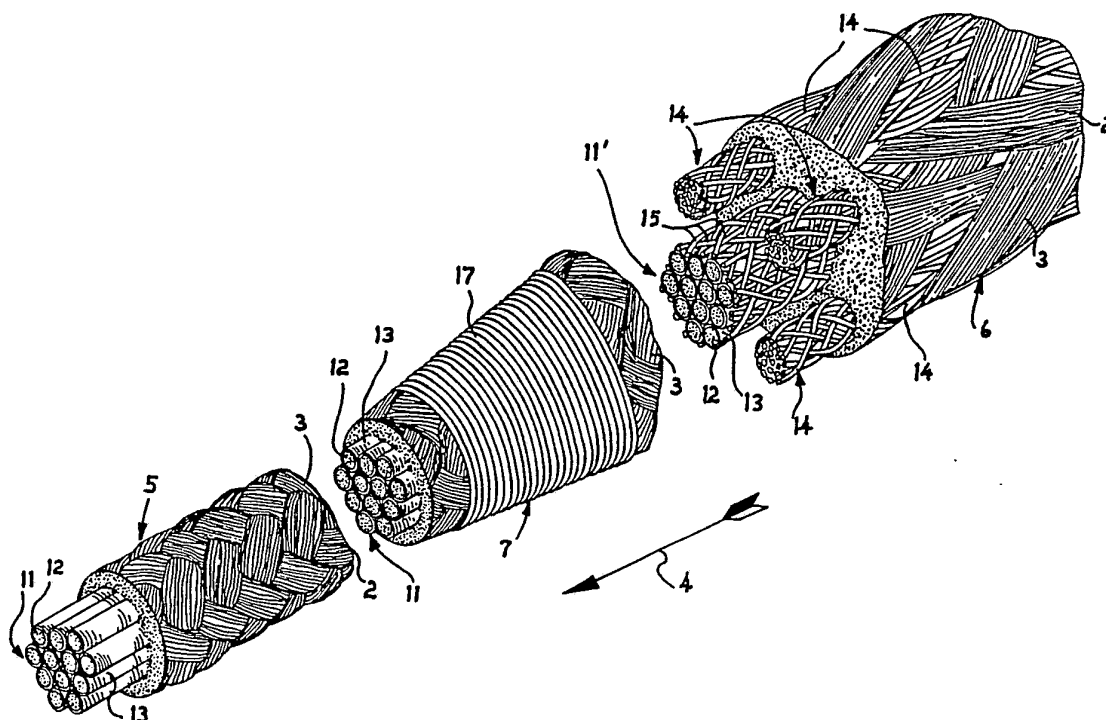




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(54) Title: SOFT TISSUE PROSTHESIS**(57) Abstract**

A soft tissue prosthesis comprising a tubular braid (6) having regions of stiffness and elasticity provided by stiff and elastomeric components (12) disposed within a channel enclosed by the tube and/or within the braid (6), and means defining a transition region (7) for minimizing relative motion among the braid components, the stiff components and the elastomeric components.

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TITLE

Soft Tissue Prosthesis

5 BACKGROUND OF THE INVENTION

 This invention relates to a soft tissue
prosthesis, and specifically to a prosthesis for use
in place of a natural ligament, such as an anterior
10 cruciate ligament.

 Soft tissue structures such as ligaments,
tendons, and the like are prevalent in vertebrate
anatomy. These soft tissue structures are inherently
susceptible to damage resulting from excessive force
15 or disease. Ligaments, in particular, have attracted
a great deal of medical attention. Ligaments are
frequently implicated in knee problems. A
particularly problematic ligament is the anterior
cruciate ligament (ACL), one of the ligaments which
20 connects the femur and tibia across the knee.

 In some situations, damaged ligaments (or
other soft tissue structures) may be repaired
surgically with minimal after-effects. In other
situations, however, damaged ligaments must be
25 replaced with a prosthetic ligament. A suitable
prosthetic ligament should be compliant at low strains
to permit movement of the interconnected bones, stiff
at high strains to prevent excessive movement, and
suitably strong to withstand breakage from the forces
30 generated during all such movement. Moreover, a
suitable prosthetic ligament should be capable of long
term attachment to the bones and should be resistant
to fraying in areas subject to abrasion. A suitable
prosthetic ligament should possess a unique
35 combination of certain over-all (global) properties
and certain local (regional) properties.

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Specifically, the region of a ligament which replaces the natural ACL in the joint space should be capable of extending to large deformations with low force (low axial stiffness), and the region of the ligament which provides bone attachment should be porous and not stretch or move relative to the bones (high axial stiffness). To achieve both requirements, a suitable ligament should have variable properties along its length. However, this creates problems in manufacturing and in structural efficiency due to stress concentrations at the interface between the regions.

SUMMARY OF THE INVENTION

The present invention solves these problems by providing an artificial prosthesis made by a special braiding technique which permits elastomeric materials to be inserted in one region, stiff materials to be inserted in another region, and a special binding system which permits the prosthesis to function without premature failure at the interface between the regions.

Specifically, the present invention solves these problems by providing in a first aspect a novel structure comprising a tube formed from a braid of stiff braiding components, said tube enclosing a channel, said tube having along its length:

(a) a central region comprising (i) an elastomeric core component within said channel, or (ii) an elastomeric warp component within said braid, or (iii) a combination of (a) (i) and (a) (ii);

(b) a porous primary attachment region comprising (i) a stiff core component within said channel, or (ii) a stiff warp component within said braid, or a combination of (b) (i) and (b) (ii); and

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(c) binding means defining a transition region extending over a portion of said central region and a portion of said primary attachment region for minimizing the relative motion of said stiff braiding components, elastomeric core components, elastomeric warp components, stiff core components, and stiff warp components, within said portions of said regions over which said binding means extends.

In its second aspect, the present invention solves these problems by providing a novel structure comprising a plurality of first braided tubes, each of which has along its length at least a first and a second region characterized by braiding angles which may be the same or different, and each of which first regions of said tubes encloses a first channel therein; said prosthesis having along its length:

(a) a central region comprising a parallel array of said first regions of said first braided tubes, at least one of which tubes comprises (i) an elastomeric core component within said first channel, or (ii) an elastomeric warp component within said first braided tube, or (iii) a combination of (a)(i) and (a)(ii);

(b) a porous primary attachment region comprising a braid formed from said second regions of said first tubes, thereby forming a single second braided tube enclosing a second channel therein said primary region further comprising (i) a stiff core component within said second channel, or (ii) a stiff warp component within said second braided tube, or (iii) a combination of b(i) and b(ii); and

(c) binding means extending over a portion of said central region and a portion of said primary attachment region for preventing said second braided tube from unbraiding.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a preferred ligament prosthesis of the first aspect of the present invention showing its various regions.

5 FIG. 2 is an exploded view of a portion of a preferred ligament prosthesis of the first aspect of the present invention showing, in section, the central region, the transition region and the primary attachment region.

10 FIG. 3 is a schematic view illustrating a preferred ligament prosthesis of the present invention implanted between adjacent bones of a knee joint in replacement of a natural anterior cruciate ligament.

15 FIG. 4 is a perspective view of a biaxially braided tube.

FIG. 5 is an exploded view of a ligament prosthesis of the present invention showing in phantom a portion of an optional over-sleeve.

20 FIG. 6 is a stylized perspective view of a braided tube in accordance with the second aspect of the present invention.

25 FIGS. 7 and 8 are exploded perspective views of portions of first braided tubes in accordance with the second aspect of the present invention, showing braiding angles of said portions.

FIG. 9 is a perspective view of the central region, transition and primary attachment regions of a prosthesis in accordance with the second aspect of the present invention.

30 FIG. 10 is an exploded view of a prosthesis in accordance with the second aspect of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

35 The present invention involves a prosthesis which is capable of providing a strong, functional

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replacement for damaged soft tissue, such as, but not limited to, ligaments, tendons, heart valve leaflets, vascular tissue, muscle tissue, fallopian tubes, ureters, and hernial grafts. Most preferably the prosthesis is a replacement for ligaments, particularly the anterior cruciate ligament (ACL). The concepts which follow apply to tendons and other soft tissue prostheses. Modifications directed to such other applications will be apparent to those skilled in the art. See, for example, U.S. Patent 4,610,688.

The following is a description of the first aspect of the present invention.

1. The Basic Braid

The basic framework of the prosthesis may be provided by a biaxially braided structure, or "circular braid," as illustrated in Figure 4. This circular braid is tubular in form and runs the entire length of the prosthesis. By "tubular", is meant that the basic braid encloses a hollow channel, which may be filled, partially or wholly, with a "core component." Although in Figure 4, tube 1 is cylindrical, it is to be understood that the tube may be in various other shapes, such as square with rounded corners, ovoid, rectangular, etc. This braid itself is fabricated from braiding components 2 and 3, depicted in Figures 2 and 4. These components are oriented in opposite directions but at substantially the same braid angle, with braid angle measured relative to the longitudinal axis 4 of the braided tube. The braid angle may be varied along the length of the tube to vary axial stiffness. Although the braiding components are shown in Figure 2 in a "two-up", "two-down" manner with respect to each other, and in Figure 4 in a "one-up", "one-down" manner, other braiding patterns may also be employed. Components 2

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and 3 may both be of the same or different diameter, as desired.

The basic framework may also be provided by a so-called 3D braided tube such as described in U.S. Patent No. 4,719,837. In that case the braiding components would not be restricted to running in opposing helices, but would also run through the thickness of the braid.

Each braiding component may comprise one or more strong, stiff monofilament and/or multifilament yarns. Suitable yarns can be made from fibers of polyesters, such as polyethylene-terephthalates (PET), including Dacron®; polyaramids, such as Kevlar® and Nomex®; polyolefins, such as polyethylenes and polypropylenes; polyglycolic acids; polylactic acids; fluoropolymers, such as polytetrafluoroethylene (PTFE; Teflon®); and suitable combinations thereof. Other suitable fibers will be readily apparent to those skilled in the art. Other suitable fibers include those fibers having a Young's modulus similar to the aforementioned strong, stiff fibers. "Young's modulus" refers to the ratio of the tensile stress placed on an object in elastic deformation to the resulting longitudinal strain. Preferably, the fibers are polyolefins, particularly polyethylene; polyaramids, particularly Kevlar®; or polyesters, particularly Dacron®. Dacron®, Kevlar®, Nomex® and Teflon® are all available from E. I. du Pont de Nemours and Company, Wilmington, Delaware, 19898.

If a braiding component comprises more than one yarn, the yarns may themselves be braided, left in parallel array or otherwise arranged. A preferred braiding component is a low angle (less than 5 degrees) biaxial braid of Dacron® polyester multifilament yarns. The number of yarns in the braid

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is optional, and will depend on the size of the finished prosthesis. Alternatively, the yarns may be randomly interlaced.

Each braiding component, as well as the yarn or groups of yarn used therein may, if desired, be wrapped with one or more yarns. Suitable yarns include the strong, stiff yarns and the elastomeric yarns discussed herein. The term "wrap", as used herein, means a helical overwinding of one or more yarns, in one or more layers. Wraps serve, among other things, to provide abrasion resistance.

2. Components Added to Basic Braid in Lengthwise Regions

In accordance with both aspects of the present invention, the braided tube is modified along its length through various types of inclusions, additions, or alterations in braiding angle or pattern or the like, which result in a desirable combination of both regional and global properties. Figures 1 and 2 illustrate regions of differentiation in a preferred ligament prosthesis of the first aspect of the present invention.

(a) The Central Region

The central region 5, as shown in Figures 1 and 2, defines one area of modification. The "central region," as used herein is, in the case of a ligament prosthesis, the area which, in vivo, substantially spans the space between the joined bones. Figure 3 depicts an implanted anterior cruciate ligament prosthesis.

The central region 5 of a ligament prosthesis requires a combination of stiffness at high strains, compliancy at low strains, and overall strength. To provide these properties, an elastomeric component is added to the core and/or the warp position of the central region of the basic braid. The term "core,"

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as used herein, designates a position within the hollow channel of the braided tube shown in Figure 4. Preferably, the elastomeric core component (which may, itself, be a complex structure) substantially fills the core of the braided tube in its rest position in vivo. The term "warp", as used herein, signifies an inclusion in the wall of the braided tube, the inclusion having an orientation parallel to the longitudinal axis 4 of the braid.

Each core and/or warp component in the central region is comprised of one or more elastomeric monofilament and/or multifilament yarns. Suitable elastomeric yarns can be made from fibers of polyurethane polymers; silicone elastomers; polyester/polyether block copolymers, such as Hytrel®; spandex-type polyurethane/urea/ether block copolymers; spandex-type polyurethane/urea/ester block copolymers; polypropylene; fluoroelastomers; elastomeric polyolefins; and suitable combinations thereof. Other suitable fibers will be readily apparent to those skilled in the art. Other suitable fibers include those fibers having a Young's modulus similar to the aforementioned elastomeric fibers. Preferably, the fibers are polyester/polyether block copolymers, particularly Hytrel®, or spandex-type polyurethane/urea/ether block copolymers. The most preferred fibers are spandex-type polyurethane/urea/ether block copolymer.

If an elastomeric core component comprises more than one yarn, the yarns may themselves be braided, left in parallel array or otherwise arranged. Each of the yarns or groups of yarns used in the core and/or warp component, may, if desired, be wrapped with one or more multifilament yarns for added abrasion resistance.

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If a less extensible prosthesis or a higher axial stiffness prosthesis is required, as, for example, in a tendon replacement, the elastomeric component may be omitted from the "central region."

5 In Figure 2, there is shown a preferred core component 11, which comprises elastomeric yarns 12 positioned in "parallel" array. The term "parallel," as used herein, refers to the sharing of a common mechanical load. Yarns which are in a parallel array
10 can be side-by-side, entwined, interbraided, etc. The elastomeric fibers 12 are shown with wrapping 13. Such wrapping is preferred. A particularly preferred central region core component consists of a parallel array of spandex yarns, wrapped with two layers of
15 Dacron® multifilament yarn.

Referring now to Figure 5, the central region 5 may have an optional over-sleeve 22 (shown in phantom) positioned over the basic braid. The over-sleeve is preferably a knitted, woven or braided
20 fabric tube. The fibers of the fabric may be the same as those used to form the biaxial components of the basic braid. Particularly preferred fibers are made of polyethylene, and a preferred fabric construction for the over-sleeve is a tubular raschel knit. The
25 over-sleeve should be sufficiently porous to permit ingrowth of fibrous tissue and must have a certain degree of stretchability. Therefore, an inherently stretchable fabric is preferred. The over-sleeve 22 is held in place by the binding means 17 in the
30 transition region 7, discussed more fully below. The over-sleeve serves to minimize abrasion between the central region 5 and the nearby bone. Alternatively, or in addition, a collar-like member may be inserted into the bone hole exits 18 (Figure 3) to provide a
35 surface less abrasive than that provided by natural bone.

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(b) Primary Attachment Region

The primary attachment region 6, as shown in Figures 1 and 2, is the region where the prosthesis is biologically fixed to the bones by tissue ingrowth.

5 Tissue ingrowth requires both porosity and a lack of stretchability in the longitudinal direction, under typical biological loads. To provide these characteristics, a strong, stiff component is added to the core position of the basic braid, included in the
10 the warp position of the basic braid, or utilized in both the warp and core positions. In addition, it is desirable to keep a low braiding angle in this region to minimize stretchability.

Each core and/or warp component in the primary
15 attachment region may be comprised of one or more strong, stiff monofilament and/or multifilament yarns. Suitable strong, stiff yarns can be made from the fibers listed for the braiding components. In addition, metals, such as titanium and biocompatible
20 ceramics may be used. Where more than one yarn is utilized, the yarns may, themselves, be braided, left in parallel array or otherwise arranged. In addition, the core component may comprise one or more strong, stiff porous plugs. Suitable porous plugs include,
25 but are not limited to, those constructed from polyolefins, such as ultrahigh molecular weight polyethylene; polysulfones; resorbable polymers such as polylactide; polyesters; calcium phosphate ceramics such as hydroxylapatite or tricalcium phosphate;
30 bioglasses; other ceramics such as alumina, barium titanate, or zirconia; metals such as stainless steel, cobalt-chrome alloys, tantalum, titanium and its alloys; natural bone and other natural materials; and suitable combinations thereof. The plug may be of
35 various shapes, including the tapered shape discussed in U.S. Patent 3,973,277. Other suitable porous plug

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materials and shapes will be readily apparent to those skilled in the art.

Preferred fibers include those made from polyolefins, particularly polyethylene; metals, particularly titanium; or polyesters, particularly polyethylene terephthalates (PET), including Dacron®. The most preferred fibers are PET. Preferred porous plugs include a composite of tricalcium phosphate and polylactide, ultrahigh molecular weight polyethylene and titanium. Most preferred is ultrahigh molecular weight polyethylene and titanium.

To best attain the stiffness and strength in the primary attachment region, and also to provide sufficient porosity to facilitate tissue ingrowth, the use of large diameter monofilament yarns in the construction of the stiff core and/or warp components is preferred. By "large" is meant a yarn diameter such that when the yarns are incorporated into the stiff core and/or warp components, voids are formed which are of sufficient size to permit ingrowth of trabecula bone and/or other tissue. Preferred large monofilament yarns have diameters in the range of about 100 to about 500 micrometers, 250 being preferred.

As with the core and warp components of the central region and the braiding components of the basic braid, the core and/or warp components of the primary attachment region, as well as each of the yarns or groups of yarns or porous plugs used therein, may, if desired, be wrapped with one or more yarns.

For ease of braiding, the elastomeric core and/or warp components of the central region may, if desired, extend continuously into the primary attachment, as shown in Figure 2.

Figure 2 illustrates a preferred embodiment of primary attachment region 6 which contains both core

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component 11' and warp components 14. Core component 11' is shown as a parallel array of wrapped elastomeric yarns 12, each having wrapping 13, the whole array being overbraided with triaxially braided monofilament yarns 15. It will be seen that the parallel array of elastomeric yarns 12, having wrapping 13, extends continuously from the central region 5. Warp components 14 are biaxially braided monofilament yarns.

10 The purpose of the primary attachment region is to provide an area for long-term biological fixation of the device to a desired body part through tissue ingrowth.

15 Referring now to Figure 3, tissue ingrowth fixation utilizing the present invention is effected as follows. First, a hole is drilled at surgery in the bone 20 to which fixation is desired, and the primary attachment region 6 of the prosthesis is placed into the resulting bone tunnel. For best results, the prosthesis should fit snugly in the tunnel. The prosthesis is held in place temporarily by the secondary attachment region, discussed below. The healing process will then provide an ingrowth of tissue into the pores supplied by the stiff components of the primary attachment region. Because of the stiffness of the primary attachment region, shearing of ingrown tissue during movement will be minimized.

25 To facilitate X-ray analysis of the prosthesis, after it has been surgically implanted, a radio-opaque substance, such as BaSO₄, may be used in the fibers of the core components of the central and primary attachment regions, as well as the wrapping yarns of the binding components in the transition region.

35 It is believed that for optimum tissue ingrowth results, the primary attachment region should

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have a surface porosity and an interconnected bulk porosity, each of about 5 to about 95 percent, preferably from about 25 to about 50 percent. Most preferably the porosities are between 30 and 50 percent. The phrase "surface porosity," as used herein, is defined as the percentage of the surface area of the tissue ingrowth region which consists of pores having a minimum dimension of about 50 micrometers. This can be determined through scanning electron microscopy. "Interconnected bulk porosity" is defined herein as the percentage of the volume of the tissue ingrowth region consisting of open areas having a minimum dimension of about 50 micrometers which are in communication with the surface of the braid in this region. This can be measured by standard mercury porosimetry techniques. For the combined reasons of structural integrity and tissue ingrowth compatibility, high porosity and/or interconnected bulk porosity is preferred.

(c) Transition Region

The transition region 7 is the area between the central region and the primary attachment region. It is here that the various modifications in the central and primary attachment regions may begin and end. The structural and functional characteristics of the central region and the primary attachment region are generally significantly different, and thus this segment of the prosthesis provides a region which accommodates these structural and functional variations.

Specifically, the transition region serves to "tie down" the various elastomeric components of the central region and the stiff components of the primary attachment region which may begin or end, as the case may be, in the transition region. Not tying loose component ends down could result in premature

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prosthesis failure due to abrasion caused by the relative motion of these components.

Accordingly, the transition region is defined by the presence of a binding means for preventing substantial relative motion of the braiding, warp, and/or core components which are present in this region. Suitable binding means include, but are not limited to, (1) a tight covering positioned around the exterior of at least a portion of this region of the basic braid, and (2) an impregnation material. Such a tight covering includes a collar or a wrapping and may be constructed from any of the fibers utilized in the stiff and/or elastomeric yarns discussed herein. Preferably, the material utilized as the tight covering is elastomeric so as to better accommodate small shifts in region components, while allowing the tight covering to remain snugly positioned. In a preferred embodiment, the tight covering of the transition region comprises a wrapping of elastomeric yarns. Suitable impregnation materials include silicones, urethanes and biocompatible glues.

Figure 2 depicts a preferred embodiment of transition region 7 wherein the binding means comprises a wrapping 17 of an elastomeric yarn. Preferably the wrapping 17 comprises at least two layers (not shown), an underlayer of bare elastomeric yarn, and an overlayer of elastomeric yarn, which is, itself wrapped with a fine multifilament yarn.

(d) Secondary Attachment Region.

To provide temporary fixation during the period of long-term biological fixation, the prosthesis may further comprise a secondary attachment region 8, as shown in Figure 1, located adjacent to each of the primary attachment regions. The secondary attachment region is defined by the presence of means for immediately fixing the prosthesis to a body part

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during surgical implantation. Suitable means include, but are not limited to an eyelet 9, as shown in Figure 1, which can be screwed to bone, and a plug or anchor (not shown) which serves to keep the prosthesis secured within the bone tunnel.

In a preferred embodiment, illustrated in Figures 1 and 3, the basic braid and any warp and/or core components in the secondary attachment region are bifurcated into two bundles to form an eyelet 9 suitable for securement by a button, screw (such as screw 16) or other conventional attachment device. Where an eyelet is utilized, it may be desirable to eliminate any core and/or warp components from the eyelet area to minimize the size of the eyelet. In addition, it is preferable to separately wrap each bundle of the eyelet with wrapping 21, shown in Figure 1, most preferably utilizing fibers from the basic braid itself. Several such eyelets could be formed next to each other in the secondary attachment region. This would make it possible to secure the device at several locations or else select the eyelet which lies at a favorable anatomic location for screw insertion.

(e) Tail Region

In a preferred embodiment, shown in Figure 1, the ligament prosthesis of the present invention may further comprise a tail region 10 located adjacent to each of the secondary attachment regions. The tail region should be stiff, strong and slender, to facilitate installation. Specifically, the tail region can be pushed through bone tunnels and can be used to pull the prosthesis into place. Following installation of the prosthesis, the tail region can be clipped off, such as at point 19, as shown in Figure 3. In this region, strong, stiff core and/or warp components, as described, above may be added to the basic braid.

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The following is a description of the second aspect of the present invention. The second aspect is similar in most respects to the previously described first aspect, with the exception that the "central region" is, instead of one braided tube, a parallel array of a plurality of individually braided tubes. Each individually braided tube of the central region becomes a single stiff braiding component used to form the "basic braid" of the primary attachment region. The prosthesis in accordance with the second aspect provides a structure with low torsional rigidity compared to the prosthesis in accordance with the first aspect of the invention. Accordingly, the prosthesis in accordance with the second aspect develops low torque during use. The use of a parallel array of braids allows the central region to flatten if it rubs against another surface, such as bone or another ligament.

The braiding angle of each individually braided tube in the central region may be the same as or different from the braiding angle of the tube as it forms a single braiding component of the basic braid in the primary attachment region. As the braiding angle is lowered, the braided tube becomes closer to a parallel array of fibers. Hence, the invention contemplates a prosthesis having a central region comprising a parallel array of a plurality of braided tubes, each of which tubes becomes yarn-like in the primary attachment region, where it serves as a single braiding component of the basic braid.

Referring now to Figure 6, there is seen a parallel array 23 of a plurality of braided tubes 24. The braided tubes are themselves braided together to form one large braided tube 25. Figure 7 shows the braiding angle "a" of individual tube 24 in the region designated "A" in Figure 6, and Figure 8 shows the

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braiding angle "b" of individual tube 24 in the region designated "B" in Figure 6.

Figure 9 shows a preferred embodiment of a ligament prosthesis in accordance with the second aspect of the invention. The central region 5' comprises a parallel array 23 of a plurality (four are shown in the Figure) of individually braided tubes 24, each of which is braided at a predetermined braiding angle. Generally, a biaxial braid is preferred. The braiding components of the braid may be the same stiff braiding components described earlier for the "basic braid" of the first aspect of the invention. Each tube 24 of the parallel array 23 of braided tubes 24 enters the transition region 7', where the tubes 24 are, themselves, braided together to form a basic braid 25, which continues into the primary attachment region 6'. In a preferred embodiment, the central region 5' is flanked by two primary attachment regions 6' and two transition regions 7'.

Figure 10 shows four individually braided tubes 24 emerging from transition region 7'. Each of the tubes 24 becomes a braiding component 2', 3' of the basic braid of the primary attachment region 6'. As shown in Figure 10, the braiding angle of each individual tube 24 can become quite low, approaching an essentially unbraided yarn. At least one of the individual tubes 24 of the parallel array 23 contains an elastomeric component 26, either in the channel of the tube or in the warp position of the braid. The primary attachment region 6' may contain a stiff component, either in the channel or in the warp. In Figure 10, there are shown stiff biaxial braids 14' in the warp and concentric braids 27 in the channel. The basic braid of the primary attachment region 6', formed from the individual tubes 24, is kept from unbraiding by binding means, such as tight wrapping

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17' positioned over a portion of the parallel array 23 and a portion of the basic braid of the primary attachment region. In addition, the binding means serves to minimize the relative motion of the braids and the elastomeric and stiff components included within the braids or within the channels enclosed by the braids.

Suitable elastomeric components include elastomeric yarns or a parallel array of elastomeric yarns. The yarns may be wrapped if desired. Unlike the first aspect of the invention, however, it is desirable that the elastomeric yarns not extend beyond the transition region (defined by the presence of binding means 17') into the primary attachment region 6'.

Suitable stiff components for the primary attachment region 6' include those already mentioned in connection with the first aspect of the invention.

Both aspects of the present invention may be symmetrical structures, in the sense that the central region is flanked by two primary attachment regions and transition regions. Alternatively, in some applications it may be preferable to have an asymmetrical structure, i.e., a "central region" and only a single primary attachment region and transition region.

If an asymmetrical prosthesis in accordance with the first aspect of the invention is used, the end of the "central region" not flanked by the transition region and primary attachment will be terminated with means for attaching the prosthesis to the desired body part. Suitable means include an eyelet formed by bifurcating the basic braid, as described earlier for the "secondary attachment region." If an asymmetrical prosthesis in accordance with the second aspect of the invention is used, the

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free ends of the individual tubes used to form the parallel array can be bound together to form an attachment site. Suitable means for binding the free ends includes a tight wrapping of elastomeric yarn.

5 Examples illustrating construction techniques for ligament prostheses of the present invention are set forth below. These examples are not to be construed as limiting the invention.

Example 1

10 This Example describes the construction of a prosthesis in accordance with the first aspect of the present invention.

Starting Materials

15 Sixteen 2200 denier Dacron® polyester multifilament yarns (each multifilament yarn comprised of 10 ends of 220 denier Dacron® yarn, lightly braided together), to be used in the Basic Braid.

20 Core Component: Triaxial braid (12.8 picks/inch) comprised of twenty-four 0.010 inch diameter polyethylene-terephthalate (PET) monofilament yarns with 12 wrapped spandex yarn bundles (5600 denier spandex monofilament yarn wrapped in the S and Z directions with 140 denier Dacron® polyester multifilament yarns) positioned in the core of the triaxial braid. Braiding tension = approximately 24 ounces.

25 Warp Component: Biaxial braid (12.8 picks/inch) of sixteen 0.010 inch diameter PET monofilament yarns. Braiding tension = approximately 24 ounces.

Production Steps

30 (1) Modify Starting Materials: Beginning with an appropriate length of the core component starting material, remove the triaxial braid from the wrapped spandex core bundles in a section where the central region will be. Cut eight warp component starting

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materials at an appropriate length. Taper one end of each warp component by cutting on an angle of approximately 30° to the longitudinal axis of the component.

5 (2) Make Up Preassembly: Leading end: align tapered ends of 4 of the warp components with each other. Tie them in a bundle at the other end by wrapping. Trailing end: align the tapered ends of the remaining warps with the end of the monofilament yarn
10 in the central region of the core, and arrange them symmetrically around the circumference. Hold them in position, both axially and circumferentially. A collet tool can be utilized for this purpose.

15 (3) Start Basic Braid and Construct First Tail Region: Place each of the sixteen 2200 denier lightly braided Dacron® multifilament yarns in a carrier under approximately 24 ounces of tension. Set the braider to give a fairly dense braid (e.g., 12.6 picks/inch). Make a short length of the Dacron®
20 basic braid. Introduce the leading end of the preassembly into the core region. Braid until a segment of the preassembly is captured within the basic braid.

25 (4) Start First Secondary Attachment Region: Move the warp components from the core region to their respective warp positions and hold them in place. In practice, the warp components are inserted into warp guide tubes. It is possible, but significantly more difficult, to maintain positions of the warp
30 components by applying tension to them. Continue braiding.

35 (5) Construct Eyelet in First Secondary Attachment Region: Stop the machine at the appropriate point. Lash one side of the eyelet by removing a bobbin from that side of the braider and passing it around the Dacron® from the remaining

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seven bobbins on that side of the braider, as well as approximately half of the warp components. Lash the other side in a similar fashion, capturing the remaining warp components. Reinstall the lashing bobbins in their carriers and resume braiding.

(6) Construct First Primary Attachment Region: Insert the core component into the center of the braid immediately following the eyelet. Adjust the machine to give an open braid (e.g., 5.8 picks/inch).

(7) Construct the First Transition Region, a Central Region and a Second Transition Region: Stop braiding just short of the point where the basic braid would begin to cover the region of the core where the monofilament was removed. Set the braiding machine to produce a dense braid (e.g. 19.2 picks/inch). Braid beyond the central region until the beginning of the second set of warp components are captured in the core region of the basic braid as in the first transition region.

(8) Complete the Second Transition Region: Move the warp components from the core region to their respective warp positions, without pulling them free from the core region, and hold them in place. Again, it is most convenient to use warp guide tubes, but other means are possible. Resume braiding.

(9) Begin Second Primary Attachment Region: Set the machine to produce the same open braid used for the first primary attachment region (i.e., 5.8 picks/inch).

(10) Construct Eyelet in Second Secondary Attachment Region: Stop braiding at an appropriate point and form a second eyelet in the same manner as the first. Continue braiding until the secondary attachment region is complete.

(11) Construct Second Tail Region and Complete the Basic Braid: Set the machine to produce a dense

- 22 -

braid (12.6 picks/inch). Braid to within a short distance from the end of the warp components. Move the warp components into the core region. Braid beyond the ends of these components.

5 (12) Remove the completed device from the machine.

(13) Wrap the device tightly on the tail Region side of the eyelet using spandex yarns.

10 (14) Wrap the transition regions tightly first using spandex yarn and then using spandex yarn wrapped with 140 denier Dacron® yarn.

15 It should be noted that the device functions best if preconditioned. To precondition the device, cyclicly load the it through its eyelet for a limited number of cycles to remove initial slack in the structure. Typical values are 5 to 200 lbs., for 10 cycles.

20 As part of the manufacturing procedure, the device should be cleaned to remove fiber finishes and other contaminants. The device should then be sterilized by exposure to gamma radiation at a dose level, for example, of approximately 2.5 megaRads.

25 To store the device, support the device in a fixture that keeps it slightly stretched to maintain the preconditioning until it is used.

The following Table provides physical properties for a ligament prosthesis made in accordance with this Example:

TABLE

30	Geometry	
	Central Region Diameter (inches)	.15
	Primary Attachment Region Diameter (inches)	.24
	Central Region Braid Angle (degrees)	45
	Primary Attachment Region Braid Angle (degrees)	21
35	Central Region Surface Porosity (percent)	<10
	Primary Attachment Region Surface Porosity (percent)	34
	Length Central Region (inches)	.75

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	Length Primary Attachment Region (inches)	1.84
	Length Transition Region (inches)	.44
5	Strength	
	Device (lbs)	423
	Secondary Attachment Region with Screw (lb)	315
	Elongation	
10	Total Device (%)	17.1
	Central Region (%)	38.2
	Stiffness (Axial)	
	Central Region (lb//in/in)	1,744
	Transition Region (lb//in/in)	3,117
15	Primary Attachment Region (lb//in/in)	4,677
	Fatigue Strength in 37° C Saline (Without binding means)	
20	Cycles to fail with axial load of 150 lb	110,000
	(With binding means)	
	Cycles to fail with axial load of:	
	150 lb	3,060,000
25	200 lb	560,000
	250 lb	100,000
	Recovery	
30	Permanent Deformation at 3,000,000 cycles at 150 lb	<2%
	Ingrowth Strength in Canine Implants	
	Femoral Tunnel	
	Pullout Strength at:	
35	12 weeks (lbs).	50
	42 weeks (lbs)	78
	Tibial Tunnel	
	Pullout Strength at:	
40	12 weeks (lbs).	64
	42 weeks (lbs)	92

Example 2

This Example describes the construction of a
 45 prosthesis in accordance with the second aspect of the
 present invention.

Starting Materials

Sixteen 140 denier Dacron® polyester
 multifilament yarns, and sixteen segments of wrapped
 50 spandex yarns (5600 denier monofilament yarn wrapped

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in the S and Z directions with 140 denier Dacron® polyester multifilament yarn).

Core Component: Multi-layered triaxial braid (12.8 picks/inch, 4 layers) comprised of twenty-four
5 0.010 inch diameter polyethelyne-terephthalate (PET) monofilament yarns. Braiding tension = approximately 24 ounces.

Warp Component: Biaxial braid (12.8 picks/inch) of sixteen 0.010 inch diameter PET
10 monofilament yarns. Braiding tension = approximately 24 ounces.

Production Steps

(1) Modify Starting Materials: Cut 2 segments of core material to appropriate lengths. Cut 8 warp
15 component starting materials at an appropriate length. Taper one end of each warp component by cutting on an angle of approximately 30° to the longitudinal axis of the component.

(2) Make Individual Braided Tubes: Braid sixteen 140 denier Dacron® polyester multifilament
20 yarns loosely (e.g., 7 picks/inch) for a length of approximately 18 inches. Insert a segment of wrapped spandex yarn into the core region of the Dacron® braid. As soon as the wrapped spandex yarn is grasped
25 by the braid, adjust the machine to give a dense braid (e.g., 80 picks/inch) and braid until the wrapped spandex yarn segment is nearly covered. Adjust the machine to give the original loose braid, and continue braiding for another 18 inches. Repeat the process to
30 make a total of sixteen individual braided tubes.

(3) Align Braided Tubes: In a parallel array, align the central sections of the braided tubes where the wrapped spandex yarn is included. Put a
35 temporary binding around this central section to maintain the alignment and parallel arrangement during subsequent operations.

- 25 -

(4) Prepare to Assemble Device: Mount the sixteen braided tubes in the braiding machine such that one end of each is attached to one of the sixteen braiding carriers and the other end is attached to the take-off. Adjust the position of the braiding point to correspond to the ends of the central sections of the braided tubes nearest the braiding carriers. Set the machine to give an open braid (e.g., 5.8 picks/inch).

(5) Construct First Primary Attachment Region: Simultaneously insert four of the warp components and one of the core components in the warp and core positions. Braid until the core component is completely covered. Stop the machine.

(6) Construct Eyelet in First Secondary Attachment Region: Lash one side of the eyelet by removing a bobbin from that side of the braider and passing the attached braided tube around the remaining braided tubes and half the warp components on that side of the braider. Lash the other side in a similar fashion. Re-install the lashing bobbins on their carriers.

(7) Construct the First Secondary Attachment Region and First Tail Region: Set the machine to produce a dense braid (e.g., 12.6 picks/inch). Braid to within a short distance from the ends of the shortest warp components. Move the warp components into the core region. Braid beyond the ends of all the warp components.

(8) Remove the structure from the braiding machine, reverse its orientation, and re-mount it in the machine as in Step (4).

(9) Assemble Second Half of Device: Repeat Steps (5) to (7) to form the second primary attachment region, second eyelet, second secondary attachment region, and second tail region.

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(10) Remove the assembled device from the machine.

5 (11) Wrap the device tightly on both sides of the parallel array of braided tubes in the central section, first using spandex yarn, and then using spandex yarn wrapped with 140 denier Dacron® yarn. Remove the temporary binding from the central section.

10 The device may function best if preconditioned. To precondition the device, cyclicly load it through its eyelet for a limited number of cycles to remove initial slack in the structure. Typical values are 5 to 200 lbs., for 10 cycles.

15 As part of the manufacturing procedure the device should be cleaned to remove the fiber finishes and other contaminants. The device should then be sterilized by exposure to gamma radiation at a dose level, for example, of approximately 2.5 megarads.

20 To store the device, support it in a fixture that keeps it slightly stretched to maintain the preconditioning until it is used.

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CLAIMS

What is claimed is:

5 1. A soft tissue prosthesis, comprising a tube formed from a braid of stiff braiding components, said tube enclosing a channel, said tube having along its length:

10 (a) a central region comprising (i) an elastomeric core component within said channel, or (ii) an elastomeric warp component within said braid, or (iii) a combination of (a) (i) and (a) (ii);

15 (b) a porous primary attachment region comprising (i) a stiff core component within said channel, or (ii) a stiff warp component within said braid, or a combination of (b) (i) and (b) (ii); and

20 (c) binding means extending over a portion of said central region and a portion of said primary attachment region for minimizing the relative motion of said stiff braiding components, elastomeric core components, elastomeric warp components, stiff core components, and stiff warp components, within said portions of said regions over which said binding means extends.

25 2. The soft tissue prosthesis of Claim 1 wherein said elastomeric core component or elastomeric warp component comprises an elastomeric yarn.

3. The soft tissue prosthesis of Claim 2 wherein said yarn is wrapped.

30 4. The soft tissue prosthesis according to Claim 2 wherein said elastomeric core component comprises a parallel array of a plurality of elastomeric yarns.

5. The soft tissue prosthesis of Claim 4 wherein each of said elastomeric yarns is wrapped.

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6. The soft tissue prosthesis of Claim 1 wherein said stiff core component or stiff warp component comprises a stiff monofilament yarn.

5 7. The soft tissue prosthesis of Claim 6 wherein said stiff core component or stiff warp component comprises a braid of stiff monofilament yarns.

8. The soft tissue prosthesis of Claim 7 wherein said braid is biaxial or triaxial.

10 9. The soft tissue prosthesis of Claim 7 wherein said monofilament yarns of said braid have a diameter of from about 100 to about 500 micrometers.

15 10. The soft tissue prosthesis of Claim 1 wherein said stiff core component comprises an elastomeric yarn overbraided with a braid of stiff monofilament yarns.

11. The soft tissue prosthesis of Claim 1 wherein said stiff core component comprises a plug of porous material.

20 12. The soft tissue prosthesis of Claim 1 wherein said tube further has along its length a secondary attachment region comprising means for fixing said prosthesis to a desired body part during surgical implantation.

25 13. The soft tissue prosthesis of Claim 12 wherein said means comprises an eyelet formed from bifurcating said braid in said secondary attachment region to form two bundles.

30 14. The soft tissue prosthesis of Claim 13 wherein each of said bundles is wrapped with a yarn.

15. The soft tissue prosthesis of Claim 1 wherein said binding means comprises a tightly wrapped yarn over said braided tube or an impregnation material.

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16. The soft tissue prosthesis of Claim 15 wherein said binding means comprises a tightly wrapped yarn over said braided tube.

5 17. The soft tissue prosthesis of Claim 1 further comprising an over-sleeve positioned over said central region and secured to said prosthesis by said binding means.

10 18. The soft tissue prosthesis of Claim 17 wherein said over-sleeve is a tubular raschel knit fabric.

19. The soft tissue prosthesis of Claim 1 further comprising a second primary attachment region and a second binding means to flank both ends of said central region

15 20. The soft tissue prosthesis of Claim 1 wherein

(a) said central region comprises an elastomeric core component comprising a first elastomeric yarn longitudinally disposed within said channel;

(b) said primary attachment region comprises a stiff core component comprising an elongate braid of stiff monofilament yarns longitudinally disposed within said channel; and

25 (c) said binding means comprises a tight wrapping of a second elastomeric yarn positioned around the exterior of said portions of said tube.

21. The soft tissue prosthesis of Claim 20 wherein said first elastomeric yarn is wrapped.

30 22. The soft tissue prosthesis of Claim 21 wherein said first elastomeric yarn extends into the stiff core component of the primary attachment region.

23. The soft tissue prosthesis of Claim 22 wherein said primary attachment region further comprises a stiff warp component comprising a braid of stiff monofilament yarns.

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24. The soft tissue prosthesis of Claim 23 wherein at least a portion of said second elastomeric yarn is wrapped.

25. A soft tissue prosthesis, comprising a plurality of first braided tubes, each of which has along its length at least a first and a second region characterized by braiding angles which may be the same or different, and each of which tubes encloses a first channel therein; said prosthesis having along its length:

(a) a central region comprising a parallel array of said first regions of said first braided tubes, at least one of which tubes comprises (i) an elastomeric core component within said first channel, or (ii) an elastomeric warp component within said first braided tube, or (iii) a combination of (a) (i) and (a) (ii);

(b) a porous primary attachment region comprising a braid formed from said second regions of said first tubes, thereby forming a single second braided tube enclosing a second channel therein, said primary region further comprising (i) a stiff core component within said second channel, or (ii) a stiff warp component within said second braided tube, or (iii) a combination of b(i) and b(ii); and

(c) binding means extending over a portion of said central region and a portion of said primary attachment region for preventing said second braided tube from unbraiding.

26. The soft tissue prosthesis of Claim 25 wherein said second braiding angle is lower than said first braiding angle.

27. The soft tissue prosthesis of Claim 26 wherein said elastomeric core component or said elastomeric warp component comprises an elastomeric yarn.

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28. The soft tissue prosthesis of Claim 27 wherein said yarn is wrapped.

29. The soft tissue prosthesis of Claim 25 wherein said stiff core component or said stiff warp
5 component comprises a stiff monofilament yarn.

30. The soft tissue prosthesis of Claim 29 wherein said stiff core component or stiff warp component comprises a braid of said stiff monofilament
yarns.

10 31. The soft tissue prosthesis of Claim 30 wherein said braid is biaxial or triaxial.

32. The soft tissue prosthesis of Claim 30 wherein said monofilament yarns of said braid have a diameter of from about 100 to to about 500
15 micrometers.

33. The soft tissue prosthesis of Claim 25 wherein said stiff core component comprises a plug of porous material.

34. The soft tissue prosthesis of Claim 25
20 wherein said second braided tube further has along its length a secondary attachment region comprising means for fixing said prosthesis to a desired body part during surgical implantation.

35. The soft tissue prosthesis of Claim 34
25 wherein said means comprises an eyelet formed from bifurcating said braid in said secondary attachment region to form two bundles.

36. The soft tissue prosthesis of Claim 35 wherein each of said bundles is wrapped with a yarn.

30 37. The soft tissue prosthesis of Claim 25 wherein said binding means comprises a tightly wrapped yarn or an impregnation material.

38. The soft tissue prosthesis of Claim 37 wherein said binding means is a tightly wrapped yarn.

35 39. The soft tissue prosthesis of Claim 25 further comprising an over-sleeve positioned over said

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central region and secured to said prosthesis by said binding means.

5 40. The soft tissue prosthesis of Claim 39 wherein said over-sleeve is a tubular raschel knit fabric.

 41. The soft tissue prosthesis of Claim 25 further comprising a second primary attachment region and a second binding means to flank both ends of said central region.

10 42. The soft tissue prosthesis of Claim 25 wherein

 (a) said central region comprises an elastomeric core component comprising a first elastomeric yarn longitudinally disposed within at least one of said first channels;

 (b) said primary attachment region comprises a stiff core component comprising an elongate braid of stiff monofilament yarns longitudinally disposed within said second channel; and

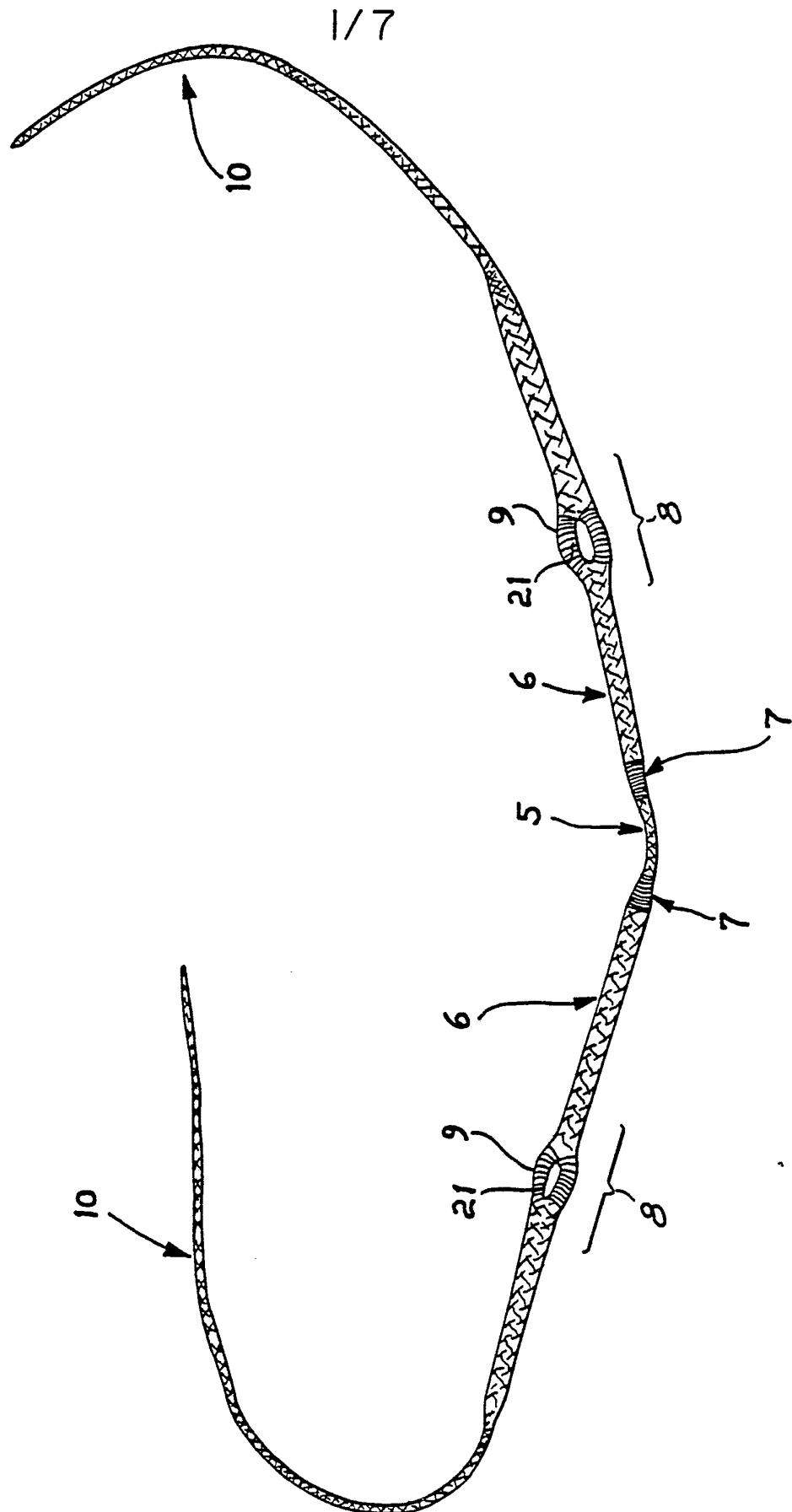
 (c) said binding means comprises a tight wrapping of a second elastomeric yarn positioned around the exterior of said portions of said regions.

25 43. The soft tissue prosthesis of Claim 42 wherein said first elastomeric yarn is wrapped.

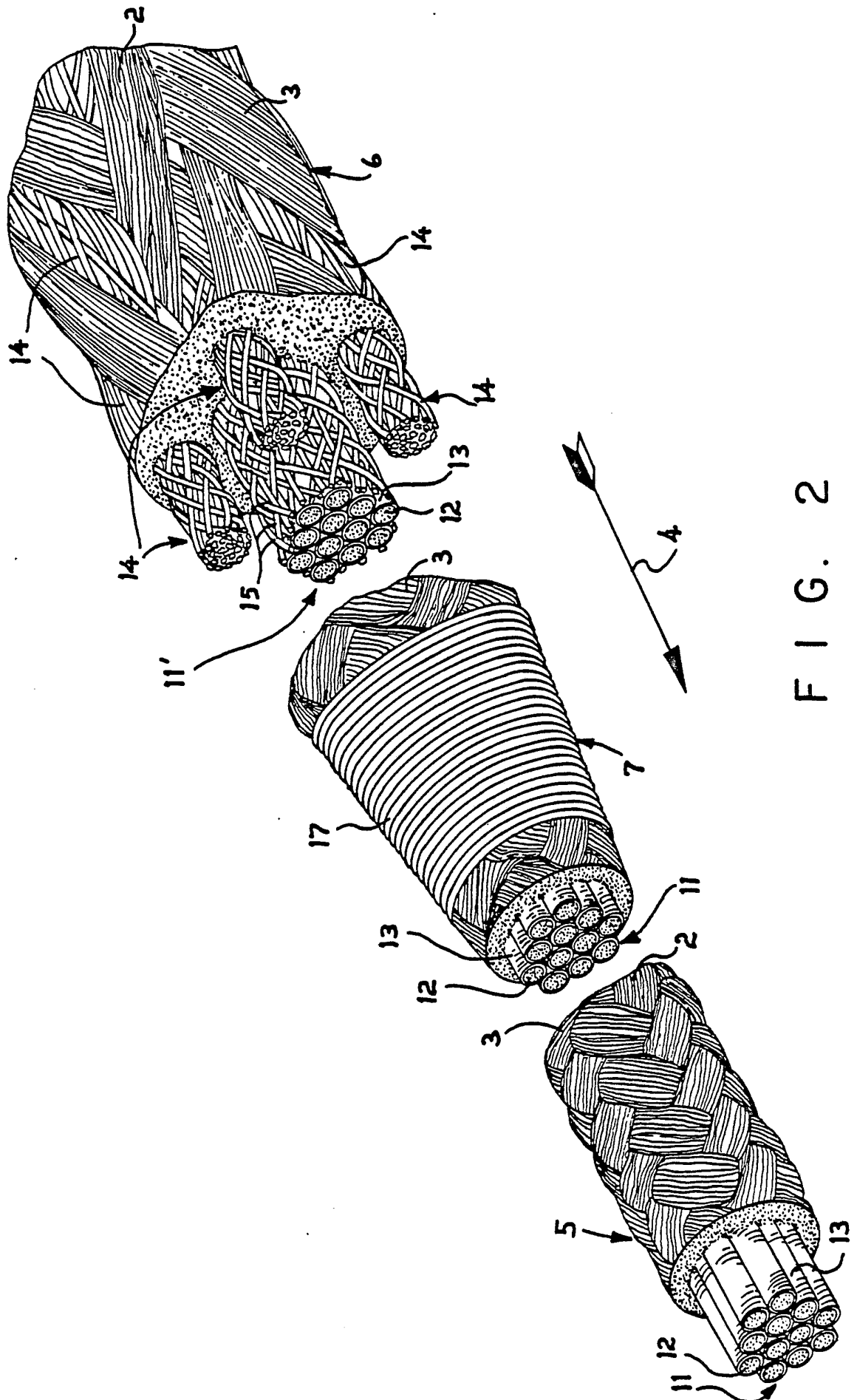
 44. The soft tissue prosthesis of Claim 43 wherein said primary attachment region further comprises a stiff warp component comprising a braid of stiff monofilament yarns.

30

FIG. 1

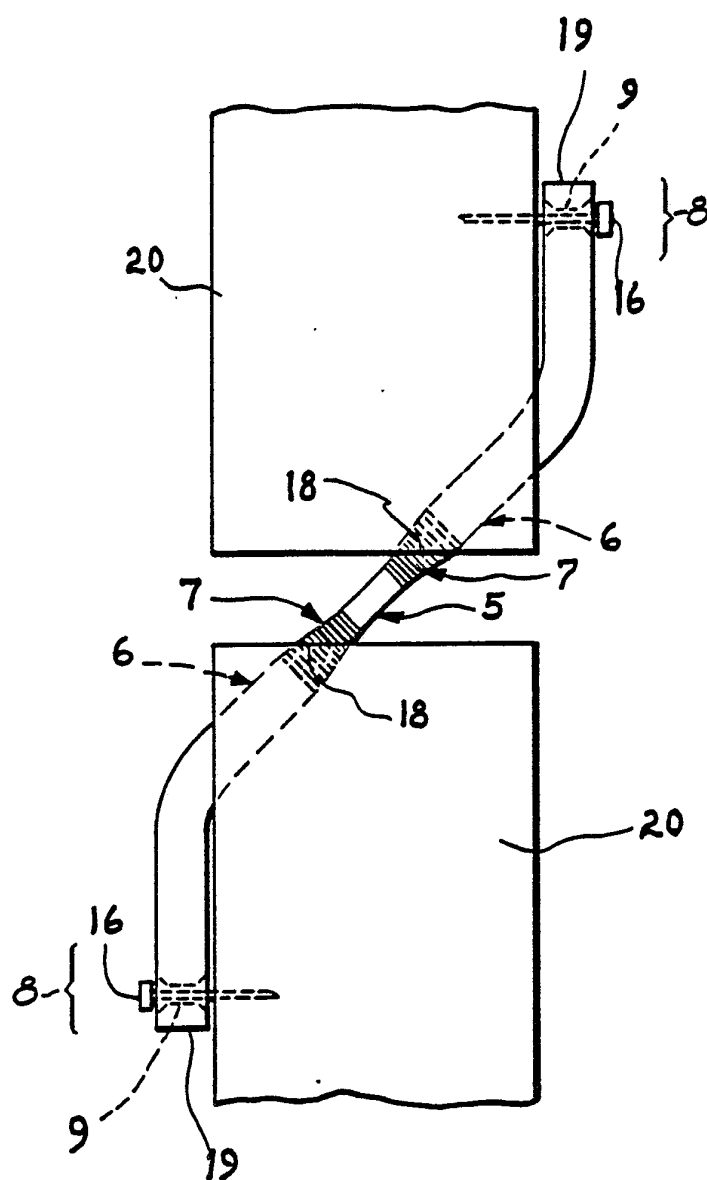


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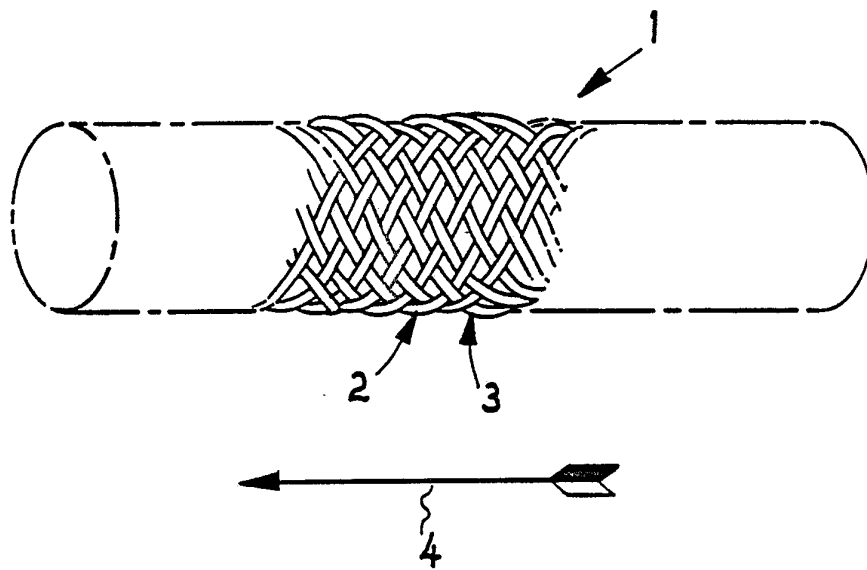
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FIG. 3

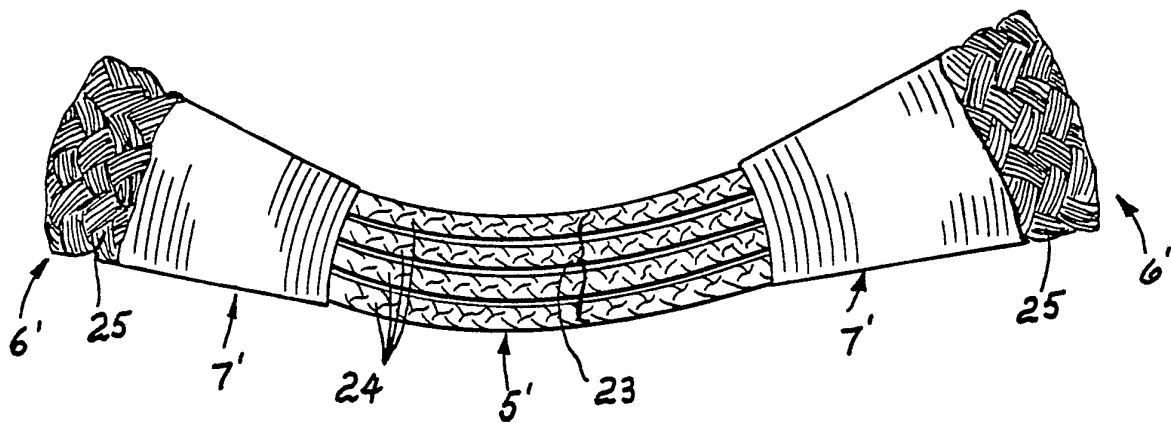


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F I G. 4

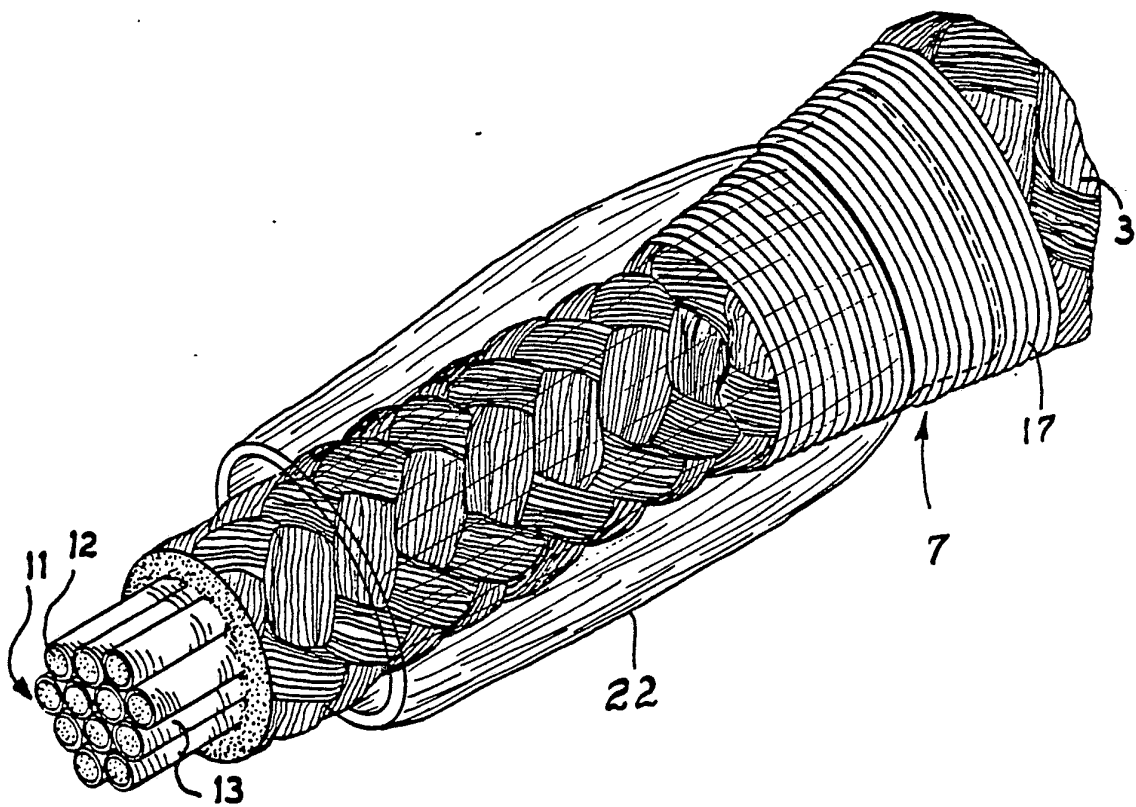


F I G. 9



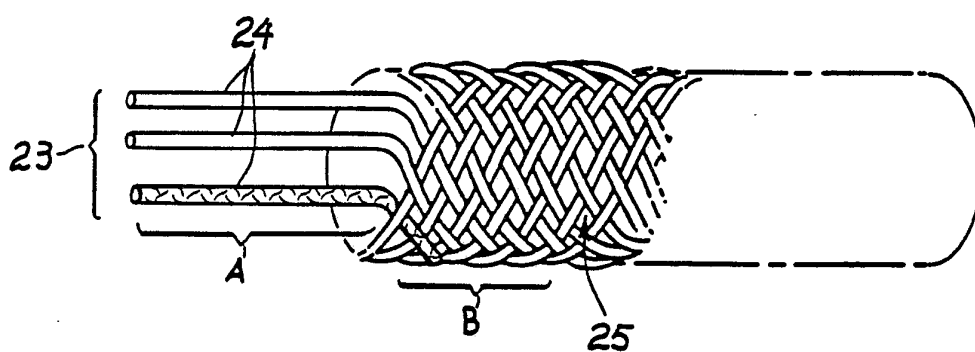
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F I G. 5

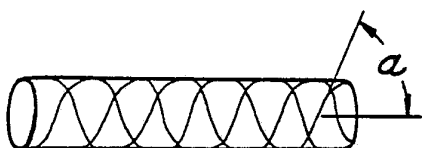


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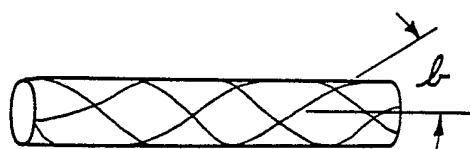
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F I G. 7



F I G. 8



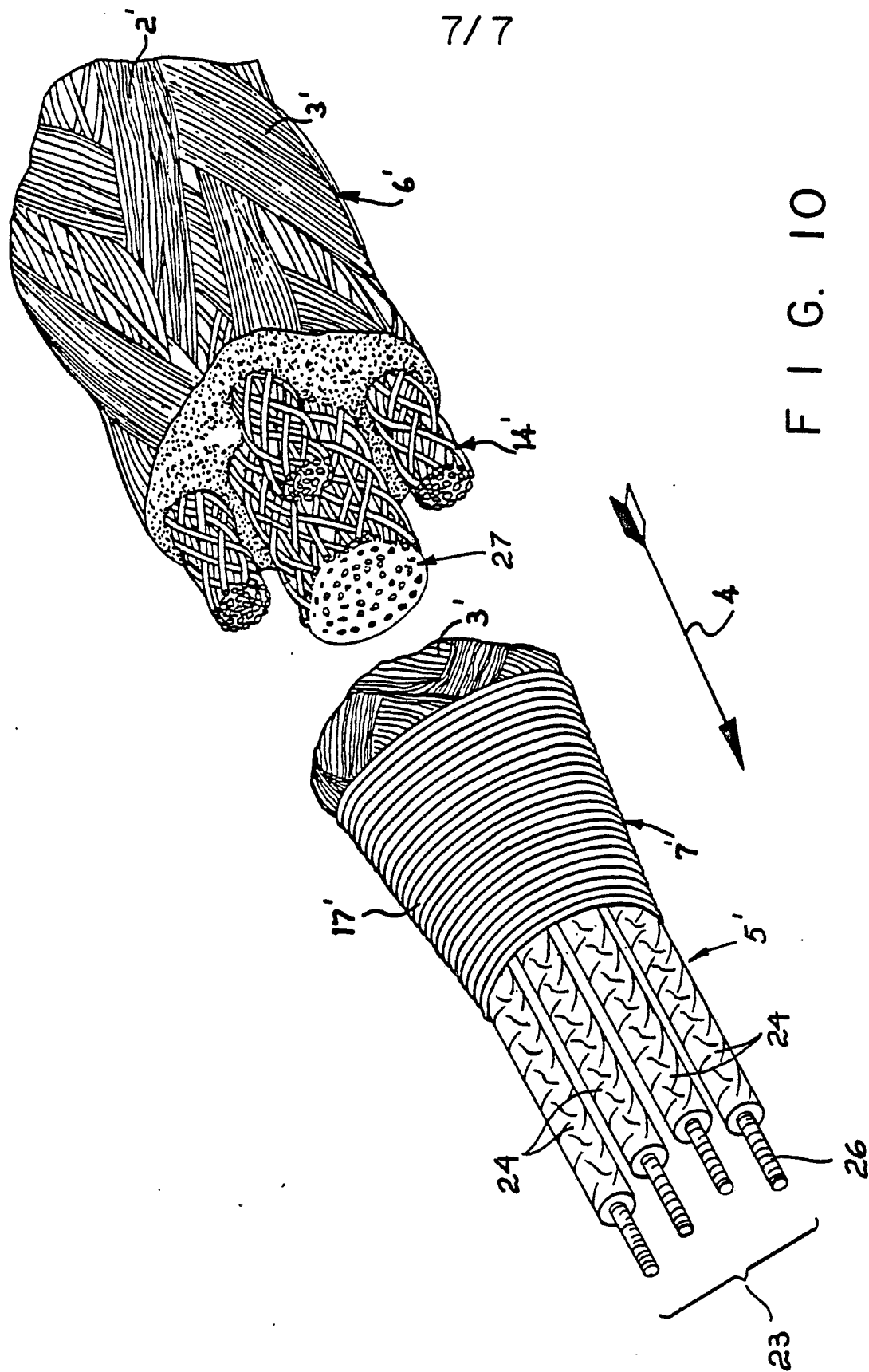


FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No.

CT/US88/02709

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4) A61F 2/08

II. FIELDS SEARCHED ~~US. Class 623/13~~Minimum Documentation Searched ⁷

Classification System

Classification Symbols

U.S.

623/1,13,16,66
128/335.5Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁸**III. DOCUMENTS CONSIDERED TO BE RELEVANT** ⁹

Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	US,A, 4,584,722 (LEVY ET AL) 29 April 1986, See col. 3, l. 7-29.	1,25
A	US,A, 4,610,688 (SILVERSTRINI ET AL) 09 September 1986, See col. 2, l. 25-30, l. 56, and col. 5, l. 50-65.	31
A	US,A, 4,642,119 (SHAH) 10 February 1987 See col. 3, l. 5-29 and col. 4, l. 45-58.	1,25
A	US,A, 4,483,023 (HOFFMAN, JR. ET AL) 20 November 1984, See col. 5, l. 54 thru col. 6, l. 56	1,25

* Special categories of cited documents: ¹⁰

"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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search

Date of Mailing of this International Search Report

15 October 1988

12 DEC 1988

International Searching Authority

Signature of Authorized Officer

ISA/US

A. Cannon

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US,A, 4,301,551 (DORE ET AL) 24 November 1981, See col. 3, l. 41-68, col. 4, l. 1-5 and col. 4, l. 35-55	1,25
A	US,A, 4,187,558 (DAHLEN ET AL) 12 February 1980, See col. 3, l. 25	1,25
A	US,A, 3,805,300 (TASCON-ALONSO ET AL), 23 April 1974, See col. 3, l. 26-68; col. 4, l. 31-68 and col. 5, l. 13-25	1,25