a meniscus repair/replacement assembly according to the present invention comprising a scaffold material implant, a sleeve at the peripheral rim of the scaffold material, and a non-stretch material inside the sleeve.

Figure 3: Shows a schematic side view of a meniscus repair/replacement assembly according to the present invention comprising a scaffold material implant, a sleeve at the peripheral rim of the scaffold material, and a non-stretch material attached directly to the peripheral rim of the scaffold material by means of a suture.

Figure 4: Shows a schematic top view of a meniscus repair/replacement assembly according to the present invention comprising a scaffold material implant, a sleeve at the peripheral rim of the scaffold material, and a non-stretch material attached directly to the peripheral rim of the scaffold material by means of a suture.

Figure 5: Shows a perspective view of a meniscus repair/replacement assembly according to the present invention including a non-stretch material that extends beyond the longitudinal ends of the peripheral rim of the scaffold material.

Figure 6: Shows a perspective view of a meniscus repair/replacement assembly according to the present invention showing direct attachment of a non-stretch material to the peripheral rim of the scaffold material by means of a suture.

Figure 7: Shows a back view of a meniscus repair/replacement assembly according to the present invention showing direct attachment of a non-stretch material to the peripheral rim of the scaffold material by means of a suture.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

[0012] The following description of various embodiments is merely exemplary in nature and is not intended to limit the application or uses.

[0013] In order to repair or reconstruct an extensively damaged meniscus or where a meniscus is lost in its entirety, a technique may be used wherein a scaffold material is implanted in order to replace the damage or lost meniscus. This process of meniscus reconstruction requires removal of remaining meniscal tissue to provide space for an implant of scaffold material including a non-stretch material attached to the peripheral rim thereof. The implant of scaffold material may need to be shaped to match the missing meniscus, either as a whole or as a portion. This shaped implant of scaffold material is then implanted in the knee joint to replace the meniscus. Improvements in tissue engineering and surgical techniques with minimal tissue damage and reduced pain

associated with tissue repair, aimed at preserving meniscal function may provide significant benefits in the potential healing response of meniscal tears. The assembly and method of the present invention provides for meniscus repair/replacement while providing full meniscal functionality including maintenance of the hoop-stress resistance to protect the joint surfaces of the femur and tibia in the knee joint.

[0014] With initial reference to Figures 1 and 2, an assembly for repairing or replacing a meniscus is shown. The assembly according to the present invention comprises a scaffold material in the shape of a meniscus **1** having a thick peripheral rim area **10**, tapering of to a thin inner border **11**. A top face of the scaffold material **2** provides support for a condyle of the femur while a bottom area **3** is to be situated on top of the tibial plateau. Along the entire length of the outer portion of the peripheral rim a sleeve **4** is connected to the scaffold material. A rectangular non-stretch material **5** is inside the sleeve and provides support for the meniscal implant assembly to maintain hoop-stress resistance. The non-stretch material preferably extends beyond both ends of the sleeve **4**. These extended ends of the rectangular non-stretch material **5** may be used as a means to secure the assembly implant into the knee joint for example on top of the tibial plateau. The assembly may be attached to the tibial plateau by way of securing the extended ends of the non-stretch material through a hole in the bone that has been drilled, or by fixing with suture anchor devices. Further, the sleeve **4** may be part of the scaffold material and be formed by way of tunnel boring a sleeve in the peripheral rim **10** of the scaffold material. Alternatively the sleeve may be connected to the peripheral rim of the through a connection means such as, for example, a suture. The scaffold material **1** provides a matrix which allows re-growth of the meniscal tissue in the scaffold material **1**. Further, the sleeve **4** and non-stretch material **5** may be attached to the scaffold material so as to ensure that the structure remains porous to blood supply and cell ingrowth. The composition of the scaffold material **1** can be any porous scaffold material such as for example comprising natural or synthetic fibers in a fabric or non-woven material, or comprising polymer foam material. This scaffold material is preferably biocompatible and/or degradable. Preferably the scaffold material comprises a biocompatible foam that is degradable.

[0015] In an alternative embodiment as shown in Figures 3 and 4, the assembly according to the present invention comprises a scaffold material in the shape of a meniscus **1** having a thick peripheral rim area **10**, tapering of to a thin inner border **11**. A top face of the scaffold material **2** provides support for a condyle of the femur joint while a bottom area **3** is to be situated on top of the tibial plateau. Along the entire length of the outer portion of the peripheral rim **10** a rectangular non-stretch material **5** is attached to the peripheral rim of the scaffold material **1**. The rectangular non-stretch material may be connected to the peripheral rim **10** of the scaffold material **2** through a means to attach the non-stretch material to the peripheral rim **10** such as, for example, one or more sutures **8**. The scaffold material **1** provides a matrix which allows re-growth of the meniscal tissue in the scaffold material **1**. Further, non-stretch material **5** may be attached to the scaffold material so as to ensure that the structure remains porous to blood supply. In addition, the rectangular non-stretch material **5** can extend beyond the longitudinal edge of the peripheral rim **10** in an extended section **7**. The extended section **7** of the non-stretch material **5** can be used to secure the implant assembly of the present invention to the knee joint, for example on the tibial plateau. The assembly may be attached to the tibial plateau by way of securing the extended ends **7** of the non-stretch material **5** through a hole in the bone that has been drilled, for example tunnel bored. In addition, the non-stretch material **5**, or the extended ends **7** thereof may further comprise another means of securing the assembly **6** to the knee joint for example by use of sutures.

[0016] Figure 5 shows a perspective view of such an assembly according to the invention comprising a scaffold material **1** and a non-stretch material **5** attached to the entire length of the peripheral rim **10** and further extending beyond the edges of the peripheral rim into an extended portion **7** which may comprise a securing means for attaching the assembly to the knee joint. The non-stretch material **5** is attached to the scaffold material **1** by means of one or more sutures **8**. Figures 6 and 7 show a top perspective view and a back view of such attachment of the non-stretch material **5** to the scaffold material 1 by means of one or more sutures **8**.

[0017] The composition of the scaffold material that is used for the scaffold material implant of the assembly according to the invention can be any porous scaffold material

such as for example comprising natural or synthetic fibers in a fabric or non-woven material, or comprising polymer foam material. Additionally, the scaffold material may further comprise additional growth promoting materials such as for example blood clot, bone marrow, platelet rich plasma (PRP), and growth factors. The scaffold material is preferably biocompatible and/or degradable. Preferably the scaffold material comprises a biocompatible polymer foam that is degradable. Such foams for use in the assembly according to the present invention have properties especially useful for such assembly, including having a modulus of compression between about 50 kPa to about 1500 kPa, preferably about 250 kPa to about 400 kPa, a tear strength of greater than or equal to about 3 N/mm, and flexibility (strain at break) of about 100 % or higher. These advantageous properties are in part due to the high molecular weight of the polymers in the foam and in part due to the interconnectivity of the polymers in the foam. This high molecular weight and interconnectivity are achieved by the process of making the polyurethane polymer and by the process of making the foam from the polyurethane polymer as described for example in International Patent Application No. PCT/IB2009/005958, filed May 19, 2009, published as WO 2009/141732. The final average molecular weight of the polymer in the foam is preferably about 110 kg/mol to about 240 kg/mol. More preferably the average molecular weight of the polymer is about 120 kg/mol to about 240 kg/mol. Even more preferably, the average molecular weight of the polymer in the foam is 140 kg/mol to about 240 kg/mol.

[0018] The polymer in such foam my be a polyurethane prepared by a process comprising the steps of: (a) reacting a diol, preferably a C_1-C_{10} alkyl diol, more preferably 1,4-butanediol, with an oxygen containing compound that can form a macrodiol by ring-opening polymerization, preferably a lactone, more preferably ε-caprolactone, to provide a macrodiol, wherein the reaction is carried out to completion, preferably until the unreacted remaining oxygen containing compound that can form a macrodiol by ring-opening polymerization is less than 0.5% by mole equivalents of the total amount of the oxygen containing compound, more preferably less than about 0.2% by mole equivalents; (b) treating the macrodiol with a diisocyanate, to obtain a macrodiisocyanate, wherein the unreacted diisocyanate is removed under a pressure of less than about 0.01 mbar, preferably less than about 0.003 mbar, preferably until the

remaining amount of unreacted diisocyanate is between -5% to 5% by mole equivalent of the calculated required amount of diisocyanate in the reaction, more preferably between -2% and 2% by mole equivalents, even more preferably between -1% and 1% by mole equivalent; most preferably between -0.5% and 0.5% by mole equivalents; and (c) reacting the macrodiisocyanate with a diol chain extender, preferably a diol, more preferably a C_1-C_{10} alkyl diol, even more preferably 1,4-butanediol, wherein the molar ratio of macrodiisocyanate:diol is 1.00:1.00 to 1.00:1.09, preferably 1.00:1.01 to 1.00:1.03.

[0019] A biocompatible foam that is degradable as may be used in the assembly according to the present invention may be prepared from such polyurethane by for example a process comprising: (a) preparing a solution of about 20% to about 50% (w/v), preferably of about 30% to about 45% (w/v), preferably about 36% (w/v) of polyurethane in an appropriate solvent, preferably wherein the polyurethane is soluble, preferably DMSO, DMF, chloroform, 1,4-dioxane, NMP, m-cresol, dimethyl acetamide, more preferably DMSO; (b) combining the solution with a non-solvent, preferably water or a C_1-C_6 alkyl diol, more preferably water, to obtain a solution, preferably the amount of non-solvent added to the solution is in an amount from 5% to 30% (v/v), more preferably 5% to 20%, most preferably from 5% to 10% (v/v); (c) adding a pore forming material not soluble in the solvent, preferably a salt, more preferably an alkali metal or alkaline earth metal salt, even more preferably an halogen salt of an alkali metal or alkaline earth metal, most preferably NaCl, to obtain a viscous mixture; (d) pouring the viscous mixture into a mold and cooling, in any order to obtain a molded material; and (e) washing the molded material with a non-solvent wherein the polyurethane polymer is insoluble but wherein the pore forming material can be dissolved to obtain a foam for use in an assembly for repairing a tear or lesion in a meniscus according to the present invention.

[0020] The non-stretch material may be a natural or synthetic ligament, or any other biocompatible fiber or braided and/or woven structure. A natural ligament can be a tendon, such as a single hamstring tendon. A synthetic ligament can be any biocompatible ligament structure such as, for example, a polyester ligament. Preferably, the non-stretch material is attached to the scaffold material in such a manner so as to

ensure that the non-stretch material-scaffold material assembly remains porous to blood supply. In addition, the non-stretch material-scaffold material assembly of the present invention is prepared from materials and shaped in such a form so as not to irritate any local tissues of the patient.

[0021] Thus the current invention provides a novel approach to total meniscal reconstruction while maintaining meniscal function including hoop-stress resistance by providing an assembly for repairing or replacing a damaged meniscus of the knee comprising a scaffold material substantially in the shape of a meniscus having a thick peripheral rim area tapering of to a thin inner border, and a rectangular non-stretch material attached to the scaffold material along the entire length of the thick peripheral rim and extending in the same direction past the peripheral rim on both longitudinal edges thereof, either directly secured to the scaffold material or passed through a sleeve attached to the entire length of the peripheral rim of the scaffold material.

[0022] Those skilled in the art can now appreciate from the foregoing description that the broad teachings of the present invention can be implemented in a variety of forms. Therefore, while this invention has been described in connection with particular examples thereof, the true scope of the invention should not be so limited since other modifications will become apparent to the skilled practitioner upon a study of the drawings, the specification and the following claims.

What is claimed is:

1. An assembly for repairing or replacing a damaged meniscus of the knee comprising:

a) a scaffold material substantially in the shape of a meniscus having a thick peripheral rim area tappering of to a thin inner border,

b) a sleeve intimately connected to the scaffold material along the length of the thick peripheral rim, and

c) a rectangular non-stretch material inside the length of the sleeve and extending outward at both ends of the sleeve,

wherein the assembly provides support and retains at least the meniscal function of hoop-stress resistance.

2. The assembly of claim 1, wherein the non-stretch material comprises at each end at least one means of securing the assembly to a knee joint.

3. The assembly of claim 2, wherein the knee joint is the tibia.

4. The assembly of claim 2 or 3, wherein the means of securing the assembly to a knee joint is the same material as the non-stretch material.

5. The assembly of any one of claims 2-4, wherein the means of securing the assembly to a knee joint is a suture.

6. The assembly of any one of claims 1-5, wherein the non-stretch material is a natural or synthetic ligament, or any other biocompatible fiber or braided and/or woven structure.

7. The assembly of claim 6, wherein the non-stretch material is a tendon.

8. The assembly of claim 6, wherein the non-stretch material is a synthetic ligament.

9. The assembly of claim 8, wherein the synthetic ligament is a polyester ligament.

10. The assembly of any one of claims 1-9, wherein the scaffold material comprises a biocompatible foam.

11. The assembly of claim 10, wherein the biocompatible foam is degradable.

12. The assembly of claim 11, wherein the biocompatible foam is polyurethane foam.

13. The assembly of any one of claims 1-12, wherein the sleeve is of the same material as the scaffold material and is tunneled into the thick peripheral rim of the scaffold material.

14. The assembly of any one of claims 1-13, wherein the sleeve is pre-woven to the scaffold material with sutures.

15. An assembly for repairing or replacing a damaged meniscus of the knee comprising:

a) a scaffold material substantially in the shape of a meniscus having a thick peripheral rim area tappering of to a thin inner border, and

b) a rectangular non-stretch material attached to the scaffold material along the entire length of the thick peripheral rim and extending in the same direction past the peripheral rim on both longitudinal edges,

wherein the assembly provides support and retains at least the meniscal function of hoop-stress resistance.

16. The assembly of claim 15, wherein the non-stretch material comprises at each end at least one means of securing the assembly to a knee joint.

17. The assembly of claim 16, wherein the knee joint is the tibia.

18. The assembly of claim 16 or 17, wherein the means of securing the assembly to a knee joint is the same material as the non-stretch material.

19. The assembly of any one of claims 16-18, wherein the means of securing the assembly to a knee joint is a suture.

20. The assembly of any one of claims 15-19, wherein the non-stretch material is a natural or synthetic ligament, or any other biocompatible fiber or braided and/or woven structure.

21. The assembly of claim 20, wherein the non-stretch material is a tendon.

22. The assembly of claim 20, wherein the non-stretch material is a synthetic ligament.

23. The assembly of claim 22, wherein the synthetic ligament is a polyester ligament.

24. The assembly of any one of claims 15-23, wherein the scaffold material comprises a biocompatible foam.

25. The assembly of claim 24, wherein the biocompatible foam is degradable.

26. The assembly of claim 25, wherein the biocompatible foam is polyurethane foam.

27. The assembly of any one of claims 15-26, wherein the non-stretch material is attached to the scaffold material with at least one suture.

28. A method for meniscal repair or replacement the method comprising:

a) providing an assembly in accordance with any one of claims 1-27;

b) inserting the assembly into the knee joint replacing a damaged meniscus in a patient; and

c) securing the assembly in place to a knee-joint providing full meniscal function including hoop-stress resistance.

29. Use of an assembly in accordance with any one of claims 1-27 for meniscal repair or replacement.

Figure 1: Shows a schematic side view of a meniscus repair/replacement assembly according to the present invention with sleeve for the non-stretch material.

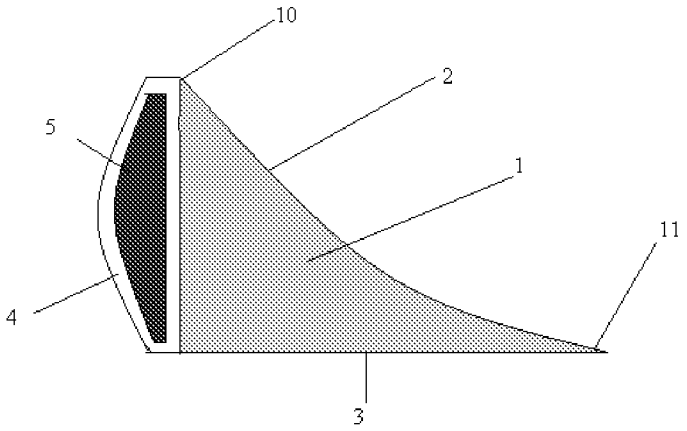


Figure 2: Shows a schematic top view of a meniscus repair/replacement assembly according to the present invention with sleeve for the non-stretch material

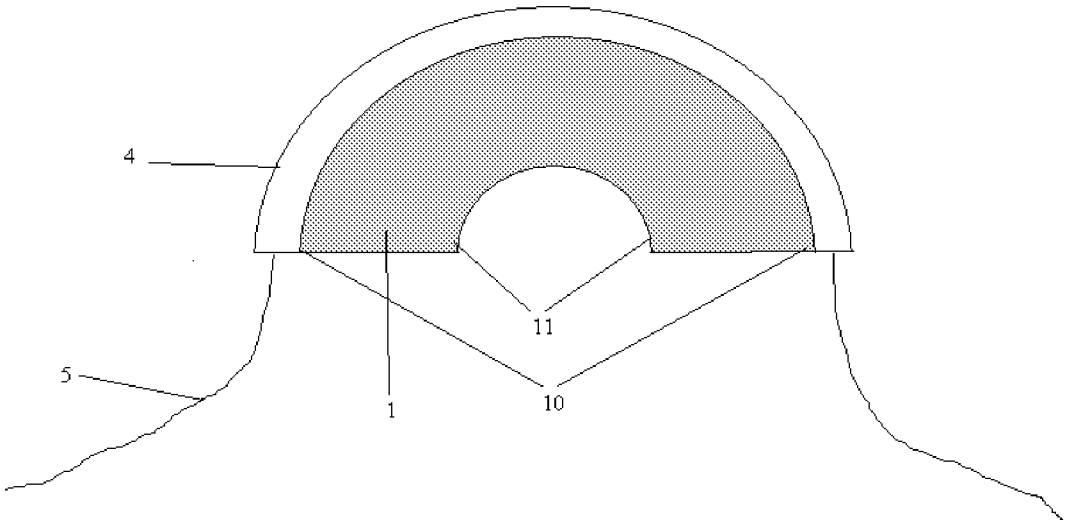


Figure 3: Shows a schematic side view of a meniscus repair/replacement assembly according to the present invention wherein the non-stretch material is attached directly to the peripheral rim of the scaffold material by means of a suture.

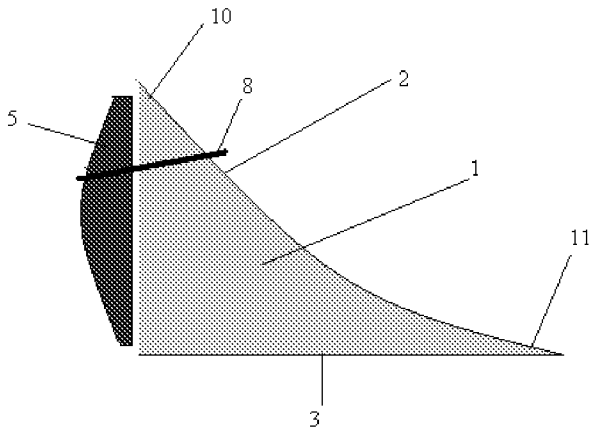


Figure 4: Shows a schematic top view of a meniscus repair/replacement assembly according to the present invention wherein the non-stretch material is attached directly to the peripheral rim of the scaffold material by means of a suture.

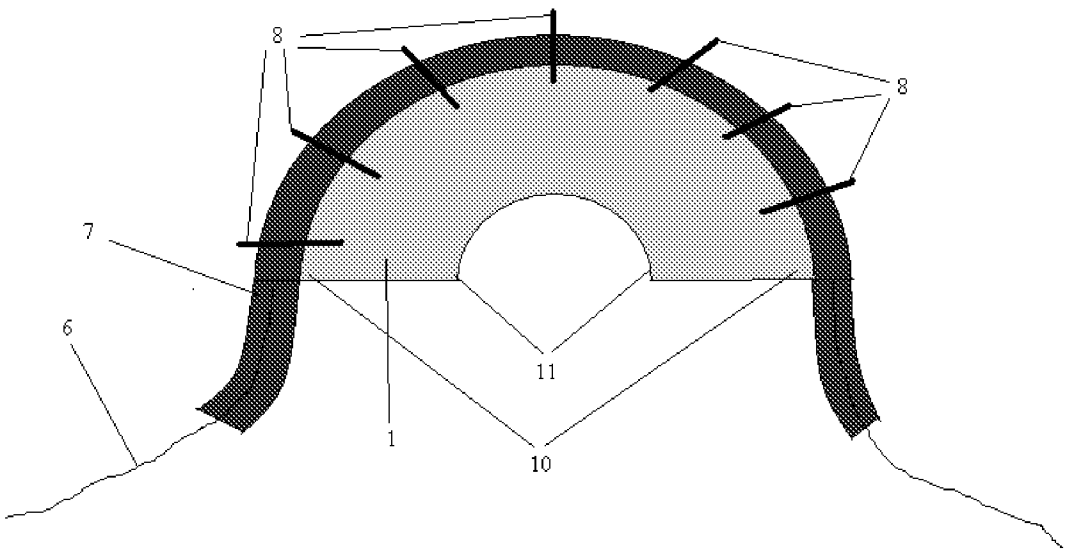


Figure 5: Shows a perspective view of a meniscus repair/replacement assembly according to the present invention including a non-stretch material that extends beyond the longitudinal ends of the peripheral rim of the scaffold material.

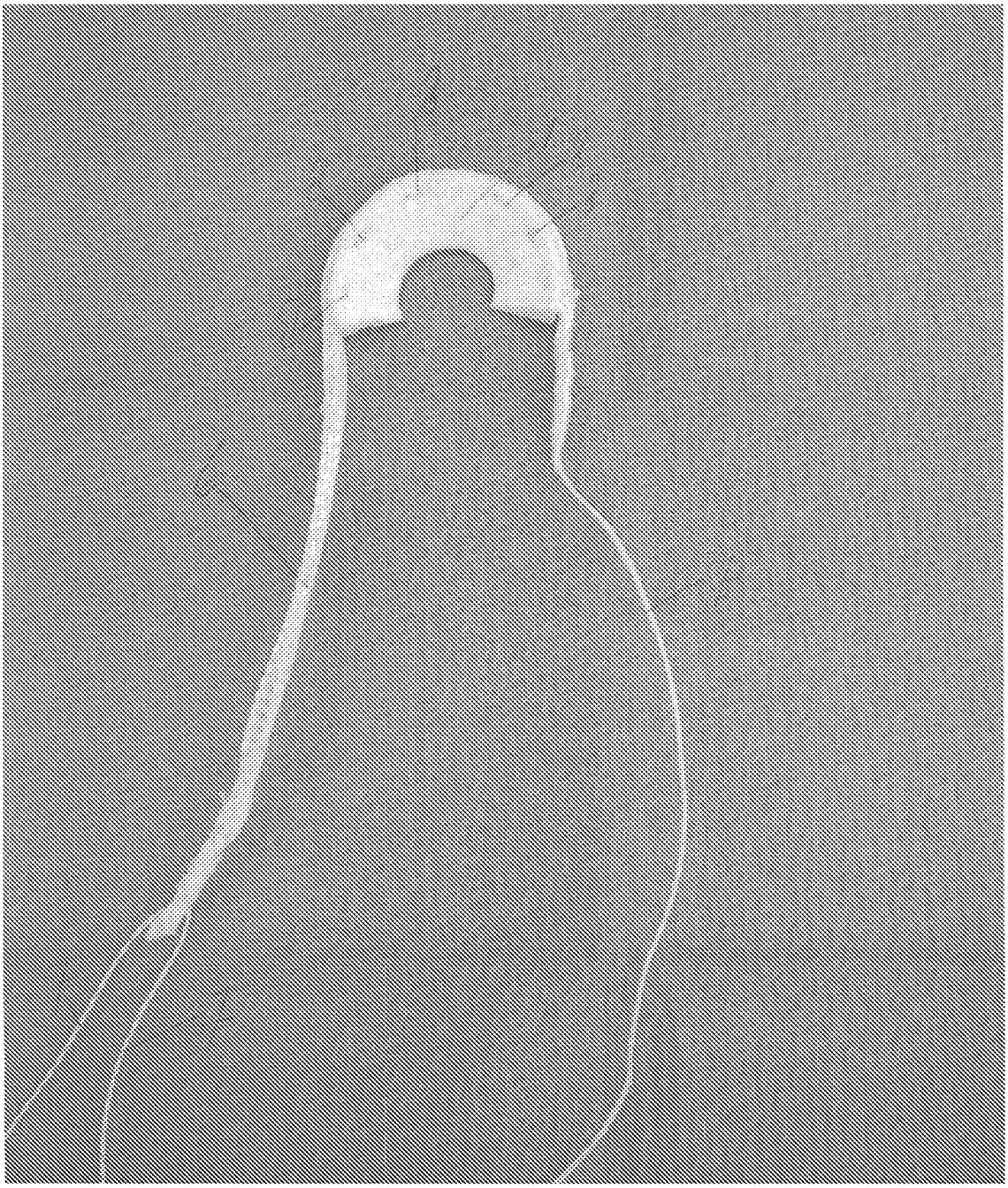


Figure 6: Shows a perspective view of a meniscus repair/replacement assembly according to the present invention showing direct attachment of a non-stretch material to the peripheral rim of the scaffold material by means of a suture.

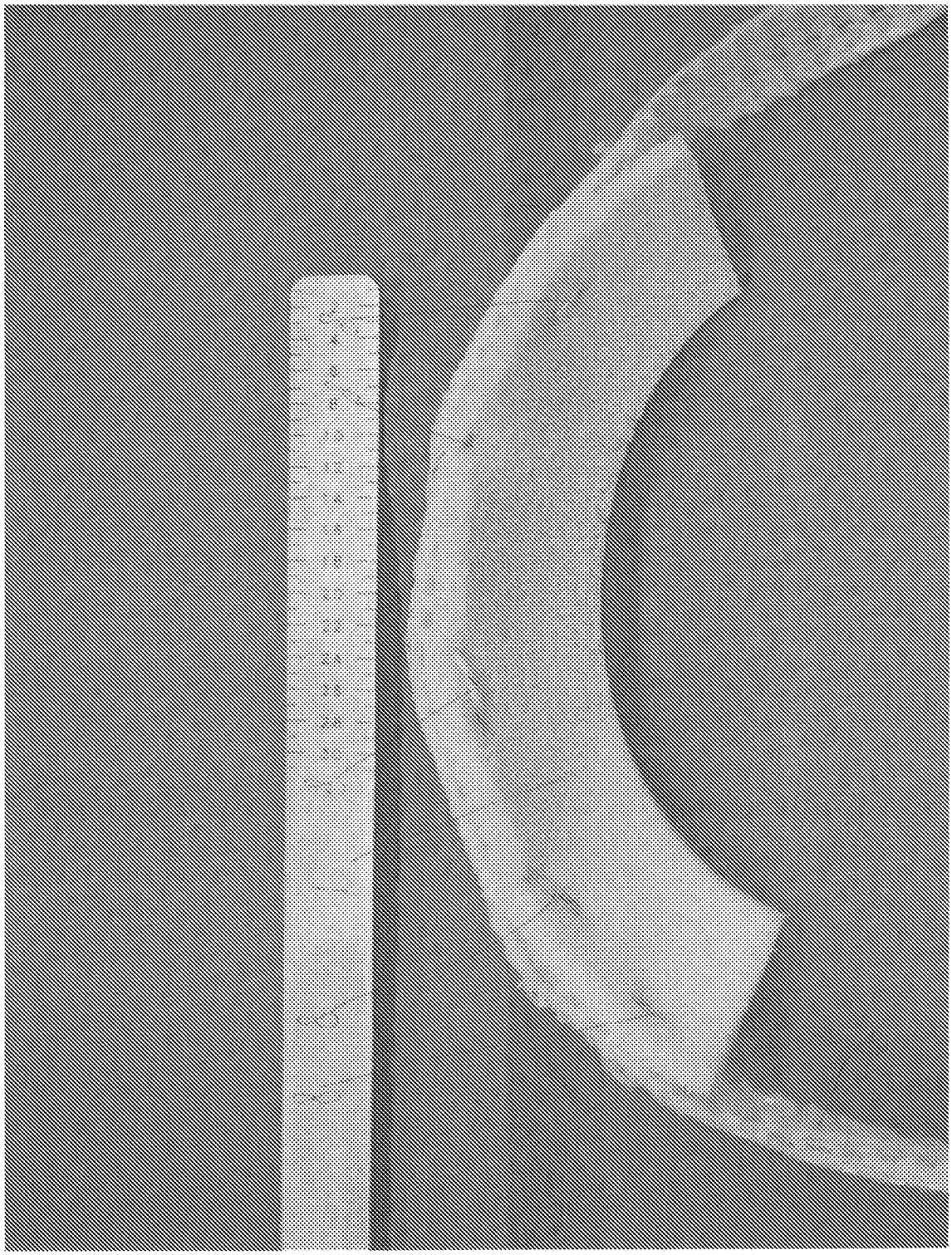
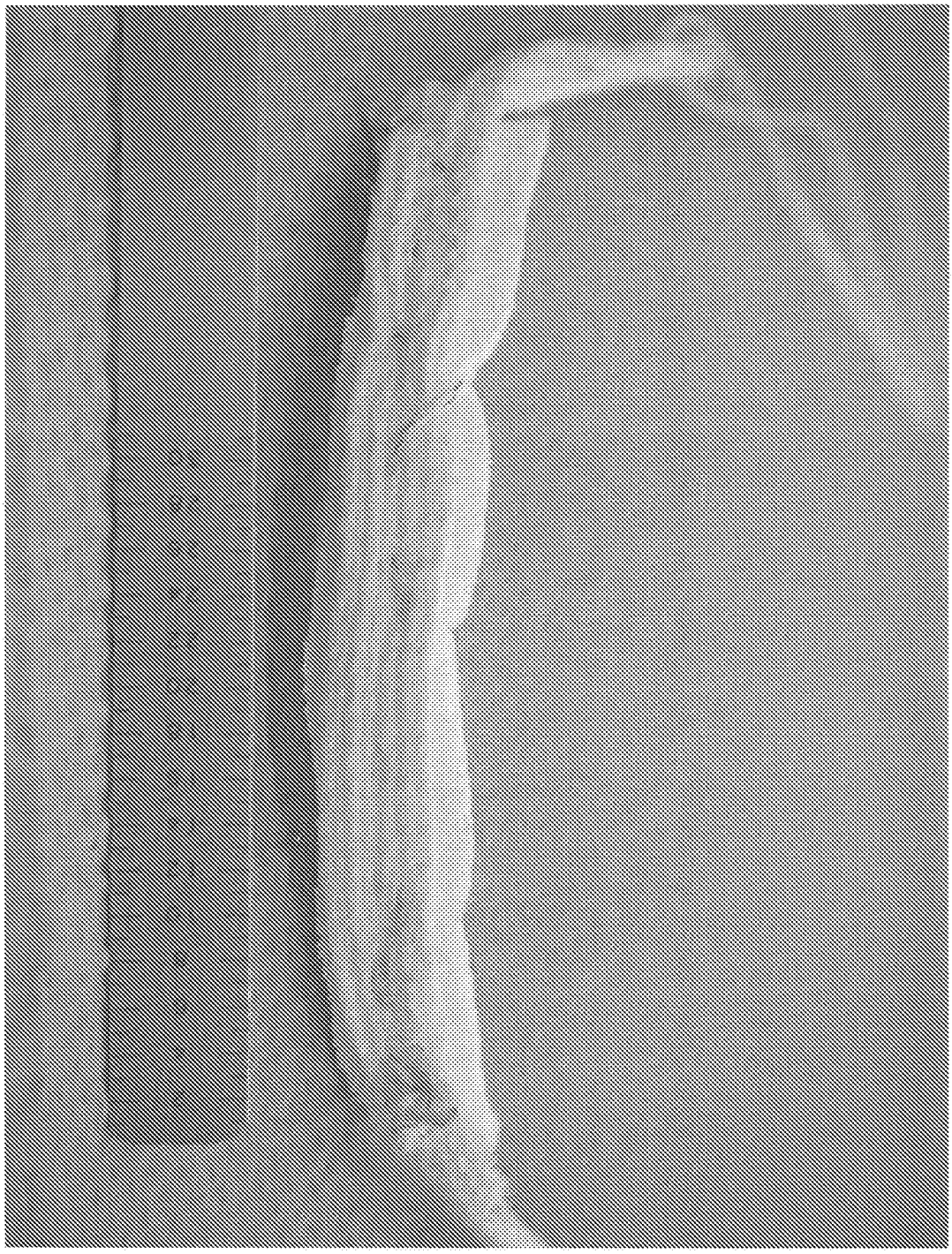


Figure 7: Shows a back view of a meniscus repair/replacement assembly according to the present invention showing direct attachment of a non-stretch material to the peripheral rim of the scaffold material by means of a suture.



INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/38
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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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 372 811 A1 (STRYKER CORP [US]) 13 June 1990 (1990-06-13) column 3, line 20 - column 8, line 13; figures 1,2	1-14 15-27

X,P	WO 2012/019248 A1 (INTIGO GISELLE NOMINEES PTY LTD [AU]; VOWLES ROBERT [AU]) 16 February 2012 (2012-02-16) figure 1	15-27

X	US 2002/022884 A1 (MANSMANN KEVIN A [US]) 21 February 2002 (2002-02-21) page 26, line 22 - page 27, line 5; figure 14	15-27

A	US 2009/259314 A1 (LINDER-GANZ ERAN [IL] ET AL) 15 October 2009 (2009-10-15) figures 7,8	1-27

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[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 application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 June 2012	06/07/2012

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

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/038548

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 296 15 920 U1 (LINK WALDEMAR GMBH CO [DE]) 15 January 1998 (1998-01-15) figures 1-6	1-27
A	WO 2009/141732 A2 (ORTEQ B V [NL]; VAN BEIJMA FOLKERT [NL]; DE GROOT JACQUELINE [NL]) 26 November 2009 (2009-11-26) cited in the application the whole document	1-27
A,P	WO 2011/106369 A1 (ORTEQ B V [NL]; KURZWEIL PETER R [US]) 1 September 2011 (2011-09-01) cited in the application the whole document	1-27

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/038548

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 28, 29
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. The step of inserting an assembly into a knee joint is clearly surgical.

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

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

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

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

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

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

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/038548

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 2011105635 A1	05-05-2011
		WO 2009141732 A2	26-11-2009
WO 2011106369 A1	01-09-2011	NONE	