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Endobutton continuous loop for bone-tendon-bone

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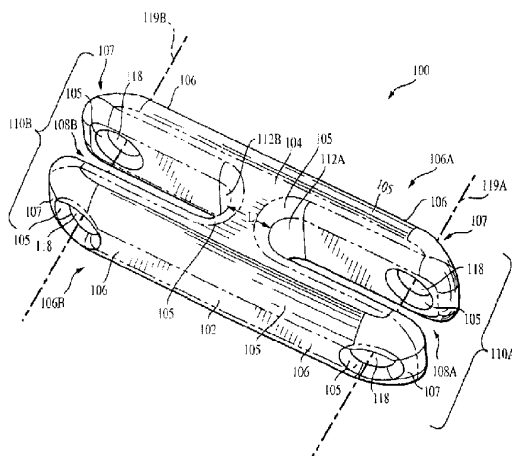
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[Continued on next page]

(54) Title: ENDOBUTTON CONTINUOUS LOOP FOR BONE-TENDON-BONE



(57) Abstract: A method of securing a tissue graft within a bone passage includes providing a graft fixation member comprising a closed-loop having a pair of opposing loop sections and capturing a first loop section of the closed-loop within the fixation member. An opposing second loop section of the closed loop is passed through an opening in the tissue graft, and the second loop section of the closed loop is secured to the fixation member.



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ENDOBUTTON CONTINUOUS LOOP FOR BONE-TENDON-BONE

TECHNICAL FIELD

This invention relates to anchoring tissue grafts.

BACKGROUND

5 An increasing number of surgical techniques are now performed arthroscopically. One type of arthroscopic procedure reconstructs the anterior cruciate ligament (ACL) in the knee. Several ACL reconstruction techniques are described in U.S. Pat. No. 5,139,520 (issued August 18, 1992) ("the '520 patent") and
10 incorporated by reference.

When the ACL has ruptured and is nonrepairable, it is usually replaced in the knee using a substitute graft harvested from the patient or from a donor. The substitute ACL graft may be a portion of a patellar tendon having so called "bone blocks" at each end. A method and an apparatus for harvesting such a patellar tendon
15 graft is described in U.S. Pat. No. 5,733,289 (issued March 31, 1998) ("the '289 patent") and incorporated by reference. Alternatively, an artificial graft formed from synthetic materials or from a combination of artificial and natural materials may be used and is sometimes referred to as a ligament augmentation device (LAD). The term "tissue graft" is used herein to encompass all of these tissue replacement items.

20 In general, the replacement tissue graft is implanted by securing one end of the tissue graft in a socket formed in a passage formed within the femur (i.e., femoral channel) and passing the other end of the graft through a passage formed in the tibia (i.e., tibial channel). Then, the graft is secured to the tibia adjacent to the tibial channel. Generally, sutures are used to affix each end of the tissue graft to a fastener
25 (e.g., an interference screw or a post), which is then secured to the bone. Descriptions of these fasteners and methods of forming the passages through the tibia and femur are described in greater detail in the '520 patent.

Another approach for affixing a tissue graft is described in U.S. Pat. No. 5,306,301, (issued April 26, 1994) ("the '301 patent") and incorporated by reference.
30 The '301 patent discloses using a fixation button to secure a tissue graft at the femoral

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cortex. The fixation button has an elongated shape and at least one pair of openings through which a suture may be passed and then tied off.

In this approach, the femoral channel has a portion having a first diameter sized to accommodate a bone block and a second portion having a smaller diameter through which the bone block cannot pass. By measuring the total length of the femoral channel and the length of the larger portion, the surgeon determines a "suture span" for attaching the fixation button to the tissue graft.

The surgeon forms an opening in the bone block to be positioned in the femoral channel and threads an end of suture through it. The surgeon then ties the suture to the fixation button, providing the suture span between the button and the bone block. The fixation button and the tissue graft are then passed through the tibial and femoral channels until the graft is properly seated within the socket portion of the femoral passage and the fixation button is firmly seated against the femoral cortex. The tissue graft is then tensioned and anchored at its opposite end using a fixation screw secured within the tibia.

Still another approach for affixing a tissue graft is described in U.S. Pat. No. 5,769,894, (issued June 23, 1998) ("the '894 patent"). The '894 patent describes a graft fixation member configured to allow the length of the suture between the fixation member and the graft to be adjusted and to maintain the adjusted length when the suture is secured to the graft fixation member.

An alternative to tying a suture to a fixation button is disclosed in PCT Application WO 99/47079 (published September 23, 1999) ("the '079 application"). The '079 application discloses an apparatus and method for attaching a continuous loop of suture to a fixation button. Using a series of rollers, the continuous loop is formed from a strand of suture repeatedly coiling the suture through openings in a fixation button. In other examples, a continuous loop of suture may be formed without a fixation member. Continuous loops, both with and without fixation buttons attached, are available from Xiros Limited, Leeds, England, in several sizes. A surgeon selects the closest matching size for a given ACL reconstruction procedure. In other examples, a continuous loop of suture may be formed without a fixation member.

U.S. 6,086,591 describes an anchor for fixing soft tissue within a bone tunnel that comprises a body configured to receive a soft tissue graft and means for engaging the

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cortical bone surface that can consist of two arms with hooks at the end. In use the device sits substantially within the bone tunnel and the hooks engage the cortical bone surface.

SUMMARY

5 In one aspect, the invention features a device for securing a tissue graft within a passage within a bone. The device includes a member having an intermediate portion and an end portion. The end portion has a pair of arms extending from the intermediate portion and defining an open channel at the end portion. Each arm has an opening extending from a first side of the arm to a second side of the arm, the opening being sized to accommodate
10 a strand of suture. The arms are configured to receive at least one bight that has been formed in a closed-loop suture.

One or more of the following features may also be included. One or more openings pass through the intermediate portion of the member. The openings are cylindrical. The opening in each arm is cylindrical. The openings in each pair of arms occupy different
15 positions on a common axis. The axis is transverse to the member. The pair of arms define a cylindrical portion of the channel having a diameter equal to the width of the channel. Each pair of arms define a cylindrical portion of the channel having a diameter greater than the width of the channel. The arms are shaped to pass through bone passage. The member is sized to pass through a bone passage. The member comprises a bio-compatible material.
20 The member comprises titanium. The member comprises a bio-absorbable material.

Embodiments may have one or more of the following advantages. The closed loop may be manufactured and purchased separate from the fixation member. This allows the surgeon the flexibility to choose the correct size closed loop from several sizes available in the operating room without a fixation member on each size loop. In turn, the patient
25 benefits from the reliability of the closed loop without the added cost of multiple fixation members. The closed loop is positively captured within the fixation member during implantation. The closed loop provides superior strength over single loops of tied suture or tape and does not extend a patient's time under anesthesia while a surgeon forms multiple loops of suture or tape by hand. The closed loop may be pre-stressed during the
30 manufacturing process to reduce its elasticity and increase its strength without accommodation for a fixation member.

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The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

5 **DESCRIPTION OF DRAWINGS**

FIG. 1 shows an example of a tissue graft being implanted during an ACL reconstruction procedure using a closed-loop suture and a graft fixation member.

FIG. 2 is an example of the graft fixation member.

10 FIG. 3 shows an exploded partial view of how closed-loop suture could be inserted into tissue graft.

FIG. 4 is an example of a graft-loop assembly before being attached to the graft fixation member.

FIG. 5 shows an exploded partial view of a graft-loop assembly partially captured by the graft fixation member.

15 FIG. 6 shows an exploded partial view of a graft-loop assembly fully captured by the graft fixation member.

FIG. 7 shows the graft fixation member positioned for implantation.

FIG. 8 shows the tissue graft implanted in a knee and secured at one end by the graft fixation member.

20 FIG. 9 shows an alternative example of a graft fixation member.

FIG. 10 shows a second alternative example of a graft fixation member.

FIG. 11 shows a third alternative example of a graft fixation member.

FIG. 12 shows a fourth alternative example of a graft fixation member and a method for capturing first and second portions of a closed-loop suture.

25 FIG. 13 shows a fifth alternative example of a graft fixation member and a method of attaching it to a tissue graft using a closed-loop suture.

DETAILED DESCRIPTION

30 Referring to FIG. 1, a tissue graft 20 is shown being implanted within a knee 10 during an anterior cruciate ligament (ACL) repair and reconstruction procedure. In one example, tissue graft 20 has bone blocks on both ends sized and shaped to fit within

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femoral and tibial channels, respectively. More specifically, one end of tissue graft 20 includes a bone block 22 shaped and sized in substantial conformity with a femoral channel 14 of femur 12 while the other end of tissue graft 20 includes a bone block 24 shaped and sized in substantial conformity with tibial channel 16 of tibia 13. In one

5 example, a closed-loop suture 30 is inserted into bone block 24 and captured within graft fixation member 100. Closed-loop suture 30 could be, but is not limited to, a continuous loop made from polyester, a strand of suture tied in a loop, or a piece of polyester closure tape tied in a loop. As will be described below, graft fixation member 100 is configured to facilitate positioning and securing the tissue graft 20.

10 Sutures 42 and 44 extend through fixation member 100 and are removably attached to passing pin 32 which is used to draw the sutures 42, 44 through the tibial channel 16, femoral channel 14, and passing channel 18. As described below, sutures 42, 44 are used to pull graft fixation member 100 through passing channel 18 and position tissue graft 20 within femoral channel 14 and tibial channel 16.

15 In one example, shown in FIG. 2, in one example graft fixation member 100 has an elongated body 102 formed of a biocompatible material (e.g., titanium or acetal) or a bioabsorbable material (e.g., polylactic acid, polyglycolic acid) with a length of about 1.14 cm, a width of about 0.41 cm, and a thickness of about 0.25 cm. Body 102 has a width allowing fixation member 100 to be pulled through tibial channel 16, femoral channel 14, and passing channel 18.

20 Body 102 includes an intermediate portion 104 having a length (L), which defines the distance between a pair of channels 108A, 108B at opposing ends of body 102, described below. In one example, length (L) of intermediate portion 104 is about 0.13 cm. Intermediate portion 104 supports closed-loop suture 30 during implantation and bears the tension of closed-loop suture 30 after tissue graft 20 has been implanted.

25 Pairs of arms 106A and 106B extend from intermediate portion 104. Arms 106 have rounded edges 105 along their length and rounded ends 107. In one example, rounded edges 105 have a radius of about 0.04 cm and rounded ends 107 have a radius of about 0.17 cm. Rounded edges 105 allow fixation member 100 to be more easily pulled through tibial channel 16, femoral channel 14, and passing channel 18.

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Channels 108A and 108B are formed by pairs of arms 106A and 106B, respectively. Channels 108A and 108B are open at end portions 110A and 110B of elongated body 102 and have cylindrical closed portions 112A and 112B formed by intermediate portion 104 and pairs of arms 106A and 106B, respectively. For example, 5 cylindrical closed portions 112A and 112B could have a diameter of about 0.13 cm and channels 108 and 108B could have a corresponding width of about 0.13 cm. Open end portions 110A and 110B of channels 108A and 108B allow closed-loop suture 30 to pass into channels 108A and 108B as described below.

10 In this particular embodiment, each arm 106 has an opening 118 located toward the end of and extending through arm 106. Openings 118 are cylindrical and have a diameter of about 0.1 cm. Openings 118 in pair of arms 106A are disposed on a common axis 119A, which is transverse to the length of elongated member 102. Openings 118 in pair of arms 106B are disposed on a common axis 119B, which is also transverse to the length of elongated member 102. In other examples, openings 118 could be skewed in relation to 15 each other or disposed at different positions along arms 106.

Referring to FIGS. 3-7, an example of a procedure for attaching graft fixation member 100 to tissue graft 20 follows. Referring to FIGS. 3 and 4, opening 28 is formed, for example, by drilling through bone block 22. A surgeon chooses a closed-loop suture 30 from closed loops of several lengths to best position the tissue graft 20 within femoral channel 14 and 20 tibial channel 16 (FIG. 1). The surgeon inserts suture grabber 52 into opening 28 until the end 54 of device 52 extends from bone block 22 and positions closed-loop suture 30 next to bone block 22. The surgeon grabs closed-loop suture 30 with suture grabber 52 and pulls both back through opening 28 in

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direction 62, forming a first bight 32 and a second bight 34 of about the same size on either side of bone block 22. Alternatively, a length of suture (not shown) could be used to pull closed-loop suture 30 into opening 28. One end of the suture could be passed through opening 28, through closed-loop suture 30, and back through opening 28. Closed-loop 30 may then be positioned in opening 28 by pulling both ends of the strand of suture.

Referring to FIGS. 5 and 6, bight 32 is positioned around graft fixation member 100 and into channels 108 so that the continuous loop of suture 30 is wrapped around intermediate portion 104 of graft fixation member 100. Bight 34 of continuous loop of suture 30 is then similarly positioned around graft fixation member 100 and into channels 108 so that the continuous loop of suture 30 wraps around intermediate member 104 of graft fixation member 100. Both bights 32, 34 are wrapped around intermediate member 104 so that the closed-loop suture 30 does not interfere with the positioning of strands of suture 42 into openings 118.

Lengths of suture 42 and 44, shown in FIG. 6, are chosen to capture closed-loop suture 30 within graft fixation member 100 during the ACL reconstruction described below. In one example, lengths of polyester closure tape could be used instead of sutures 42, 44. End 43 of suture 42 is passed through opening 118 (FIG. 2) in either arm 106 of pair of arms 106A and over closed-loop suture 30. End 43 is then passed through opening 118 in the corresponding arm 106 of pair of arms 106A thereby capturing closed-loop suture 30 within graft fixation member 100. It is important that suture 42 passes over, and not under, closed-loop suture 30. Allowing suture 42 to pass under closed-loop 30 would not capture closed-loop 30 within graft fixation member 100. Similarly, end 45 of suture 44 is passed through opening 118 in either arm 106 of a pair of arms 106B and over closed-loop suture 30. End 45 is then passed through opening 118 in the corresponding arm 106 of pair of arms 106B thereby further capturing closed-loop suture 30 within graft fixation member 100. It is important that suture 44 passes over and not under closed-loop suture 30. As was the case with suture 42, passing suture 44 under closed-loop 30 does not capture closed-loop 30 within graft fixation member 100. In this manner, closed-loop suture 30 is captured twice within fixation member 100.

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Referring to FIG. 7, pulling to sutures 42 and 44 removes slack from closed loop suture 30 and positions graft fixation member 100 to pass through tibial channel 16, femoral channel 14, and passing channel 18 (FIG. 2).

5 An example of a procedure for placing graft fixation member 100 in the position shown in FIG. 8 follows with reference to FIG. 1. Drilling procedures are performed to provide the appropriately sized tibial channel 16 extending through tibia 13 and femoral passage 14 in the manner described in the '301 patent. Sutures 42 and 44 are removably attached to passing pin 50. Passing pin 50 (FIG. 1) is then inserted through an incision below the knee and advanced through tibial channel 16, femoral channel 14, passing
10 channel 18, the quadriceps tissue, and skin 11 of the thigh. Ends of sutures 42 and 44 are withdrawn beyond the skin 11 using passing pin 50.

The surgeon then pulls graft fixation member 100 by pulling suture 42 through tibial channel 16, femoral channel 14, and passing channel 18 to position graft fixation member 100. It is important that the surgeon keep closed-loop suture 30 captured within
15 channel 108B by taking up any slack in suture 44 while advancing graft fixation member 100 through passing channel 18 with suture 42. However, the surgeon must be careful not to apply too much tension on suture 44 in relation to the tension on suture 42 or graft fixation member 100 will wedge within tibial channel 16, femoral channel 14, or passing channel 18. Once fixation member 100 has been pulled through passing channel 18, the
20 surgeon positions fixation member 100 transversely to passing channel 18 and across opening 19. Fixation member 100 is secured against femur 12 by attaching tissue graft 20 to tibia 13 and tensioning tissue graft 20 and closed-loop suture 30 according to methods described in the '301 patent.

Other embodiments are within the scope of the claims.

25 For example, referring to FIG. 9, cylindrical portions 112A and 112B of graft fixation member 100 may have a diameter that is larger than the width of channels 108A and 108B, respectively. In one example, portions 112A, 112B have a diameter of about 0.2 cm and channels 108A, 108B have a width of about 0.13 cm. As the diameter of portions 112A and 112B increases, graft fixation member 100 can accommodate a thicker closed-
30 loop suture (i.e., having an increased number of windings). The width of channels 108A

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and 108B do not constrain the use of thicker closed-loop sutures because a closed-loop suture may be flattened to pass through channels 108A and 108B.

Referring to FIGS. 10 and 11, intermediate portion 152 of fixation member 150 has a length (L) and defines openings 154, 156 extending through intermediate portion 152. In the example shown in FIG. 10, intermediate portion has a length of about 0.68 cm and openings 152, 154 are about 0.2 cm in diameter. In the example shown in FIG. 11, intermediate portion has a length of about 0.6 cm and openings 152, 154 are about 0.15 cm in diameter. A closed-loop suture 30 may be attached to fixation member 150 using the method described in the '079 application. Alternatively a first and second end of a length of suture or closure tape may be threaded through openings 154, 156, respectively, and tied together. Increasing length L adds material to intermediate portion 152 and increases the strength of graft fixation member 150.

Referring to FIG. 12, fixation member 200 has only one pair of arms 206 extending from intermediate portion 204 and forming a single channel 208 at end 210. Arms 206 include cylindrical openings for capturing closed-loop suture 30 and positioning fixation member 200. End 212 is closed and rounded to facilitate passing fixation member 200 through bone passages during the positioning and attachment of tissue graft 20. End 212 may include opening 222 through which a strand of suture may be threaded to improve a surgeon's ability to position fixation member 200 during an ACL reconstruction procedure.

Closed-loop suture 30 is captured in fixation member 200 by positioning arms 206 through bights 32, 34 and threading suture 42 (not shown) through a first opening 218, over bights 32, 34, and through the second opening 218. In one example, bight 32 is positioned on a first arm 206 and bight 34 is positioned on a second arm 206. In another example, bights 32, 34 could be positioned on the same arm.

Referring to FIG. 13, fixation member 300 includes openings 304, 308 in intermediate portion 302 and a pair of arms 306 with an opening 318 through each arm. Closed-loop suture 30 is formed in openings 304, 308 according to the method described in the '079 application. Alternatively, a piece of suture or closure tape could be tied into a loop passing through openings 304, 308 as described above. After forming bight 32 by passing closed-loop suture 30 into opening 28 in bone block 22, closed-loop suture 30 is

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captured by fixation member 300 by positioning either arm 306 through bight 32 and threading a strand of suture (not shown) through openings 318, as described above.

Other embodiments include an alternative approach for securing a tissue graft within a bone passage using fixation member 100. Specifically, the fixation member 100 and tissue graft 20 could be pulled first through a femoral channel and then through a tibial channel.

Although the tissue graft described above has at least one bone block, other types of grafts may be attached to graft fixation member including ligament augmentation devices (LAD) formed of artificial ligament material to which the tissue is sutured.

In general, graft fixation member 100 can be used to secure any suitable kinds of grafts, such as allografts, autografts, and xenografts and can be used in surgical soft tissue reconstruction procedures other than those related to ACL reconstruction.

Accordingly, other embodiments are within the scope of the following claims.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

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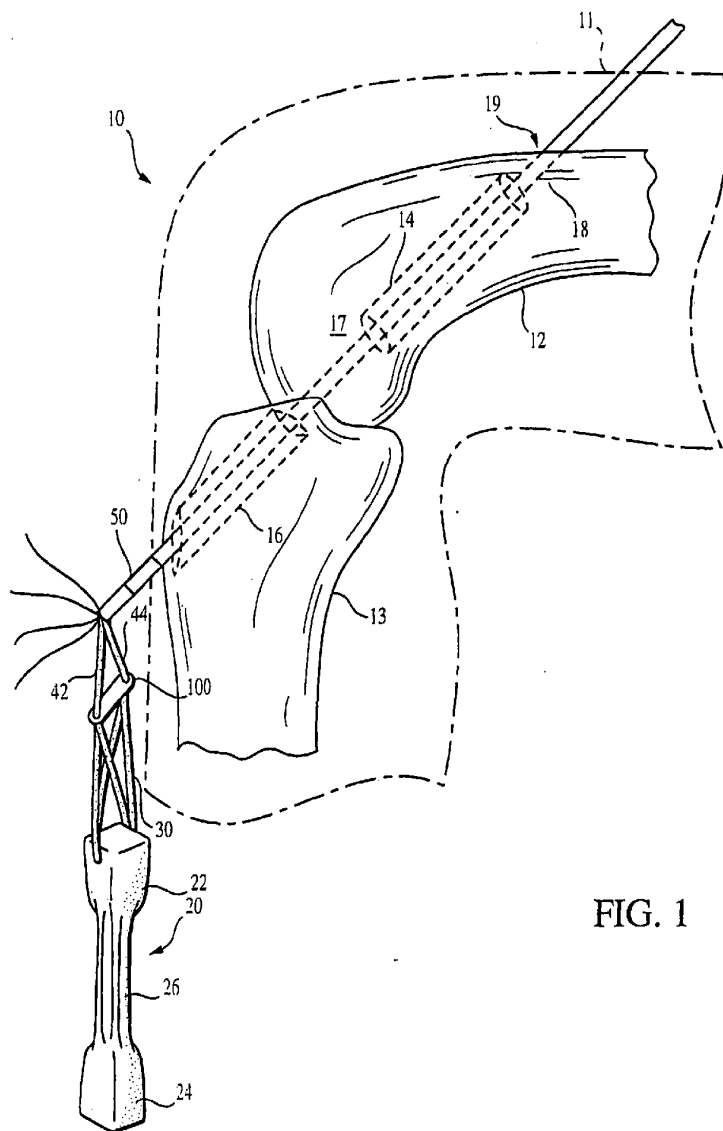
THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for securing a tissue graft within a passage within a bone comprising: a member comprising an intermediate portion and an end portion; said end portion
5 comprising a pair of arms extending from the intermediate portion and defining an open channel at said end portion; each arm comprising an opening extending from a first side of the arm to a second side of the arm, the opening being sized to accommodate a strand of suture; and wherein the arms are configured to receive at least one bight that has been formed on a closed-loop suture.
10
2. The device of claim 1 wherein one or more openings pass through the intermediate portion of the member.
3. The device of claim 2 wherein the openings are cylindrical.
15
4. The device of any preceding claim further comprising a second pair of arms, each arm comprising an opening extending from a first side of the arm to a second side of the arm, the opening being sized to accommodate a strand of suture.
- 20 5. The device of any preceding claim wherein the opening in each arm is cylindrical.
6. The device of any preceding claim wherein the openings in a pair of arms occupy different positions on a common axis.
- 25 7. The device of claim 6 wherein the axis is transverse to the member.
8. The device of claims 1-7 wherein a pair of arms define a cylindrical portion of the channel having a diameter equal to the width of the channel.
- 30 9. The device of claims 1-7 wherein a pair of arms define a cylindrical portion of the channel having a diameter greater than the width of the channel.

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10. The device of any preceding claim wherein the arms are shaped to pass through bone passage.
- 5 11. The device of any preceding claim wherein the member is sized to pass through a bone passage.
12. The device of any preceding claim wherein the member comprises a bio-compatible material.
- 10 13. The device of any preceding claim wherein the member comprises titanium.
14. The device of claims 1 to 12 wherein the member comprises a bio-absorbable material.
- 15 15. A device for securing a tissue graft, substantially as described with reference to the drawings and/or Examples.



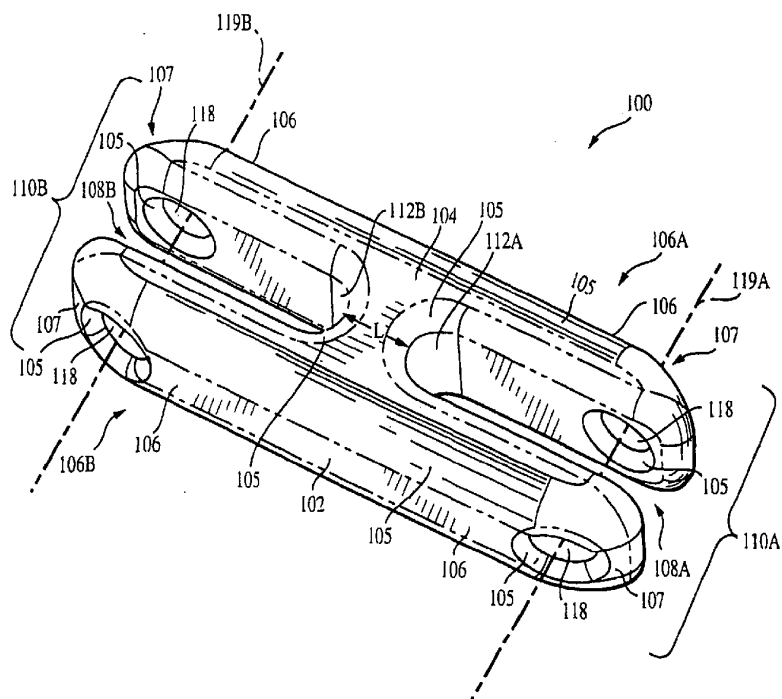
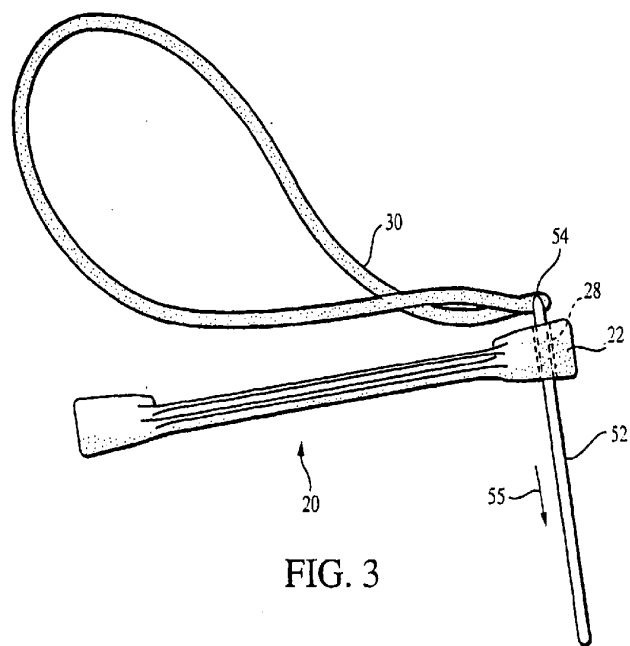


FIG. 2



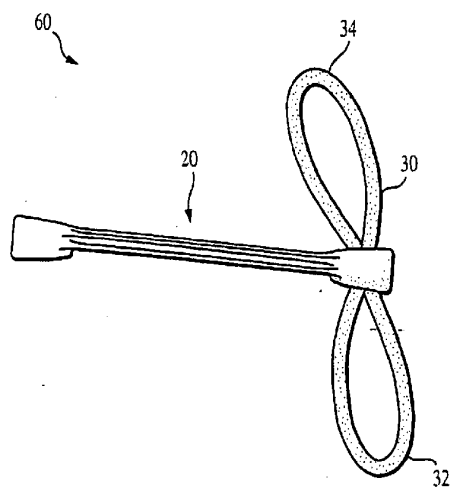


FIG. 4

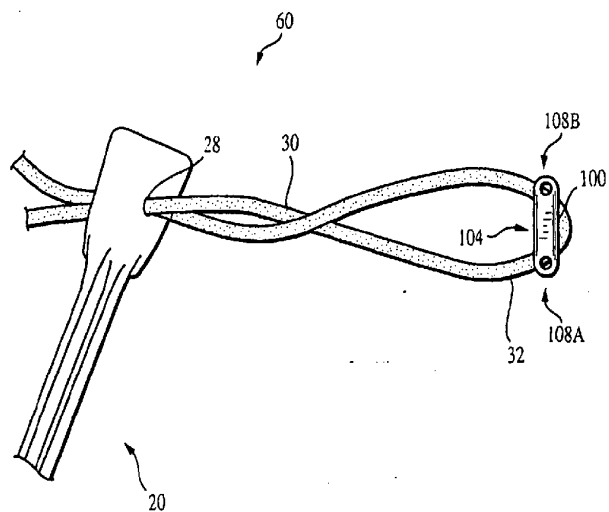


FIG. 5

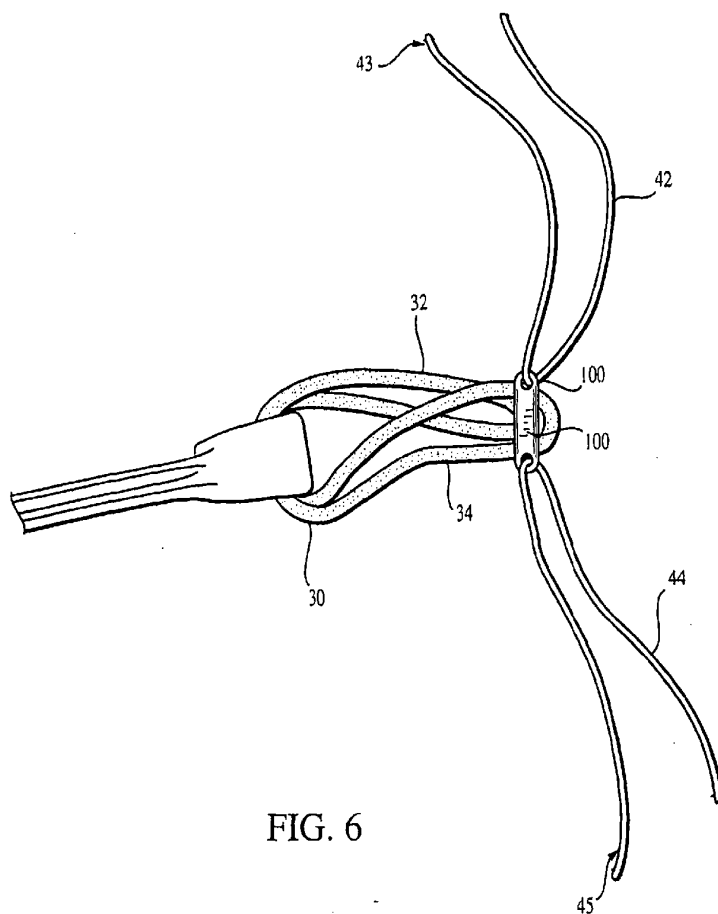


FIG. 6

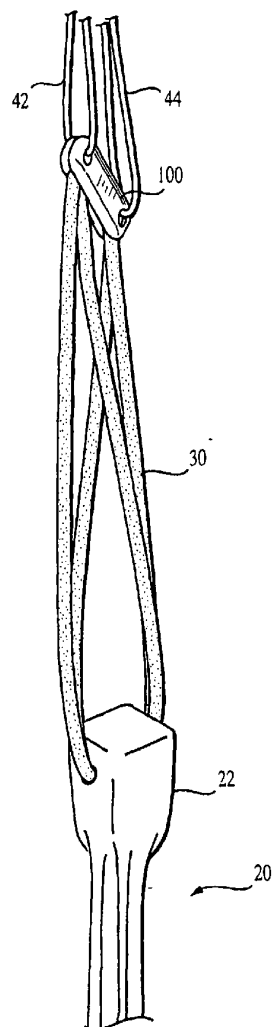


FIG. 7

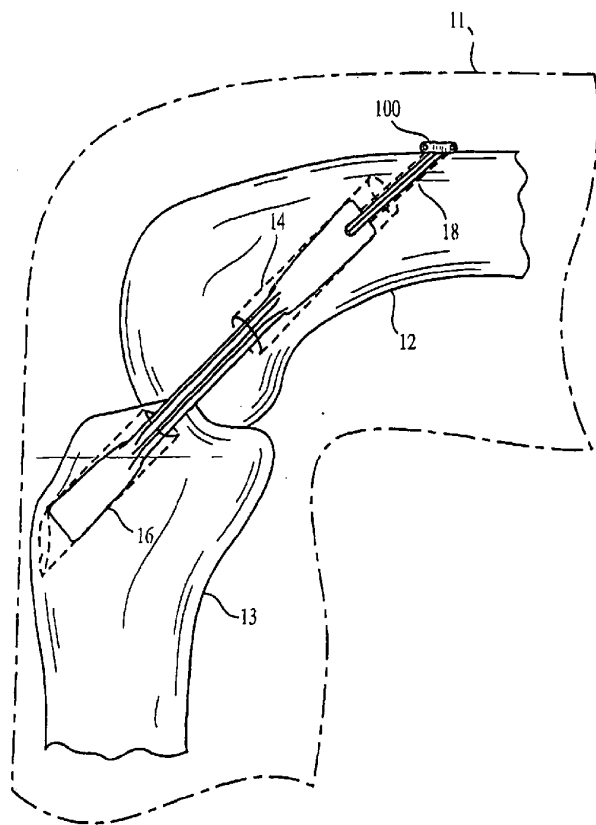


FIG. 8

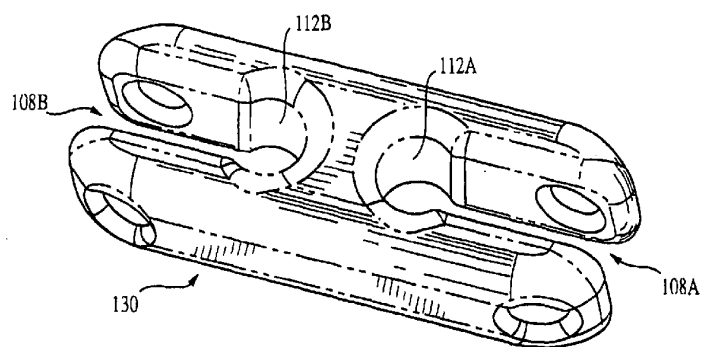


FIG. 9

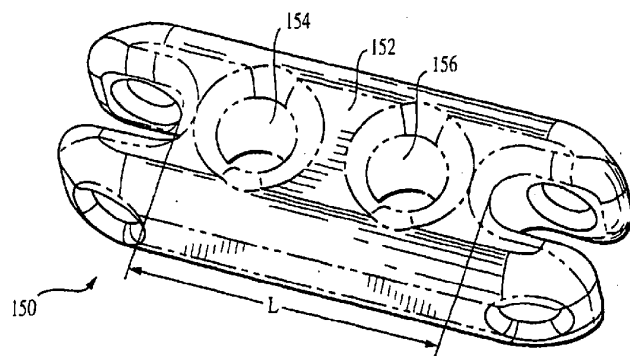


FIG. 10

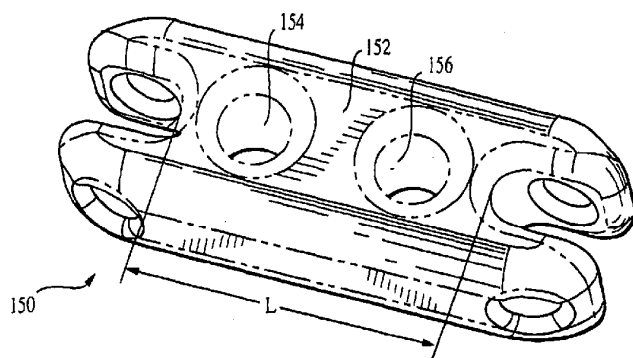


FIG. 11

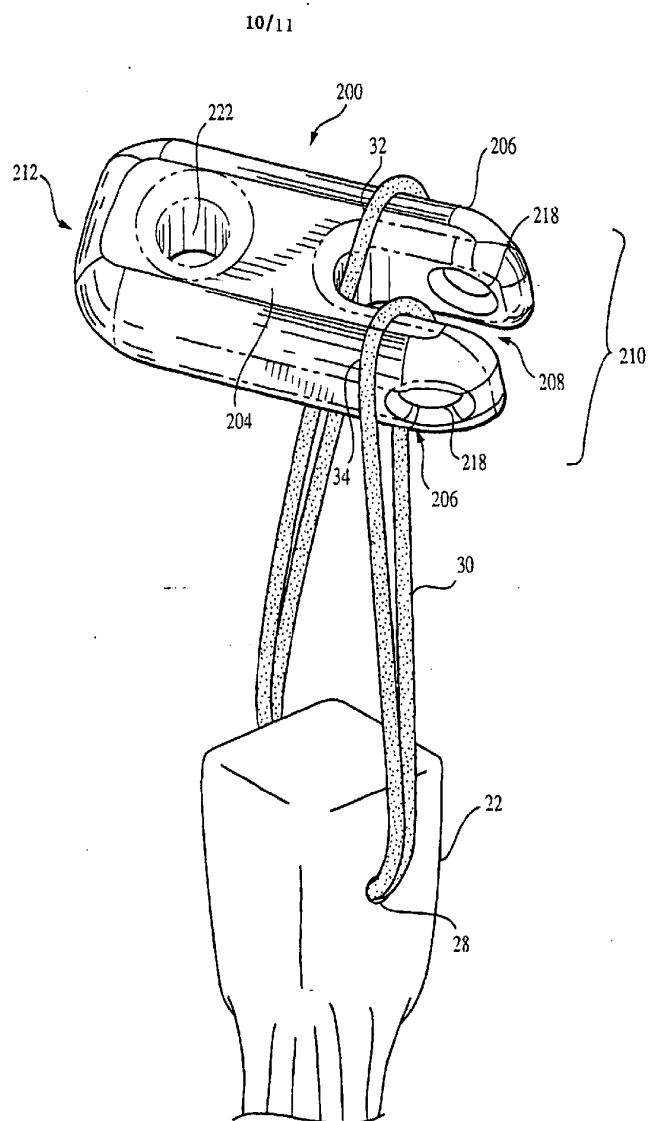


FIG. 12

