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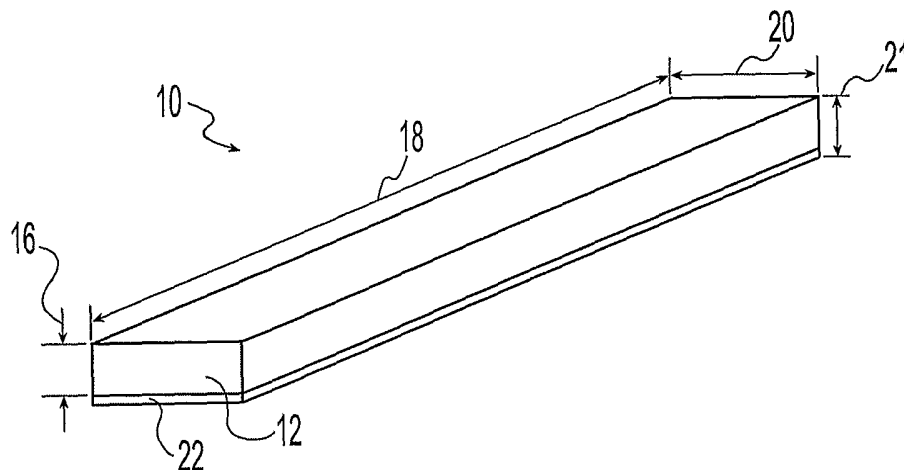
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[Continued on next page]

(54) Title: STRIP IMPLANTS OF BONE PIECES



(57) Abstract: The present invention provides an implant for use in fusing adjacent bony structures. The implant comprises a plurality of bone pieces formed into at least one load bearing layer.

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STRIP IMPLANTS OF BONE PIECES

BACKGROUND

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Implants for use in fusing adjacent bony structures facilitate fusion by maintaining the adjacent bony structures in a predetermined spaced relationship while bone grows between them. In some cases these implants are formed from body tissues. In forming an implant from body tissue, a source of tissue, such as a bone, is formed into pieces meeting the desired shape and strength requirements for a particular implant. In the case of bone, the requirements are often specified in terms of a minimum wall thickness, minimum load bearing capacity, and/or geometric size and shape. A portion of the source tissue, including pieces removed in forming implants, will fall short of the requirements to form an integral implant. Thus, it is often difficult to obtain a high yield from a particular source.

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SUMMARY

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The present invention provides an implant for use in fusing adjacent bony structures.

In one aspect of the invention, an implant for use in fusing adjacent bony structures comprises a plurality of elongate bone pieces formed into at least one load bearing layer.

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In another aspect of the invention, an implant for use in fusing adjacent bony structures comprises a plurality layers, each layer comprising a plurality of elongate bone pieces.

In another aspect of the invention, a method for use in fusing adjacent bony structures comprises the steps of combining a plurality of layers to form a layered implant, each layer comprising a plurality of elongate bone pieces and positioning the implant between adjacent bony structures in load bearing relationship.

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In another aspect of the invention, an implant for use in fusing adjacent bony structures comprises a plurality of elongate bone pieces formed into at least one load bearing layer, at least some of the elongate bone pieces further comprising holes formed

therethrough; and a flexible, elongate, biocompatible connector, the connector being threaded through the holes to interconnect the pieces.

In another aspect of the invention, an implant for use in fusing adjacent bony structures comprises a plurality of elongate bone pieces formed into at least one load bearing layer, the elongate bone pieces being woven together.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will be discussed with reference to the appended drawings. These drawings depict only illustrative embodiments of the invention and are not to be considered limiting of its scope.

FIG. 1 is a perspective view of an illustrative embodiment of a bone piece used to make an implant according to the present invention.

FIG. 2 is a perspective view of a load bearing layer for an implant made from a bone piece as in FIG. 1.

FIG. 3 is a perspective view of a multi-layered implant made by repeatedly stacking load bearing layers as in FIG. 2 to form a thicker implant.

FIG. 4 is a perspective view of a multi-layered implant made by folding back on itself a load bearing layer as in FIG. 2 to form a thicker implant.

FIG. 5 is a perspective view of a multi-layered implant made by rolling up a load bearing layer as in FIG. 2 to form a thicker implant.

FIG. 6 is a perspective view of a multi-layered implant like that of FIG. 5 but oriented perpendicularly to that of FIG. 5 and also depicting its use in conjunction with supplemental fixation device mounted on a bone.

DETAILED DESCRIPTION

Embodiments of a bone implant include a plurality of bone pieces formed into a load bearing implant for use in fusing adjacent bony structures. The adjacent bony structures may include vertebrae, long bones, and cranial bones, among others. Bone for the implant may be obtained from any suitable bone source including the implant recipient as in an autograft, another source of the same species as in an allograft, or a source of a different species as in a xenograft. Suitable examples of musculoskeletal tissue include humerus, tibia, femur, fibula, patella, ulna, radius, rib, vertebral bodies, etc. The bone

pieces may be formed by machining, planing, grinding, grating, cutting, milling, splintering, chopping, crushing, and/or other suitable means for removing bone or reducing the source bone into smaller pieces. The pieces may be in the form of particles, random shaped chunks, fibers, strips and/or sticks of bone. Each of the bone pieces may
5 comprise an elongated cortical bone layer running along substantially the entire length of the piece. The cortical bone layer may include a demineralized portion to give flexibility to the piece. Further, each cortical bone piece may have a predetermined cortical layer thickness or geometry less than a predetermined minimum wall thickness or geometry associated with an integral or assembled implant formed of the donor bone. Combining a
10 plurality of bone pieces into an implant thereby allows donor bone having less than a predetermined minimum load bearing strength or geometry to be used to form a load-bearing implant.

The bone pieces may have any suitable longitudinal length, any suitable width, and any suitable height. Additionally, each of the plurality of pieces may further include a
15 cancellous bone layer adjacent to the cortical bone layer along a portion or substantially all of the length of the piece. The plurality of pieces may be formed into a bone implant layer, mass or geometry, and one or more of the implant layers, masses or geometries may be formed into the load-bearing bone implant. The bone pieces in each bone implant layer, mass or geometry may be interconnected by weaving, pinning, suturing, pressing,
20 incorporating a binding agent, collagen cross-linking, or any other method of interconnecting the pieces.

If the pieces are woven, the pieces may be woven together in a predetermined pattern to form a woven bone layer. The pieces may be partially or fully demineralized to facilitate weaving. The bone pieces oriented in one direction of the weave pattern may be
25 demineralized more than the bone pieces in a second direction of the weave pattern so that the more demineralized pieces bend around the less demineralized pieces as they are woven. The pieces may further be segmentally demineralized at one or more spaced apart discrete portions such that each individual piece has a plurality of mineralized segments separated by relatively more flexible demineralized segments. The demineralized
30 segments act like flexible hinges to facilitate the bending of the segmentally demineralized pieces around adjacent pieces in the weave pattern.

If the pieces are pinned, holes may be formed in the pieces and rigid pins made of bone, ceramic, metal, polymers, and/or other suitable materials may be pressed into the holes to interconnect the pieces.

If the pieces are sutured together, holes may be formed in the pieces and a flexible, elongate, biocompatible connector may be threaded through the holes to interconnect the pieces. The connector may be a suture and/or elongate pieces of body tissue. Examples of materials for such connectors include pericardium, demineralized bone, fascia, cartilage, tendon, ligament, skin, collagen, elastin, reticulum, intestinal submucosa, metal, resorbable polymer, and nonresorbable polymer, and/or other suitable material.

If a binding agent is used to interconnect the pieces, it may be an adhesive binding agent, a cementitious binding agent, and/or other suitable binding agent. Examples of adhesive binding agents include fibrin glue, cyanoacrylate, epoxy, polymethylmethacrylate, gelatin based adhesives, and other suitable adhesives and combinations thereof. Examples of cementitious binding agents include settable ceramics, calcium carbonate, calcium phosphate, plaster, and other suitable materials and combinations thereof.

If the pieces are interconnected by collagen cross-linking, the bone pieces may be partially demineralized to expose collagen fibers which may then be crosslinked by application of heat, pressure, chemicals, and/or other suitable cross-linking means.

Additionally, if a plurality of implant layers is utilized, they may be formed such as by folding or rolling a single layer to form multiple layers or by stacking multiple single layers adjacent to one another. The plurality of layers may be secured together by one or more of the interconnection mechanisms already described. Implants having one or more layers may have a layer axis substantially normal to the one or more layers and a load bearing axis along which load is applied to the implant from the adjacent bony structures. The implant may be oriented with its layer axis substantially perpendicular to, substantially parallel to, or at some other suitable angle to the load bearing axis. A layer made of elongate bone pieces may be arranged so that the bone pieces are arranged with their longitudinal axes substantially parallel to one another. This uni-directional layer may then be oriented in the implant with the longitudinal axes of the bone pieces substantially perpendicular to, substantially parallel to, or at some other suitable angle to the load bearing axis. For example, the bone pieces could derive from a long bone source and be

oriented in a layer with their longitudinal axes substantially parallel to the implant load bearing axis so that the individual pieces are loaded similarly to how they were naturally loaded in the source bone.

The implant may further include one or more openings through the implant to facilitate fusion of the adjacent bony structures. The one or more openings may be formed by drilling, cutting, punching, or other suitable means. The implant may further include one or more bone growth promoting materials within the one or more layers, between the layers, and/or in the one or more openings, if present. Examples of bone growth promoting materials include growth factors, osteogenic proteins, bone morphogenic proteins, including human recombinant bone morphogenic proteins, LIM mineralization proteins, bone paste, bone chips, demineralized bone, hydroxyapatite, hormones, platelet derived growth factors, bone marrow aspirate, stem cells, and/or other suitable bone growth promoting materials.

Referring to the drawing, FIG. 1 depicts an illustrative piece of bone 10 having an elongate strip or stick form. The piece 10 has an elongate cortical bone layer 12 running along substantially the entire length of the strip. The piece 10 has a cortical layer thickness 16, length 18, and width 20. The piece may have a predetermined cortical layer thickness 16 less than a predetermined minimum wall thickness or geometry associated with an integral or assembled implant formed of the donor bone. The piece may further include a cancellous bone layer 22 adjacent to the cortical bone layer 12 along a portion or substantially all of the length of the piece yielding an overall implant thickness 21 greater than the cortical thickness 16.

FIG. 2 depicts an illustrative implant layer 24 formed by weaving together individual elongate pieces of bone. The weave pattern includes warp pieces 13 oriented in a first direction and filler pieces 17 oriented in a second direction. Both the warp pieces 13 and the filler pieces 17 may comprise the elongate bone pieces of FIG. 1. The pieces 13,17 may be sufficiently flexible to permit weaving. Alternately, weaving may be facilitated by partially demineralizing the pieces. In the illustrated embodiment, only a portion 14 of the pieces has been demineralized to form segmentally demineralized bone pieces having one or more spaced apart discrete demineralized portions 14 such that each individual piece 10 has a plurality of mineralized segments 15 separated by relatively more flexible demineralized segments 14. The demineralized segments act like flexible

hinges to facilitate the bending of the segmentally demineralized pieces around adjacent pieces in the weave pattern. Both the warp 13 and filler 17 pieces can be demineralized or one can be demineralized and the other left fully mineralized as illustrated.

One or more implant layers, whether woven or otherwise formed, may be formed into a bone implant. FIG. 3 depicts an illustrative implant 26 comprising a plurality of individually woven layers, described relative to FIG. 2, stacked together to form a thicker implant. The layers are interconnected by an interconnection mechanism 28 comprising rigid bone pins pressed into holes formed in the layers. The implant has a layer axis 27 normal to the layers.

FIG. 4 depicts an illustrative implant 25 comprising a single layer 24 folded back on itself to form a plurality of layers. The layer 24 comprises a plurality of bone pieces of any suitable shape interconnected in any suitable manner. The layers in this illustrative embodiment are interconnected by an interconnection mechanism 28 comprising an elongate flexible connector threaded through holes formed in the layers. The implant has a layer axis 27 normal to the layers.

FIGS. 5 and 6 depict an illustrative implant 29 comprising a single layer 24 rolled to form a plurality of layers overlying one another radially in a substantially cylindrical wound spiral construct. The implant 29 has a layer axis 27 normal to the layers. FIG. 5 depicts the implant 29 in load bearing relationship to adjacent bony structures 33 with the layer axis 27 substantially parallel to the load bearing axis 35. FIG. 6 depicts the implant 29 in load bearing relationship to adjacent bony structures 33 with the layer axis 27 substantially perpendicular to the load bearing axis 33. A supplemental fixation device 62 may be used in conjunction the implant 29. The fixation device 62 may include one or more anchor mechanisms 72, such as screws, pins, wires, and/or other mechanisms for attaching it to the adjacent bony structures 33 to limit the relative motion between them. The fixation device 62 may substantially prevent all relative motion, or it may allow a predetermined amount of motion, such as to allow the implant 29 to remain in contact with the adjacent bony structures 33 during the healing and fusion processes. Suitable examples of a fixation device 62 include plates, internal or external rod systems, cable systems, cerclage systems, screws, and other suitable devices and combinations thereof.

The plurality of bone pieces comprising cortical bone may have a predetermined layer thickness and geometry, measured radially from the longitudinal axis of the donor

bone, less than a predetermined minimum wall thickness and geometry. For example, the predetermined layer thickness and geometry may be in the range of less than 2 mm thick in one embodiment, less than 1.8 mm thick in another embodiment, less than 1.5 mm thick in yet another embodiment, less than 1.0 mm thick in still another embodiment, and less than 0.5 mm thick in another embodiment. Further, for example, the predetermined minimum wall thickness and geometry may relate to a minimum acceptable thickness or geometry associated with forming an integral or assembled load bearing implant. The predetermined minimum cortical geometry may vary depending on the application. For example, a minimum geometry for use in the cervical spine may be substantially less than a minimum cortical geometry for the lumbar spine. For instance, a predetermined minimum wall thickness or geometry for integral or assembled cortical wedge cervical spine implant, such as may be formed from a fibula, may be 3.0 mm in one embodiment, 2.5 mm in another embodiment, 2.0 mm in yet another embodiment, and 1.8 mm in still another embodiment. On the other hand, a minimum cortical geometry for an integral or assembled lumbar implant may be 4.5 mm in one embodiment, 4.0 mm in another embodiment, and 3.5 mm in another embodiment.

Implants formed from a plurality of bone pieces may have a compressive strength, or load bearing capability, in the range of 50N to 20,000N. For instance, embodiments may have compressive strength greater than 70N, or greater than 800N, or greater than 1000N, or greater than 1200N, or greater than 3000N, or greater than 5000N, or greater than 7000N, or greater than 10,000N, or greater than 12,000N, or greater than 15,000N, or greater than 17,000N. This compressive strength provides load-bearing capability greater than typical cancellous bone and up to that of typical cortical bone.

Bone may be obtained from any suitable bone source including the implant recipient as in an autograft, another source of the same species as in an allograft, or a source of a different species as in a xenograft. Suitable examples of musculoskeletal tissue include humerus, tibia, femur, fibula, patella, ulna, radius, rib, vertebral bodies, etc. The bone pieces may be machined, milled, cut, planed, grated, crushed, splintered and/or otherwise removed and/or formed from the donor bone.

Although embodiments of implants and methods of making implants have been described and illustrated in detail, it is to be understood that the same is intended by way of illustration and example only and is not to be taken by way of limitation. Accordingly,

variations in and modifications to the implants and methods will be apparent to those of ordinary skill in the art, and the following claims are intended to cover all such modifications and equivalents.

What is claimed is:

1. An implant for use in fusing adjacent bony structures, the implant comprising a plurality of elongate bone pieces formed into at least one load bearing layer.
2. The implant of claim 1 wherein the elongate bone pieces are interconnected by at least one interconnection mechanism selected from the group consisting of weaving, pinning, suturing, pressing, incorporating a binding agent, and cross-linking exposed collagen fibers.
3. The implant of claim 1 wherein the elongate bone pieces are interconnected by a biocompatible adhesive.
4. The implant of claim 3 wherein the adhesive comprises at least one adhesive selected from the group consisting of fibrin glue, cyanoacrylate, epoxy, polymethylmethacrylate, and gelatin based adhesives.
5. The implant of claim 1 wherein the elongate bone pieces are interconnected by at least one binding agent selected from the group consisting of settable ceramics, calcium carbonate, calcium phosphate, apatite, hydroxyapatite, and plaster.
6. The implant of claim 1 wherein the elongate bone pieces further comprise exposed collagen and the exposed collagen of adjacent pieces is crosslinked to interconnect the elongate bone pieces.
7. The implant of claim 1 wherein at least some of the elongate bone pieces further comprise holes formed therethrough and a flexible, elongate, biocompatible connector, the connector being threaded through the holes to interconnect the pieces.

8. The implant of claim 7 wherein the connector comprises at least one connector selected from the group consisting of elongate pieces of body tissue and sutures.

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9. The implant of claim 7 wherein the connector comprises at least one material selected from the group consisting of pericardium, demineralized bone, fascia, cartilage, tendon, ligament, skin, collagen, elastin, reticulum, intestinal submucosa, metal, resorbable polymer, and nonresorbable polymer.

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10. The implant of claim 1 wherein the elongate bone pieces are woven together.

11. The implant of claim 10 wherein at least some of the elongate bone pieces are at least partially demineralized to increase their flexibility.

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12. The implant of claim 11 wherein the elongate bone pieces are woven with a portion of the pieces being oriented in a first direction and a portion of the pieces being oriented in a second direction angled relative to the first direction, the pieces lying in the first direction being at least partially demineralized to increase their flexibility.

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13. The implant of claim 12 wherein the elongate bone pieces lying in the second direction comprise fully mineralized bone.

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14. The implant of claim 10 wherein at least some of the elongate bone pieces are individually at least partly demineralized at one or more spaced apart discrete portions such that each individual piece comprises a plurality of mineralized segments separated by relatively more flexible demineralized segments.

15. The implant of claim 1 wherein the individual pieces of bone have less than a predetermined minimum load bearing capacity and the combined pieces form an implant that achieves a predetermined load bearing capacity greater than the predetermined minimum load bearing capacity.

16. The implant of claim 1 wherein the individual pieces of bone have a predetermined geometry outside of a predetermined standard associated with a unitary implant and the combined pieces form an assembled implant that achieves the predetermined geometry.

17. The implant of claim 1 wherein the individual elongate pieces of bone comprise an elongate cortical bone layer running along substantially the entire length of the piece.

18. The implant of claim 17 further comprising a predetermined cortical layer thickness less than a predetermined minimum thickness for an integral bone implant

19. The implant of claim 17 wherein the individual elongate pieces of bone further comprise a cancellous bone layer adjacent to the cortical bone layer along at least a portion of the length of the piece.

20. The implant of claim 1 further comprising a layer axis substantially normal to the layer and a load bearing axis along which load is applied to the implant from the adjacent bony structures, the layer axis being substantially parallel to the load bearing axis.

21. The implant of claim 1 further comprising a layer axis substantially normal to the layer and a load bearing axis along which load is applied to the implant from

the adjacent bony structures, the layer axis being substantially perpendicular to the load bearing axis.

22. The implant of claim 1 wherein each of the plurality of elongate bone pieces has a longitudinal axis and the plurality of elongate bone pieces are arranged in the layer with their longitudinal axes being substantially parallel.

23. The implant of claim 22 further comprising a load bearing axis along which load is applied to the implant from the adjacent bony structures, the longitudinal axes of the plurality of bone pieces being substantially perpendicular to the load bearing axis.

24. The implant of claim 22 further comprising a load bearing axis along which load is applied to the implant from the adjacent bony structures, the longitudinal axes of the plurality of bone pieces being substantially parallel to the load bearing axis.

25. The implant of claim 1 comprising a plurality of layers, each layer comprising a plurality of elongate bone pieces.

26. The implant of claim 25 wherein the plurality of layers comprises a plurality of radial layers formed by rolling a single layer into a substantially cylindrical shape.

27. The implant of claim 26 wherein each layer comprises a plurality of elongate bone pieces woven together, the implant being formed by first weaving the elongate bone pieces to form a single layer and then rolling the single layer into a substantially cylindrical shape.

28. The implant of claim 25 wherein the plurality of layers comprises a single layer folded back on itself at least once to form the plurality of layers.

29. The implant of claim 28 wherein each layer comprises a plurality of elongate bone pieces woven together, the implant being formed by first weaving the elongate bone pieces to form a single layer and then folding the layer back on itself one or more time.

30. The implant of claim 25 wherein the plurality of layers comprises a stack of individual discrete layers.

31. The implant of claim 30 wherein each layer comprises a plurality of elongate bone pieces woven together.

32. The implant of claim 25 further comprising one or more interconnection mechanisms securing the layers together.

33. The implant of claim 32 further comprising at least one interconnection mechanism selected from the group consisting of weaving, pinning, suturing, pressing, incorporating a binding agent, and cross-linking exposed collagen fibers.

34. The implant of claim 32 wherein the layers are interconnected by a biocompatible adhesive binding agent.

35. The implant of claim 34 wherein the adhesive comprises at least one adhesive selected from the group consisting of fibrin glue, cyanoacrylate, epoxy, polymethylmethacrylate, and gelatin based adhesives.

36. The implant of claim 32 wherein the layers are interconnected by at least one binding agent selected from the group consisting of settable ceramics, calcium carbonate, calcium phosphate, apatite, hydroxyapatite, and plaster.

37. The implant of claim 32 wherein the layers further comprise exposed collagen and the exposed collagen of adjacent layers is crosslinked to interconnect the layers.

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38. The implant of claim 32 further comprising an elongate biocompatible connector, the connector being threaded through the layers to interconnect the layers.

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39. The implant of claim 38 wherein the connector comprises at least one connector selected from the group consisting of elongate pieces of body tissue and sutures.

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40. The implant of claim 38 wherein the connector comprises at least one material selected from the group consisting of pericardium, demineralized bone, fascia, cartilage, tendon, ligament, skin, collagen, elastin, reticulum, intestinal submucosa, metal, resorbable polymer, and nonresorbable polymer.

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41. The implant of claim 25 further comprising one or more openings through the implant to facilitate the fusion of the adjacent bony structures.

42. The implant of claim 41 further comprising a bone growth promoting material within the one or more openings.

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43. The implant of claim 42 wherein the bone growth promoting material comprises at least one material selected from the group comprising bone derived growth factors, osteogenic proteins, bone morphogenic proteins, human recombinant bone morphogenic proteins, LIM mineralization proteins, bone paste, bone chips, demineralized bone, hydroxyapatite, hormones, and platelet derived growth factor.

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44. The implant of claim 25 wherein the plurality of layers overlie one another along a layer axis normal to the layers, the implant further comprising a load bearing axis along which load is applied to the implant from the adjacent bony structures, the layer axis being substantially parallel to the load bearing axis.

45. The implant of claim 44 wherein the layers overlie one another radially in a wound spiral construct.

46. The implant of claim 44 wherein the layers comprise a single layer folded back on itself one or more times.

47. The implant of claim 44 wherein the layers comprise a stack of individual discrete layers.

48. The implant of claim 25 wherein the plurality of layers overlie one another along a layer axis substantially normal to the layers, the implant further comprising a load bearing axis along which load is applied to the implant from the adjacent bony structures, the layer axis being substantially perpendicular to the load bearing axis.

49. The implant of claim 48 wherein the layers overlie one another radially in a wound spiral construct.

50. The implant of claim 48 wherein the layers comprise a single layer folded back on itself one or more times.

51. The implant of claim 48 wherein the layers comprise a stack of individual discrete layers.

52. The implant of claim 1 further comprising a fixation device attached to said adjacent bony structures to limit relative motion therebetween.

53. An implant for use in fusing adjacent bony structures, the implant comprising a plurality of layers, each layer comprising a plurality of elongate bone pieces.

54. The implant of claim 53 wherein the layers overlie one another radially in a wound spiral construct.

55. The implant of claim 53 wherein the layers comprise a single layer folded back on itself one or more times.

56. The implant of claim 53 wherein the layers comprise a stack of individual discrete layers.

57. The implant of claim 53 further comprising at least one interconnection mechanism selected from the group consisting of weaving, pinning, suturing, pressing, incorporating a binding agent, and cross-linking exposed collagen fibers.

58. The implant of claim 53 further comprising a fixation device attached to said adjacent bony structures to limit relative motion therebetween.

59. A method for use in fusing adjacent bony structures, the method comprising the steps of:
combining a plurality of layers to form a layered implant, each layer comprising a plurality of elongate bone pieces; and
positioning the implant between adjacent bony structures in load bearing relationship.

60. The method of claim 59 wherein the step of combining further comprises the step of interconnecting the plurality of elongate bone pieces in the individual layers.

5 61. The method of claim 59 wherein the plurality of layers overlie one another along a layer axis substantially normal to the layers, and the step of positioning the implant comprises positioning the implant with the layer axis substantially parallel to a load bearing axis along which load is applied to the implant from the adjacent bony structures.

10 62. The method of claim 59 wherein the plurality of layers overlie one another along a layer axis substantially normal to the layers, and the step of positioning the implant comprises positioning the implant with the layer axis substantially perpendicular to a load bearing axis along which load is applied to the implant
15 from the adjacent bony structures.

63. The method of claim 59 further comprising the step of attaching a fixation device to said adjacent bony structures to limit relative motion therebetween.

20 64. An implant for use in fusing adjacent bony structures, the implant comprising:
a plurality of elongate bone pieces formed into at least one load bearing layer, at least some of the elongate bone pieces further comprising holes formed therethrough; and
25 a flexible, elongate, biocompatible connector, the connector being threaded through the holes to interconnect the pieces.

65. The implant of claim 64 wherein the connector comprises at least one connector selected from the group consisting of elongate pieces of body tissue and
30 sutures.

66. The implant of claim 64 wherein the connector comprises at least one material selected from the group consisting of pericardium, demineralized bone, fascia, cartilage, tendon, ligament, skin, collagen, elastin, reticulum, intestinal submucosa, metal, resorbable polymer, and nonresorbable polymer.

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67. The implant of claim 64 further comprising a fixation device attached to said adjacent bony structures to limit relative motion therebetween.

68. An implant for use in fusing adjacent bony structures, the implant comprising a plurality of elongate bone pieces formed into at least one load bearing layer, the elongate bone pieces being woven together.

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69. The implant of claim 68 wherein at least some of the elongate bone pieces are at least partially demineralized to increase their flexibility.

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70. The implant of claim 69 wherein the elongate bone pieces are woven with a portion of the pieces being oriented in a first direction and a portion of the pieces being oriented in a second direction angled relative to the first direction, the pieces lying in the first direction being at least partially demineralized to increase their flexibility.

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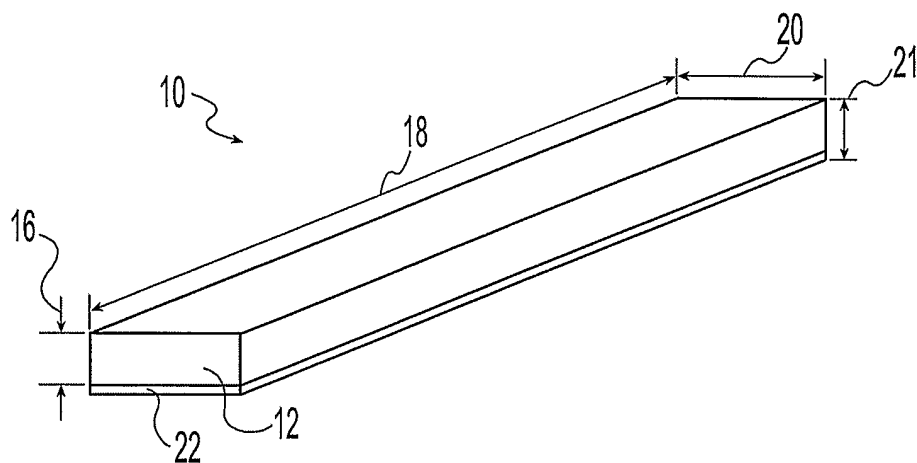
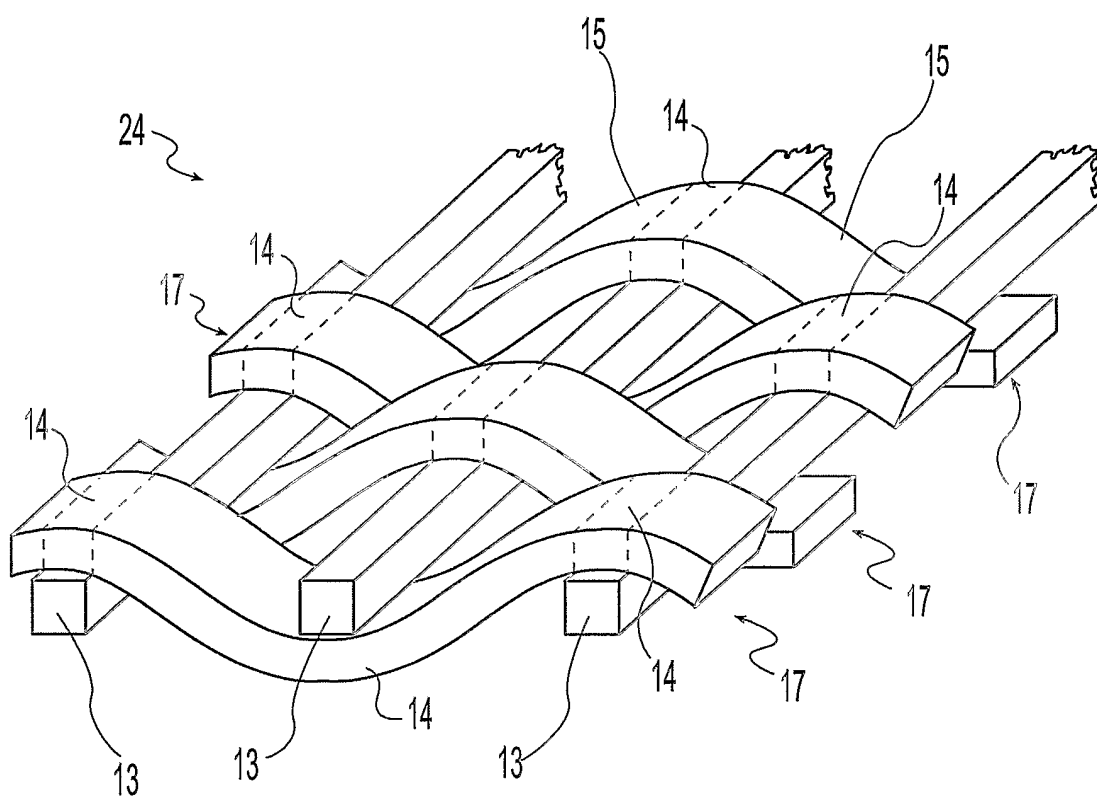
71. The implant of claim 70 wherein the elongate bone pieces lying in the second direction comprise fully mineralized bone.

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72. The implant of claim 68 wherein at least some of the elongate bone pieces segments are individually at least partly demineralized at one or more spaced apart discrete portions such that the piece comprises a plurality of mineralized segments separated by relatively more flexible demineralized.

73. The implant of claim 68 further comprising a fixation device attached to said adjacent bony structures to limit relative motion therebetween.

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*Fig. 1**Fig. 2*

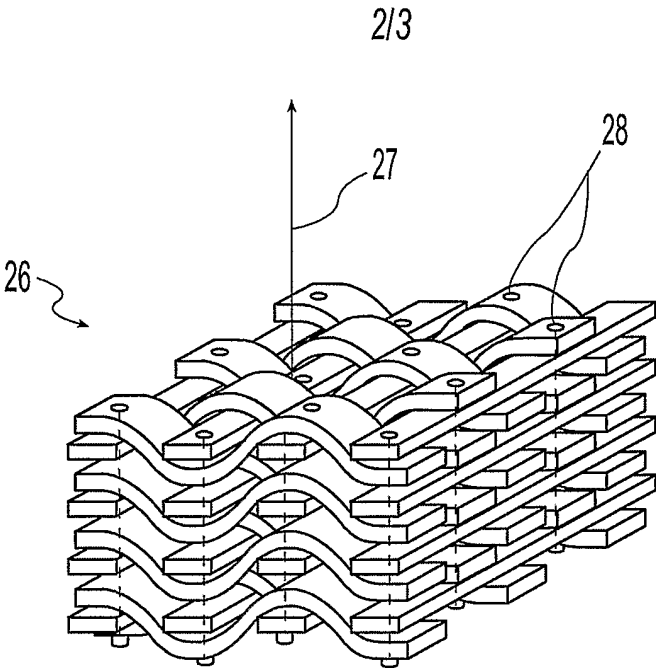


Fig. 3

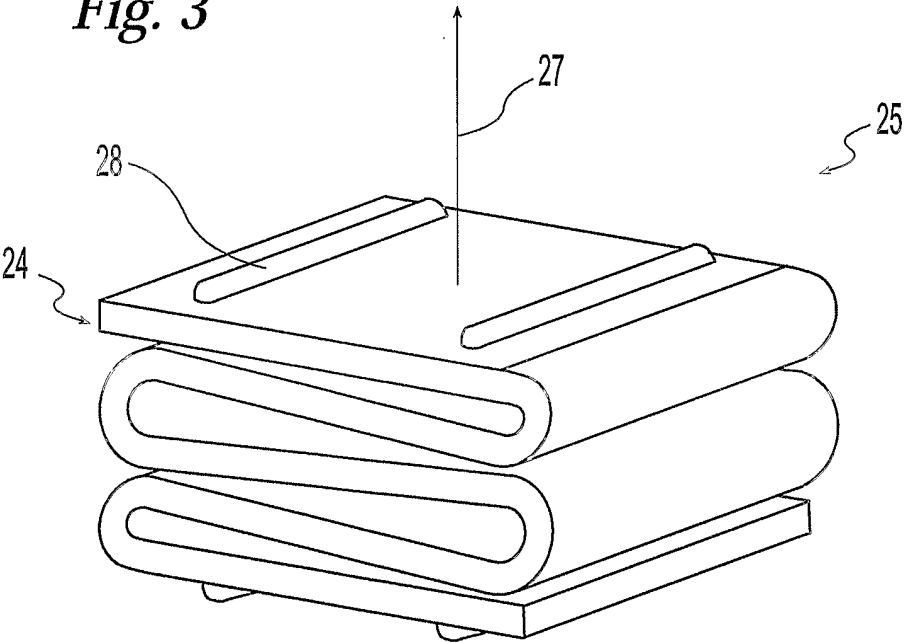


Fig. 4

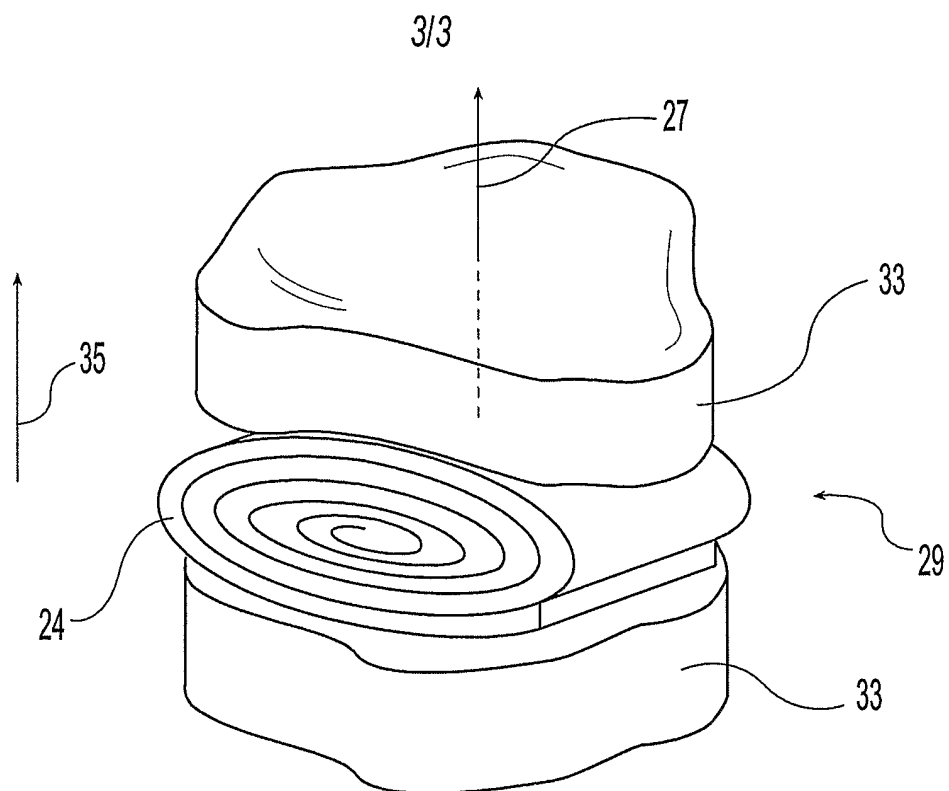


Fig. 5

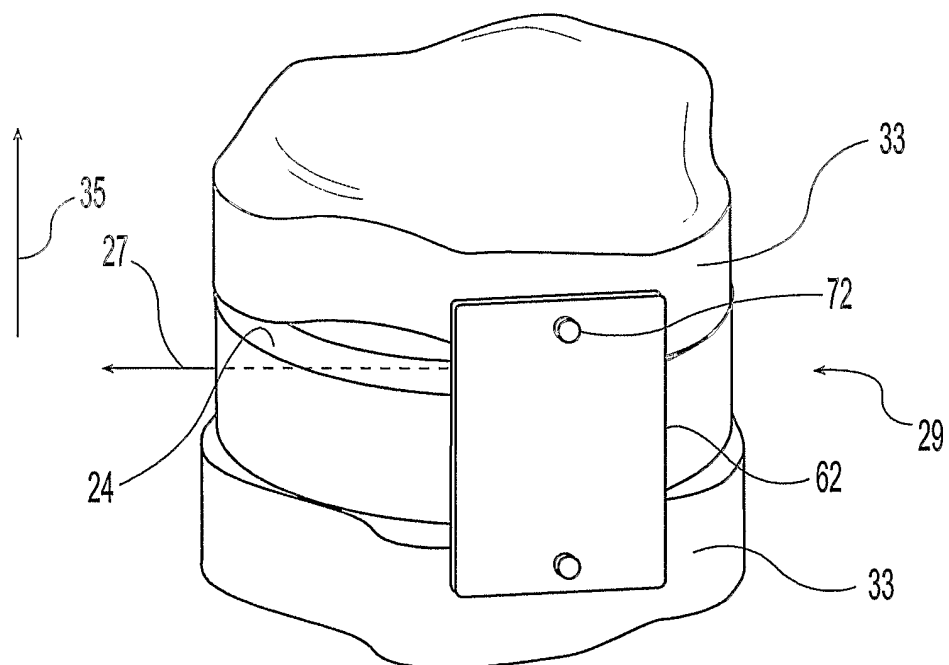


Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/017780

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L27/36 A61F2/28

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 A61L A61F A61B

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/069818 A (SYNTHES USA) 12 September 2002 (2002-09-12) page 1, lines 5-18 page 2, lines 26-31 page 4, lines 24-35 page 5, lines 7-23 page 6, lines 3-10 page 12, lines 5-35 page 14, lines 11-28 page 15, lines 3-6 page 20, lines 29-33 figures 4A, 11 ----- -/-	1-3, 10-31, 44, 45, 53, 54, 59-63, 68-73

☒ Further documents are listed in the continuation of box C.

☒ 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.

G document member of the same patent family

Date of the actual completion of the international search

5 November 2004

Date of mailing of the international search report

15/11/2004

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Authorized officer

Böhm, I

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/017780

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 123 731 A (BOYCE TODD M ET AL) 26 September 2000 (2000-09-26) column 2, lines 7-12,33-43,66,67 column 3, lines 1-14 column 4, lines 2-5,17-50 column 5, lines 39-53 column 6, lines 28-65 column 7, lines 1-5,63-67 claims	1-3,5,6, 15-17, 19-22
A	US 2002/091447 A1 (ANNUNZIATO STEVEN ET AL) 11 July 2002 (2002-07-11) paragraphs '0001! - '0006!, '0027!, '0070!, '0071!	1,53,59, 68
A	DE 195 04 955 A (MERCK PATENT GMBH) 22 August 1996 (1996-08-22) column 1, lines 25-32 column 2, lines 29-50	1
A	EP 0 141 004 A (OSCOBAL AG) 15 May 1985 (1985-05-15) abstract	1
A	US 5 067 962 A (CAMPBELL TODD D ET AL) 26 November 1991 (1991-11-26) column 2, lines 13-24 claims	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/017780

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:
Although claims 59–63 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the bone implant.
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:

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

International Application No

PCT/US2004/017780

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02069818	A	12-09-2002	US 2002120346 A1	29-08-2002
			US 2002120338 A1	29-08-2002
			US 2002120347 A1	29-08-2002
			US 2003045935 A1	06-03-2003
			CA 2439278 A1	12-09-2002
			EP 1424948 A2	09-06-2004
			WO 02069818 A2	12-09-2002
			WO 03020143 A1	13-03-2003
			US 2004107003 A1	03-06-2004
			US 2004210222 A1	21-10-2004
			US 2002120335 A1	29-08-2002
			CA 2459032 A1	13-03-2003
			EP 1427342 A1	16-06-2004
			WO 03020142 A1	13-03-2003
US 6123731	A	26-09-2000	AU 2588699 A	23-08-1999
			BR 9907670 A	18-12-2001
			CA 2320481 A1	12-08-1999
			CA 2446400 A1	12-08-1999
			CN 1290182 T	04-04-2001
			EP 1053032 A1	22-11-2000
			HU 0102991 A2	28-11-2001
			JP 2002502637 T	29-01-2002
			NO 20003961 A	03-10-2000
			NZ 506577 A	31-05-2002
			PL 342266 A1	04-06-2001
			WO 9939757 A1	12-08-1999
			US 6294041 B1	25-09-2001
US 2002091447	A1	11-07-2002	AU 2583102 A	15-05-2002
			CA 2423603 A1	10-05-2002
			EP 1330215 A2	30-07-2003
			WO 0236049 A2	10-05-2002
DE 19504955	A	22-08-1996	DE 19504955 A1	22-08-1996
			AT 205731 T	15-10-2001
			CN 1137928 A	18-12-1996
			CZ 9600430 A3	11-09-1996
			DE 59607698 D1	25-10-2001
			EP 0727231 A2	21-08-1996
			ES 2161926 T3	16-12-2001
			JP 8238264 A	17-09-1996
			PL 312811 A1	19-08-1996
			US 5725813 A	10-03-1998
EP 0141004	A	15-05-1985	EP 0141004 A1	15-05-1985
			AT 31616 T	15-01-1988
			CA 1242653 A1	04-10-1988
			DE 3375073 D1	11-02-1988
			ES 8605673 A1	16-09-1986
			JP 1839098 C	25-04-1994
			JP 5053506 B	10-08-1993
			JP 60168462 A	31-08-1985
			US 4654464 A	31-03-1987
US 5067962	A	26-11-1991	NONE	