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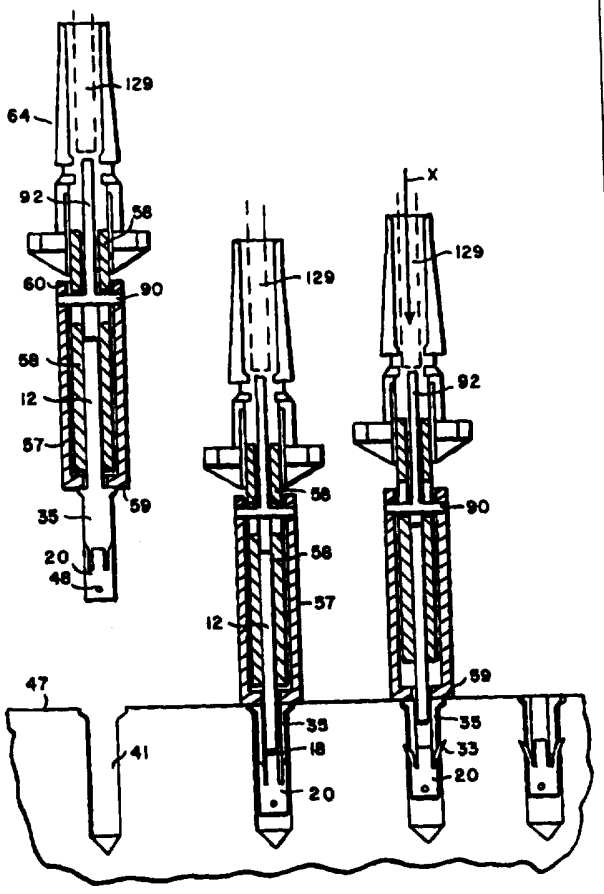
(57) Abstract

A suture anchor assembly is described which includes an elongated insertion stem and an approximately cylindrical anchoring element having an axial channel for receiving the insertion stem. In its nonexpended state, the anchoring element can be placed into a pre-drilled opening in a bone. An expander element loaded onto the insertion stem is engaged with a proximal end of the anchoring element. The proximal end of the anchoring element is capable of telescoping movement over the distal end of the expander element so that resilient proximal portions of the anchoring element are forced outward against the expander element, causing the resilient proximal portions of the anchoring element to expand into the bone hole, fixing the anchoring element in a pressure fit firmly within the opening. A kit for emplacing and removing the suture anchor is also provided as well as methods for attaching a suture to a bone using the present assembly.



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SUTURE ANCHOR ASSEMBLY AND METHODS

A variety of techniques are available for affixing objects such as soft tissue to bone. The oldest technique utilizes thread passed through the bone and the tissue to sew the tissue down to the bone. Many sizes, shapes and types of suture and suture needles are available to accomplish this task. Today, this method is still used for repair of tendons and ligaments in older osteoarthritic patients, although passing a suture through bone is generally difficult and tedious.

Soft tissue repairs also have been accomplished with metal screws or staples that attach soft tissue to bone. Metal screws and/or staples are, however, subject to corrosion and consequent loss of structure. Moreover, the presence of metal in an anatomical site can interfere with imaging and diagnostic or therapeutic treatments near the site. For example, any metal implants may have to be removed by surgery prior to magnetic resonance imaging. Patient sensitivity to nickel ions and stainless steel implants has fueled a growing controversy regarding the use of materials containing high quantities of nickel including nickel-titanium alloys such as Nitinol. Also, it is almost impossible to adjust the compression exerted by screws and staples on soft tissue. Thus, these devices are not fully satisfactory for soft tissue repair.

Other devices employ a suture anchor installation affixed to an arc of wire or a plurality of barbs disposed on an outer surface of the suture anchor body. The barbs or arc of wire are set into a bone by applying traction to the suture. Unfortunately, it is not always possible to position the anchor at a precise location within a bone if an anchor is being drawn upwards in a bone hole by applying tension to a suture. Furthermore, many of the fastening devices require some type of impact or impulse to set the fastener in position. Impact emplacement or

setting of bone/suture anchors may result in injury to the patient as well as placing unnecessary strain on the bone/suture fastener itself. This is especially problematic when suture anchors are intended to be placed in soft bone such as in procedures to repair anterior cruciate ligaments or repair torn rotator cuffs.

Summary of the Invention

One embodiment of the invention is an anchoring device to affix a suture in a bone. The suture anchor includes an expander element having proximal and distal ends, the distal end for engagement with a proximal end of an anchoring element. The anchor also includes an anchoring element for insertion into a bone hole, the element being adapted for movement within the bone hole from a first position, where a proximal end of the insertion element is in facing relationship to the distal end of the expander element, to a second position, where the anchoring element moves proximally within the bone hole so that its proximal end telescopes over the distal end of the expander element, forcing the proximal end of the anchoring element into a wall of the bone hole. The anchor further includes means for moving the anchoring element from the first to the second position.

In a further embodiment, the device includes a tubular anchoring element for engagement with a hole drilled in a bone that has opposed proximal and distal ends connected by way of a central longitudinal axis. The element has defined between the ends an axial channel extending from the proximal end of the element to the distal end of the element and having inner and outer peripheral surfaces forming a wall between the surfaces. The wall further has defined in it a series of axially-oriented slots beginning at the proximal end and extending distally. A

suture retainer is engaged with the anchoring element. The anchoring element further includes a plurality of wall sections that are defined between the axially-oriented slots. Proximal ends of the wall sections include a first camming surface for mating with another camming surface on an expander element so that the first camming surface is arranged for telescoping movement over the other camming surface to expand the wall sections into the bone.

The invention also encompasses an anchoring device to affix a suture in a bone that includes a tubular anchoring element having opposed proximal and distal ends and an axial channel extending from the proximal end of the element to the distal end of the element. The anchoring element has several flexible wall sections that are adapted for movement from a first position, where the flexible wall sections are arranged along the outer peripheral surface of the element, to a second position, where proximal ends of the flexible wall sections are forced to obliquely expand outwardly into a wall of the bone hole. A suture retainer is also engaged with the element. Preferably, the wall sections are more flexible at their respective proximal ends than at their respective distal ends. Other embodiments of the anchoring element include those having screw threads disposed on the distal end at an inner peripheral surface.

The invention also pertains to a suture anchor assembly. The assembly includes an insertion stem having proximal and distal ends, the distal end for engagement with a distal end of a tubular anchoring element; a tubular anchoring element of the invention; and a tubular expander element having an axial channel defined between the proximal and distal ends. The expander element is adapted for loading onto the stem and has a distal end designed to engage with the proximal end of the tubular anchor element. The anchor element is adapted for

movement from a first position, where its proximal end is engaged with the distal end of the expander element, to a second position, so that the tubular anchor element telescopes over the distal end of the expander element and the flexible wall sections of the anchoring element expand into a wall of the bone hole. Most preferably, the insertion stem includes a frangible section adjacent to its distal end and designed to break when sufficient tension is applied to the stem The proximal end of the expander element may include a peripheral flange integral with the proximal end. Included at the distal end of the expander and the proximal end of the flexible wall sections are camming surfaces adapted to engage with each other in order to expand the wall sections into the bone.

The preferred assembly of the invention also includes a tool for removing the anchor element once the anchor element is deployed in bone hole and a tool for applying tension to the insertion stem.

A kit for deploying a suture anchor in a bone hole includes the suture anchor assembly of the invention, a drill, a drill guide, a deployment device, and a tool for removing the anchor element once deployed.

Methods for deploying a suture anchor in a bone hole are described and include providing an anchoring element of the invention for insertion into an opening in a bone and engaging the anchoring element with an insertion stem. Next, an expander element is engaged with the insertion stem so that a distal end of the expander element is engaged with a proximal end of the anchoring element. The insertion stem with its loaded anchoring element is placed into the bone hole and the expander element is fixed in position in the bone hole. A tensional force is applied to the insertion stem so that the proximal end of the anchoring element telescopes over the distal end of the expander element and an outer surface of the

anchoring element engages with the bone. The insertion stem is then released from the anchoring element. Most preferably, the step of releasing includes activating a frangible section of the insertion stem so that it breaks.

It is an object of the present invention to provide a suture anchor of simple design and construction.

It is another object of the present invention to provide a suture anchor having one or more bioabsorbable components.

It is yet another object of the present invention to provide an apparatus for emplacing a suture anchor in a bone that does not require an impact or impulse in order to deploy the anchor.

It is another object of the present invention to provide a method for emplacing a suture anchor that can be used in soft bone and can be removed from the soft bone after deployment.

Brief Description of the Drawings

The following description of the preferred embodiments serves in conjunction with the drawings to explain the invention in further detail, in which:

Figure 1 is an exploded view of a suture anchor of the invention;

Figure 2 is a partial cut-away view through the suture anchor of Figure 1 emplaced in a bone hole;

Figure 3 is a plan view of the embodiment of Figure 2;

Figure 4 is a partial cut-away view through the suture anchor of Figure 1 as it is being deployed in a bone hole;

Figure 5 is a partial cut-away view through the suture anchor of Figure 4 after emplacement in a bone hole;

Figure 6 is a plan view of another embodiment of the suture anchor emplaced in a bone hole;

Figure 7 is a partial cut-away view through a third embodiment of the suture anchor emplaced in a bone hole;

Figure 8 illustrates deployment of the suture anchor of Figure 7, in which Figure 8A illustrates deployment of the suture anchor and Figure 8B illustrates removal of the insertion stem from the bone hole;

Figure 9 is a partial, cut-away view of deployment of the suture anchor of Figure 1 using a pop-rivet gun;

Figure 10 is cut-away view of another embodiment of the suture anchor deployment device;

Figure 11 is a cross-sectional view of a hand-held deployment means used with the device of Figure 10; and

Figure 12 is a cut-away view of a device and method for removing the suture anchor of the present invention.

Detailed Description of the Invention

The suture anchor assembly, according to the invention, generally includes an elongated insertion stem and an approximately cylindrical anchoring element having an axial channel for receiving the insertion stem. In its nonexpended state, the anchoring element can be placed into a pre-drilled opening in a bone. An expander element is engaged with a proximal end of the anchoring element. The term "proximal" refers to a point that is spaced-apart from the bottom of a bone hole in a direction towards the point of origin of the assembly (i.e. towards the surgeon), as opposed to a "distal" point that is closer to the bottom of the bone

hole (i.e. farthest from the point of origin; the surgeon). The anchoring element is capable of moving proximally within the bone hole (i.e. towards the bone surface) so that the proximal end of the anchoring element telescopes over a distal end of the expander element. As a result of this movement, resilient proximal portions of the anchoring element are forced outward against the expander element, causing the resilient proximal portions of the anchoring element to expand into the bone hole, fixing the anchoring element in a pressure fit firmly within the opening. The term "telescopes" has its commonly understood meaning in this context and refers to surfaces that slide against each other in which one surface is forced into another. In particular, the distal end of the expander is forced into the proximal end of the moving anchoring element.

A. **The Insertion Stem**

Figure 1 illustrates an exploded view of one embodiment of the suture anchor assembly of the invention containing an insertion stem onto which is loaded an anchoring element and an expander element.

One component of the suture anchor assembly 10 is an insertion stem 12, an elongated cylinder having distal 14 and proximal 16 ends. Distal end 14 is preferably formed as a shoulder 15 designed to engage a distal end 24 of an anchoring element 20. The insertion stem 12 has a frangible portion 18 disposed some distance proximal to end 14. The term "frangible" refers to a portion of stem 12 that is breakable or fragile. In particular, Figure 1 illustrates frangible portion 18 as a section of stem 12 having a thinner diameter than the remainder of the stem. The frangible section 18 is designed to sever or break when sufficient tension is applied to the stem 12 in a proximal direction (shown by arrow A) that is parallel to longitudinal axis (B-B) of the stem. The frangible portion, however,

may be other than a thin-walled section of stem 12 and may include a series of spokes or webbing or a plurality of very attenuated membranes.

B. **The Anchoring Element**

Anchoring element 20 is substantially tubular, having opposed proximal 22 and distal 24 ends connected by way of a central axial channel 26 extending from the proximal end 22 of element 20 to the distal end 24 of the element. Distal end 24 is engaged with shoulder 15 of stem 12. Element 20 has inner 28 and outer 30 peripheral surfaces forming a wall. Defined in the wall, and in communication with axial channel 26, are a series of axially-oriented slots 34 that begin at the proximal end 22 and extend some distance towards the distal end 24.

Each of the series of axially-oriented slots 34 in the anchoring element 20 define a flexible wall section 33 located between each slot. Each wall section 33 is more flexible at its respective proximal end, in part because the wall section is defined between slots that extend directly from the proximal end 22 of the anchoring element. The distal ends of the respective wall sections 33 are co-extensive with the distal end 24 of anchoring element 20.

Figure 1 also illustrates a suture retainer 48 located adjacent the distal end 24 of anchoring element 20. Suture retainer 48 is most preferably an aperture for receiving an intermediate portion of a suture (i.e. a segment between the free ends of the suture). This allows the anchoring element to be a so-called "slidable" suture anchor. The suture retainer may be configured in a variety of other ways, including any number of suture retaining configurations, such as a slit, a groove, a clip or wire and the like.

C. **The Expander Element**

Expander element 35 is substantially tubular, having opposed proximal 38 and distal 40 ends connected by way of a central axial channel 36, the axial channel defining a longitudinal axis (D-D). The respective inner diameters of the expander element 35 and anchoring element 20 are of sufficient size to allow them to be loaded onto stem 12, anchoring element 20 being engaged first, so that proximal end 22 of the anchoring element 20 is engaged in facing relationship to distal end 40 of expander element 35.

This is shown in Figure 2 which illustrates in partial cross-section the configuration resulting when anchoring element 20 and expander element 35 are disposed by way of stem 12 into a hole 41 drilled in a bone 42. The proximal end 22 of each of the flexible wall sections 33 has a camming surface 44 that is designed to mate with a corresponding camming surface 46 at the distal end of the expander element 35. The camming surface 46 of expander element 35 is preferably tapered or beveled, the taper ranging from about 10 degrees to about 45 degrees. relative to axes (B-B) and (D-D). Most preferably, the tapered camming surface is at an angle of about 30° degrees relative to these longitudinal axes. Corresponding tapered camming surfaces 44 of the anchoring element 20 are also disposed at the proximal end 22 of wall sections 33.

Figures 3 and 4 illustrate operation of this embodiment of the suture assembly and the forces imposed on the components of the assembly in order to set the suture anchor into a bone hole 41. Expander element 35 is substantially fixed at the bone surface 47 and this may be accomplished by using an expander element 35 containing a flange 50 that is integral with the proximal end 38 of element 35 and extending radially outwardly around the periphery of the proximal

end 38. In this embodiment, flange 50 serves as a support/countersink to brace the expander element 35 against the bone surface 47 and against a housing 57 of the stem 12 (Shown in Figure 4) to provide a solid surface onto which a force is exerted that is opposite to the tension force applied to stem 12.

When tension is applied to stem 12 (in the direction shown by arrow A), the stem 12 and anchoring element 20 are forced in the indicated direction (i.e. proximal to the bone hole) but the expander element 35 remains substantially immobile within the bone hole 41 as the result of a distally-applied counterforce (arrow X) exerted against flange 50 by a distal end 59 of the stem housing 57 (See also Figure 6). A proximally directed force that is substantially equal in magnitude and in direction to the stem tension force (arrow A) is applied to the proximal end of anchoring element 20. The anchoring element moves proximally in the bone hole and camming surfaces 44, 46 are forced into mating engagement.

As shown in Figure 4, anchoring element 20 telescopes over the substantially fixed expander element 35. In the embodiment illustrated, distal camming surfaces 46 of expander element 35 remain substantially fixed in position within the bone hole and proximal camming surfaces 44 of anchoring element 20 are forced to ride over them.

Wall sections 33 defined between the series of axially-oriented slots 34 are flexible and will expand into the bone when the camming surfaces are mutually engaged and the anchoring element 20 telescopes over the expander element 35 when tension is applied to the stem 12. Wall sections 33 have proximal ends that are more flexible then other portions thereof. As a result, expansion of the wall sections 33 by the telescoping movement of the anchoring element 20 over the fixed expander element 35 results in the wall sections 33 having a substantially

arcuate cross section when fully deployed and expanded in the bone, the proximal ends of the wall sections being driven radially outward and in an oblique direction (i.e., at an angle relative to the longitudinal axis of the stem). The frangible portion 18 of stem 12 is adapted to break when the flexible wall sections are in their fully expanded position. Once severed, the stem 12 may be removed from the rest of the assembly, leaving the anchoring element 20, expander element 35 and attached suture (not illustrated) locked in the bone hole (See Figure 5). The frangible portion 18 of insertion stem 12 is preferably located at a distance above the distal end 14 of the stem so that, when the stem is removed, the remaining severed stub of the insertion stem does not extend above the level of the bone surface 47.

In other embodiments of the invention, expander element 35 need not have a proximal flange 50. Figure 6 is a partial, plan section of a bone hole 41 into which a non-flanged expander element 35 is disposed. The distal end 59 of stem housing 57 is wide enough so that it is partially coextensive with the bone hole 41 opening and thus simultaneously contacts both the bone surface 47 and proximal end 38 of expander element 35. Functionally, this configuration may be considered similar to that of Figure 3 because engagement of proximal end 38 of expander element 35 and the distal end 59 of stem housing 57 also serve to set up a counterforce (arrow E) in opposition to the tension force applied to the insertion stem 12, the counterforce sufficient to fix element 35 in position within bone hole 41.

In further embodiments, illustrated in Figure 7, distal portions of insertion stem 12 may include screw threads 52 for mating engagement with corresponding screw threads 54 on the inner surface 28 of anchoring element 20. Stem 12

includes a proximal slot 49 for engagement with a screwdriver. Expander element 35 may include proximal flange 50 and stem 12 is rotatable within the expander 35. Expander element 35 is countersunk into the bone so that flange 50 rests upon a shoulder 51 defined in the wall 53 of the bone hole 41. The screw threads 52,54 provide for positioning of the anchoring element 20 in the hole 41 at its desired depth and for applying a desired telescoping force to the anchoring element by turning the insertion stem 12 into the axial channel 26 of the anchoring element 20. In such a turnable screw thread configuration, illustrated in Figure 8A, as the threaded insertion stem 12 is turned clockwise, the expander element 35 remains fixed in the bone hole 41 by way of counterforce pressure against flange 50, but the proximal end 22 of anchoring element 20 is forced to telescope over the distal end 40 of expander element 35 as the threads on the insertion stem are turned. Camming surfaces 44,46 engage and flexible wall sections 33 are expanded into the bone 42. Once the anchoring element is fixed into the bone, the stem and expander may be released by backing out the threaded stem (See Figure 8B).

In another embodiment of the assembly, the distal end 14 of insertion stem 12 and the distal end 24 of anchoring element 20 are attached as an integral unit so that only the expander element 35 need be loaded onto the insertion stem. Alternately, the assembly may comprise the integral anchoring element and insertion stem and an expander element that is molded to, or extruded integrally with, a distal end of a housing as described below with reference to Figure 9.

The component parts of the suture anchor assembly may be fabricated by conventional molding or extrusion procedures. Element 20 is preferably constructed of a biocompatible material. The term "biocompatible" means that the anchoring element material is chemically and biologically inert. Suitable

materials for the anchoring element include, for example, an implant grade high density polyethylene, low density polyethylene (PE 6010 and PE 2030); acetal (trademark "Delrin", manufactured by Dupont Chemical Co.) and polypropylene (13R9A and 23M2: all made by Rexene, Dallas, Texas). Of these, PE 6010 and 13R9A have been FDA listed as class 6 materials.

The anchoring element may also be bioabsorbable. The term "bioabsorbable" refers to those materials that are meant to be decomposed or degraded by bodily fluids, such as, for example, blood and lymph. The anchoring element is preferably made from a biodegradable polymer or copolymer of a type selected in accordance with the desired degradation time. That time in turn depends upon the anticipated healing time of the tissue which is the subject of the surgical procedure. Known bioabsorbable polymers and copolymers range in degradation time from about 3 months for polyglycolide to about 48 months for polyglutamic-co-leucine. A common bioabsorbable polymer used in absorbable sutures is poly (L-lactide) which has a degradation time of about 12 to 18 months. The preferred anchoring element is comprised of an absorbable copolymer derived from glycolic and lactic acids, such as a synthetic polyester chemically similar to other commercially available glycolide and lactide copolymers. Glycolide and lactide degrade and absorb in the body by hydrolysis into lactic acid and glycolic acid which are then metabolized by the body.

The following Table set forth below lists polymers which are useful for the bioabsorbable material employed for the anchoring element, and other parts of the bone fastener as described below. These polymers are all biodegradable into water-soluble, non-toxic materials which can be eliminated by the body. Their safety has been demonstrated and they are listed as approved materials by the U.S.

Food and Drug Administration.

TABLE

Polycaprolactone	Poly (L-lactide)
Poly (DL-lactide)	Polyglycolide
95:5 Poly (DL-lactide-co-glycolide)	Polydioxanone
Polyesteramides	
Copolyoxalates	
Polycarbonates	
Poly (glutamic-co-leucine)	
90:10 Poly (DL-lactide-co-glycolide)	
85:15 Poly (DL-lactide-co-glycolide)	
75:25 Poly (DL-lactide-co-glycolide)	
50:50 Poly (DL-lactide-co-glycolide)	
90:10 Poly (DL-lactide-co-caprolactone)	
75:25 Poly (DL-lactide-co-caprolactone)	
50:50 Poly (DL-lactide-co-caprolactone)	

D. **Apparatus for Deployment**

A preferred deployment apparatus of the invention retains the insertion stem, expander element and anchoring element prior to emplacement and includes a tool for exerting tension on the insertion stem. The preferred apparatus also allows for separating the insertion stem and expander element from the anchoring element after the frangible section is severed.

Figure 9 is a partial, plan view illustrating one embodiment of a deployment apparatus of the invention and its mode of operation. The insertion stem 12 is pre-loaded with the anchoring element 20 and the expander element 35 and the stem 12 is then placed into an apparatus similar to a pop-rivet gun 56. The stem 12 is encased within a housing 57 of the apparatus so that a toothed collet 58 or other similar grasping means engages the insertion stem 12. The anchor assembly is then placed in a hole 41 drilled into a bone 42 and a distal end 59 of the housing 57 is pressed into contact with the bone surface 47. This helps fix the flange 50 of expander element 35 into position at the bone surface 47. Activation of the apparatus 56 retracts the insertion stem 12 proximally (arrow A) to induce tension on the stem. The camming surfaces 44,46 of the respective anchor 20 and expander 35 elements come into telescoping contact and the flexible wall sections 33 of anchoring element 35 are set into the bone 42. Tension is continually exerted on stem 12 until the stem shears off from the remainder of the suture assembly at the frangible section 18. In those embodiments of the apparatus in which expander element 35 is molded or extruded integrally as one-piece with distal end 59 of housing 57, once the stem is sheared the rest of the stem and the expander element are removed to leave the anchoring element with its attached suture (and severed stem) in the bone. In the other embodiments where the expander element is not integral with the housing, the severed stem and the expander element are left in the bone.

Figure 10 illustrates another embodiment of an emplacement apparatus of the invention and its mode of operation. The apparatus includes a housing 57 which encloses insertion stem 12 held co-axially in place by a toothed collet 58. The proximal end 60 of the housing 57 is engaged with arms 90 of a push rod 92

in the shape of an inverse T. Proximal end 60 of housing 57 also includes an aperture (not shown) for receiving the collet 58. The collet 58 is integral with a bayonet-type connector 64 that allows the combined connector and housing to be removably attached to a hand held means 120 (See Figure 11). The stem 12 is thus co-axially arranged around the collet 58 and the collet can move co-axially within the housing 57. The anchoring element 20 and expander element 35 are threaded on the stem and the stem 12 is positioned in the collet.

Referring now to Figure 11, the hand-held means 120 is of similar design to the hand held means described in co-pending and commonly assigned patent application Serial Number 08/163,130, "Bone Fastener", filed December 6, 1993, incorporated herein by reference. Briefly, the hand held means 120 consists of two handle elements 122, 124 slidably engaged to provide a comfortable pistol grip 126 by which handle element 124 can be moved in a proximal-distal direction with respect to the handle element 122 by squeezing the pistol grip 126. The distal end 123 of the handle element 122 is adapted for removably mounting the bayonet connector 64. The distal end 125 of handle element 124 includes a rod 129 whose distal end 127 abuts push rod 92 when the handle elements are assembled and the connector 64 is mounted onto end 123 of handle element 122.

With the apparatus so assembled, the surgeon grasps the apparatus by the pistol grip 126, and directs the anchoring assembly into the predrilled hole in the bone. The distal end 59 of the housing 57, and optionally the flange 50 of the expander element, engage the bone surface. Then, the surgeon squeezes the grip 126 sliding the handle 124 frontward with respect to the handle element 122, as indicated by the arrow 131. Rod 129 presses against push rod 92 in the distal direction (arrow X in Figure 10) and the downward force is transmitted through

the inverse-T arms 90 to the housing 57 and against the bone surface 47. At the same time, the connector 64 and attached co-axially moveable stem 12 are urged proximally (arrow A), translating the distal force on the push rod 92 to a proximal, tensioning force on the insertion stem 12.

E. **Apparatus for Removal**

A significant feature of the present suture assembly is that the anchor element may be removed after deployment by forcing the anchoring element distally back down into the bone hole 41. A removal apparatus as illustrated in Figure 12 consists of a cannulated rod 60 whose distal end 62 is adapted to engage with distal end 24 of anchoring element 20 or with the severed end of the insertion stem 12 at the frangible section. As illustrated, rod 60 is engaged with anchoring element 20 and pressed distally (arrow F) to drive the anchor element 20 back down into the bone hole until the flexible wall sections 33 are substantially parallel to the longitudinal axis (F-F) of the bone hole and extend in a proximal -distal direction. A sheath 64 is then slid (arrow G) over the rod 60 to engage outer peripheral surfaces of the anchoring element 20. This engagement may be facilitated by a series of detents (not shown) located on the distal end 65 of sheath 64 which fixedly engages the anchoring element. The anchoring element, any insertion stem remaining, and sheath are removed (arrow H) from the bone hole as a unit.

F. **Methods**

One method, although by no means the only method, for attaching soft tissue to bone will be described below.

To attach soft tissue to bone, a surgeon takes the sharpened proximal end of a K-wire (manufactured, for example, by Kirschner Medical Company) and spears the tissue that is to be attached. The proximal end of the K-wire is then placed over the bone surface at the approximate site of attachment. The K-wire is then drilled into the bone at that site. If the location is where the surgeon wants it, the surgeon then threads a cannulated drill of the appropriate size over the K-wire. A hole is then drilled into the bone using the cannulated drill. Then drill and K-wire is are removed. It will be understood that the use of a K-wire is not essential to this method of drilling a bone hole.

Whether or not the K-wire is used, the suture assembly of the invention is then loaded within an emplacement apparatus (for example, described above with reference to Figures 9-11). The assembly is pressed downwards through the tissue and into the bone hole so that the anchoring element is emplaced into the bone hole. If the surgeon decides that the orientation of the assembly and soft tissue is correct, the emplacement apparatus is triggered by applying a tensional force to the insertion stem so that the proximal end of the anchoring element telescopes over the distal end of the expander element. The outer, flexible surfaces of the anchoring element engage with the bone and the insertion stem is released from the anchoring element to set the anchor element within the bone hole. The apparatus is removed. Other variations on this technique include first drilling a bone hole and then punching a hole through the soft tissue. The tissue is then moved over the bone hole using, for example, a K-wire or a suture passer grasping device.

It is an important feature of the present invention that the force needed to telescope the anchoring element may be substantially continuous and spread out

over time. The anchoring element is telescoped over the expander element with a compressive motion that is axially delivered in a direction substantially parallel to the longitudinal axis of the insertion stem. Thus, the apparatus for deploying the present assembly requires an advancing drive mechanism which lacks any impact or impulse characteristics.

The components of the bone fastener of the invention may be included in a surgical fastener kit. An exemplary kit may include an anchoring element of the invention; an insertion stem of the invention and a holder for engaging with the anchoring element, the holder capable of maintaining the anchoring element in position with the bone opening. Other embodiments of the kit may include a grasper/manipulator for grasping free ends of the suture to pass the suture through soft tissue. Such a suture-grasping device is described in commonly assigned and co-pending application Serial Number _____, filed 26 July 1993, incorporated herein by reference. A K-wire, drill and drill guide may also be also included. Preferably, the kit is encased in a sterile tray or other receptacle for use by an operator at a site.

The invention will now be illustrated by the following non-limiting examples.

Three different polysulfone anchor elements were fabricated by machining polysulfone, extruded bar stock. The elements included several of 2.8 mm length (wall thickness of 0.018, 0.024 and 0.035 inches); 3.5 mm long (0.018 " wall thickness) and 3.8 mm long (0.025" wall thickness). Anchors were attached to sutures and were set using the procedures described herein into an artificial bone made of open-cell foam made by Sawbones, Inc., P.O. Box 589, Vashon, Washington 98070. Tension was applied to the sutures by a stainless steel

hardened wire attached to the back of the anchor. Tension was measured by a force gauge. The foam/suture assembly was observed for anchor failure. Results are presented below in the Table.

Diameter (mm)	Wall (inches)	Force (lb)	Observations
2.8	0.018	29.0	Failure; 3 wall sections bent back on themselves; foam cone pulled out 0.25 " diameter
	0.024	32.8	Failure; 4 wall sections bent back on themselves; foam cone pulled out 0.23 " diameter
	0.035	33.4	Failure; 4 wall sections bent back on themselves; foam cone pulled out 0.23 " diameter

Diameter (mm)	Wall (inches)	Force (lb)	Observations
3.5	0.018	37.2	Failure; anchor broken with half pulled through; wall sections on the broken half were straight.
	0.018	43.0	Failure; wall sections bent back over themselves
3.8	0.025	33.0	No anchor failure; foam bone wedge pulled out and only 2 wall sections were spread; foam pullout .5 " diameter/.25" deep
	0.025	51.0	No anchor failure; all wall sections spread; foam bone wedge pulled out; .75: diameter/.25" deep

Equivalents

It should be understood that various changes and modifications of the preferred embodiments may be made within the scope of the invention. Thus it is intended that all matter contained in the above description be interpreted in an illustrative and not limited sense.

1. A suture anchor comprising:

an expander element having proximal and distal ends and an anchoring element adapted for movement within a bone hole from a first position, where a proximal end of the anchoring element is in facing relationship to the distal end of the expander element, and then to a second position, where the anchoring element moves proximally within the bone hole so that its proximal end telescopes over the distal end of the expander element, forcing the proximal end of the anchoring element into a wall of the bone hole.

2. The anchor of claim 1, further comprising means for moving the anchoring element from the first to the second position.

3. An suture anchoring device to affix a suture in a bone, comprising:

a tubular anchoring element for engagement with a hole drilled in a bone, the element having opposed proximal and distal ends connected by way of a central longitudinal axis, the element having defined therein an axial channel extending from the proximal to the distal end thereof, the element having inner and outer peripheral surfaces forming a wall therebetween, wherein the wall has defined in it a plurality of axially-oriented slots beginning at the proximal end of the anchoring element and extending distally, the slots in communication with the axial channel; and

a plurality of flexible wall sections further defined between the axially-oriented slots, wherein a proximal surface of a wall section comprises a first camming surface for mating with a second camming surface on an expander element, the first camming surface arranged to telescope over the second camming surface so that, when the anchoring element is disposed in the bone hole

and moved proximally against the expander element, the flexible wall sections expand into the bone.

4. The anchoring device of claim 3, further comprising a suture retainer engaged with the anchoring element.

5. The anchoring device of claim 3, wherein each flexible wall section of the plurality of flexible wall sections is more flexible at its proximal end than at its distal end, so that each proximal end of each said flexible wall section expands into the bone at an oblique angle to the central longitudinal axis.

6. A suture anchoring device to affix a suture in a bone, comprising:

a tubular anchoring element for engagement with a hole drilled in a bone, the element having opposed proximal and distal ends, the element having defined therein an axial channel extending between the proximal and distal ends of the element, the element having inner and outer peripheral surfaces forming a wall therebetween,

wherein the wall comprises a plurality of flexible sections adapted for movement from a first position, where the flexible wall sections are arranged along the outer peripheral surface of the element parallel to the axial channel, to a second position, where proximal ends of the flexible wall sections are forced to expand into a wall of the bone hole; and

a suture retainer engaged with the element.

7. The anchoring device of claims 3 or 6, further comprising screw threads disposed on the inner peripheral surface of the anchoring element at its distal end.

8. A suture anchor assembly, comprising:

an insertion stem having proximal and distal ends, the distal end for engagement with a distal end of a tubular anchoring element;

a tubular anchoring element having defined therein an axial channel for loading onto the stem and having a distal end for engagement with the distal end of the stem, the anchoring element including inner and outer peripheral surfaces forming a wall therebetween, the wall having defined therein a plurality of axially-oriented slots in communication with the axial channel, the slots beginning at a proximal end of the element and extending distally, wherein the plurality of slots further define a plurality of flexible wall sections disposed between adjacent, axially-oriented slots; and

a tubular expander element having defined therein an axial channel, the expander element for loading onto the stem and having a distal end for engagement with the proximal end of the tubular anchor element, wherein the tubular anchor element is adapted for proximal movement within a bone hole from a first position, where a proximal end thereof is engaged with the distal end of the expander element, to a second position, where the proximal end of the tubular anchor element telescopes over the distal end of the expander element so that flexible wall sections expand into a wall of the bone hole.

9. The assembly of claim 8, wherein the insertion stem includes a frangible section adjacent the distal end thereof that is adapted to break when sufficient proximal force is applied to the stem.

10. The assembly of claim 8, further comprising a camming surface disposed on at least one proximal end of at least one flexible wall section, the camming surface adapted to engage with at least one camming surface disposed at a distal end of the expander element.

11. The assembly of claim 8, wherein a proximal end of the expander element includes a peripheral flange integral therewith.

12. The assembly of claim 8, further comprising a tool for removing the anchor element from the bone hole.

13. The assembly of claim 8, further comprising a tool for applying proximally-directed tension to the insertion stem.

14. A kit for deploying a suture anchor in a bone hole, comprising:

the suture anchor assembly of claim 1; a drill; a drill guide; a deployment device; and a tool for removing the anchor element once deployed.

15. A method for deploying a suture anchor in a bone hole, comprising:

providing a suture anchoring element of claim 1 to an opening in a bone,

fixing an expander element within the bone hole that a distal end of the expander element is in facing relationship to a proximal end of the anchoring element;

moving the anchoring element proximally within the bone hole so that the proximal end of the anchoring element telescopes over the distal end of the expander element and a flexible outer surface of the anchoring element engages the bone.

16. The method of claim 15, wherein the step of providing comprises engaging the anchoring element with an insertion stem and placing the insertion stem into the bone hole.

17. The method of claim 16, wherein the step of fixing comprises engaging the expander element with the insertion stem so that the distal end of the expander element is engaged with a proximal end of the anchoring element.

18. The method of claim 17, wherein the step of moving comprises applying a proximal tensional force to the insertion stem so that the proximal end of the anchoring element telescopes over the distal end of the expander element.

19. The method of claim 18, further comprising releasing the insertion stem from the anchoring element.

20. The method of claim 19, wherein the step of releasing includes activating a frangible section of the insertion stem so that it breaks.

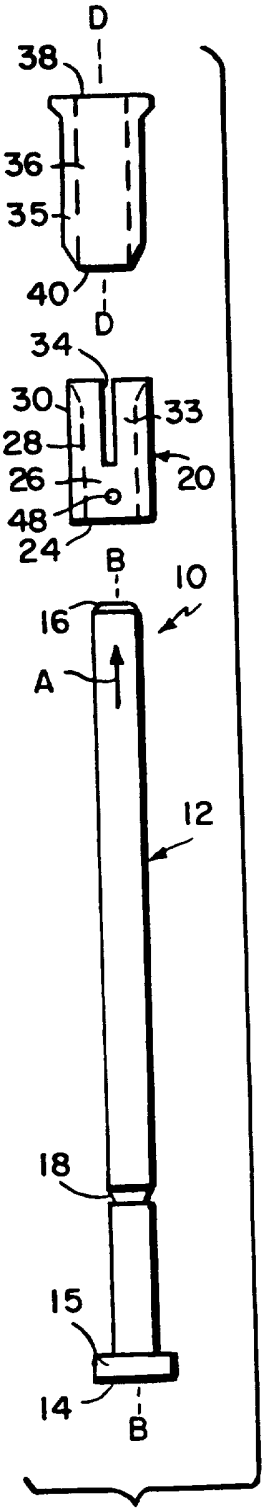


FIG. 1

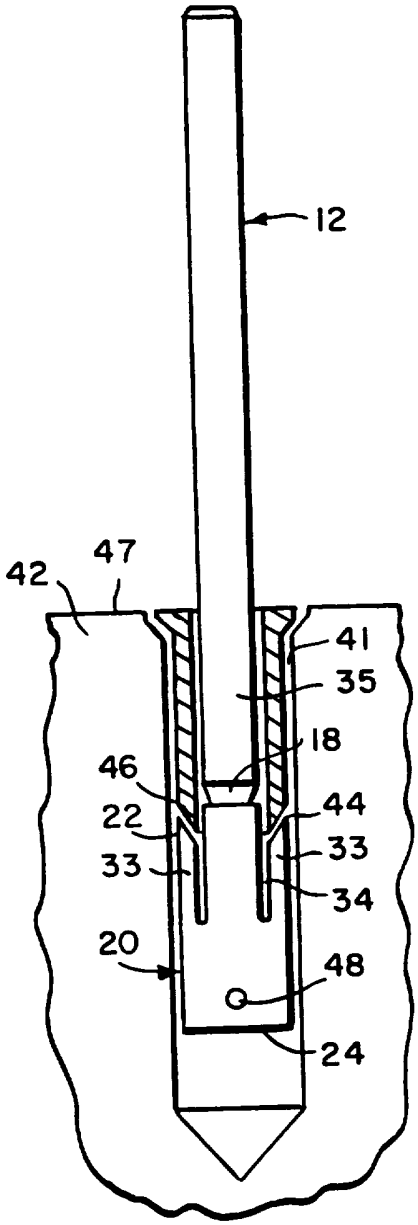
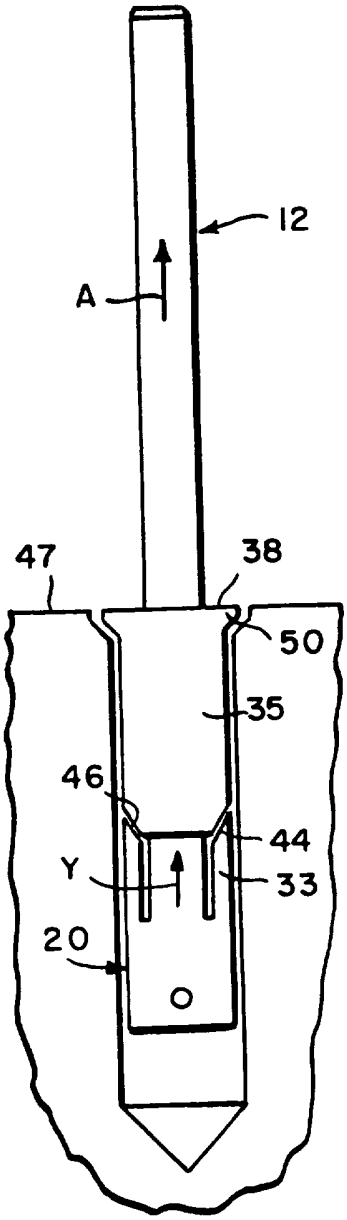


FIG. 2



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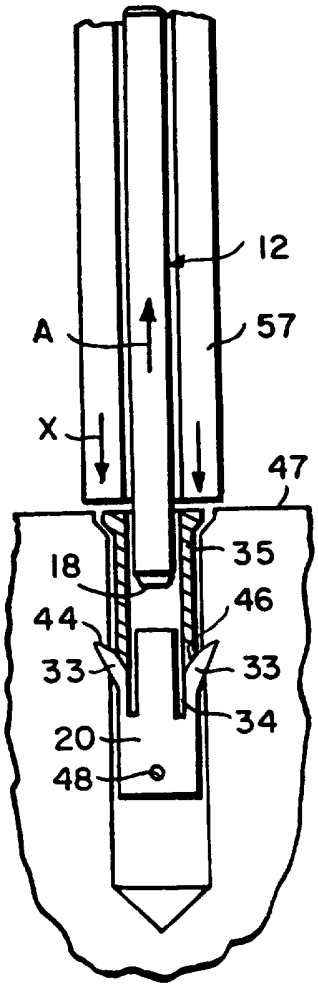


FIG. 4

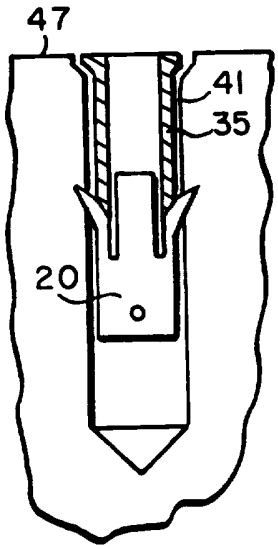
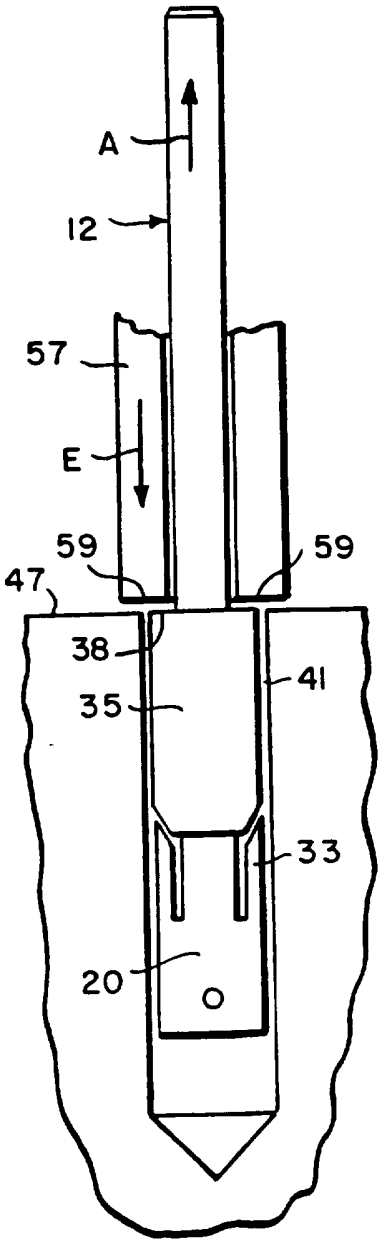


FIG. 5



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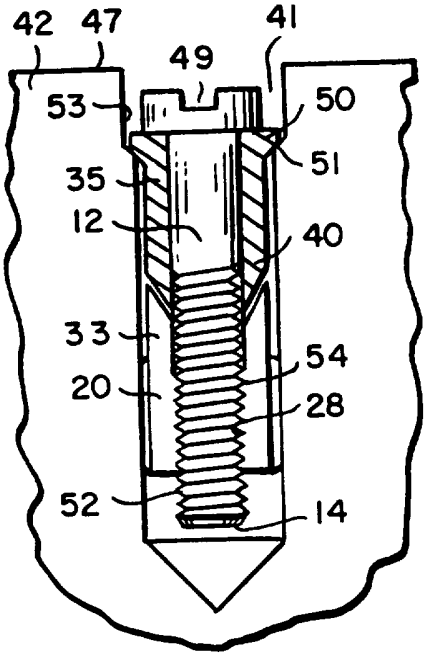


FIG. 7

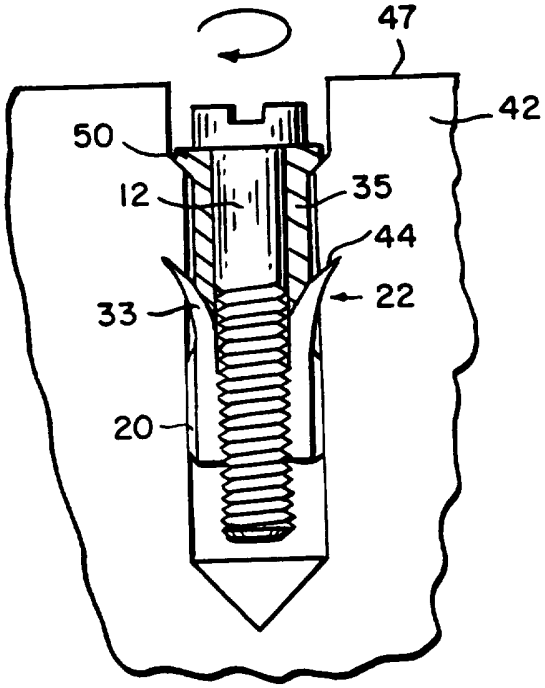


FIG. 8A

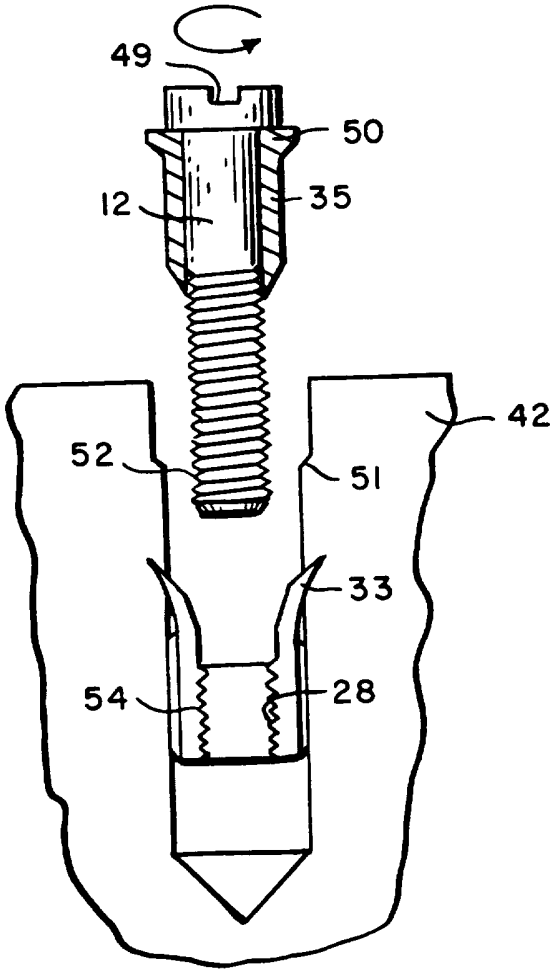
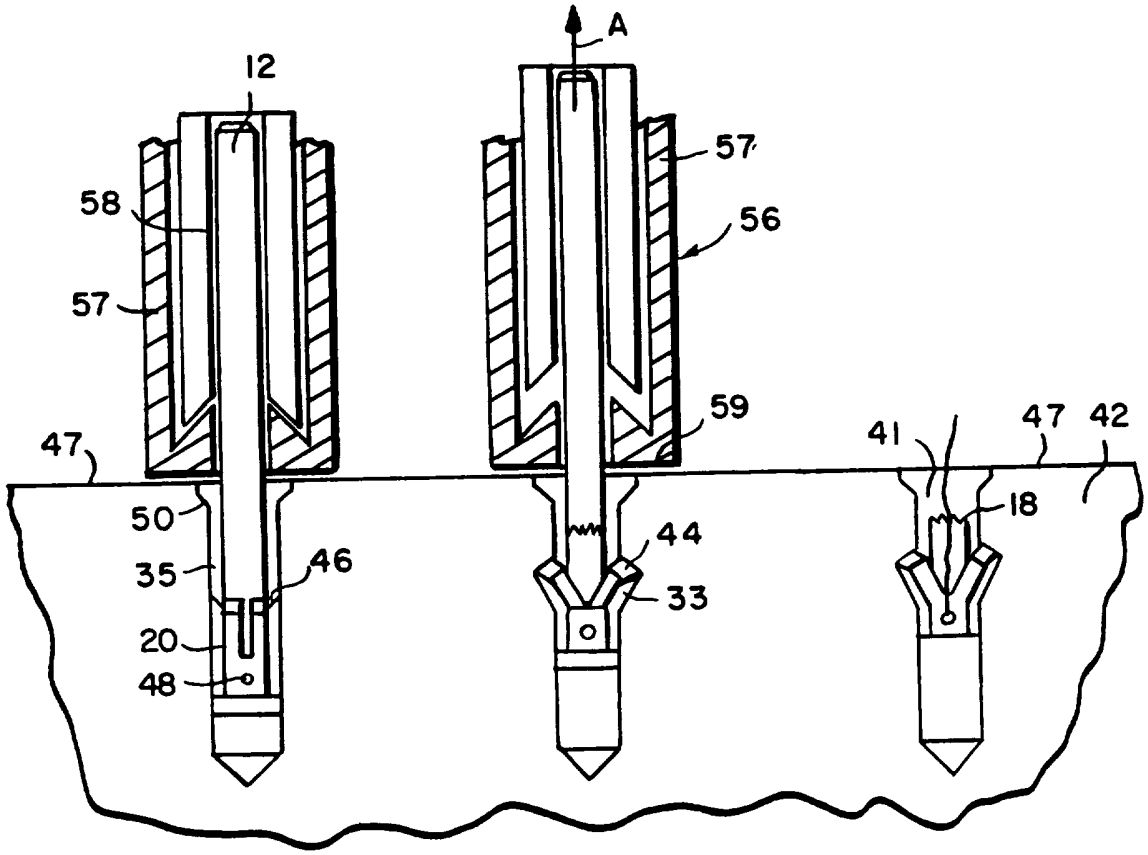


FIG. 8B



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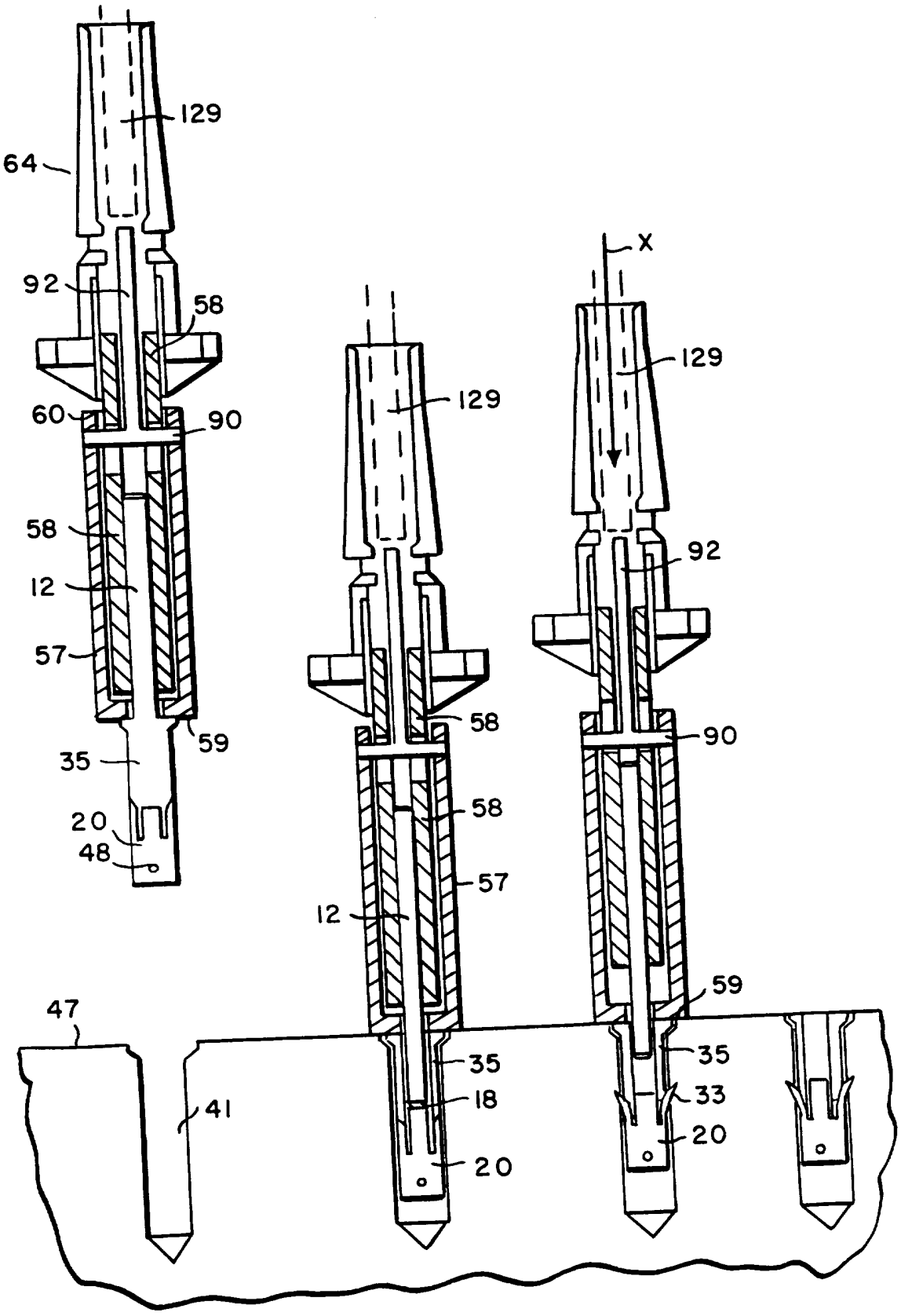
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FIG. 10

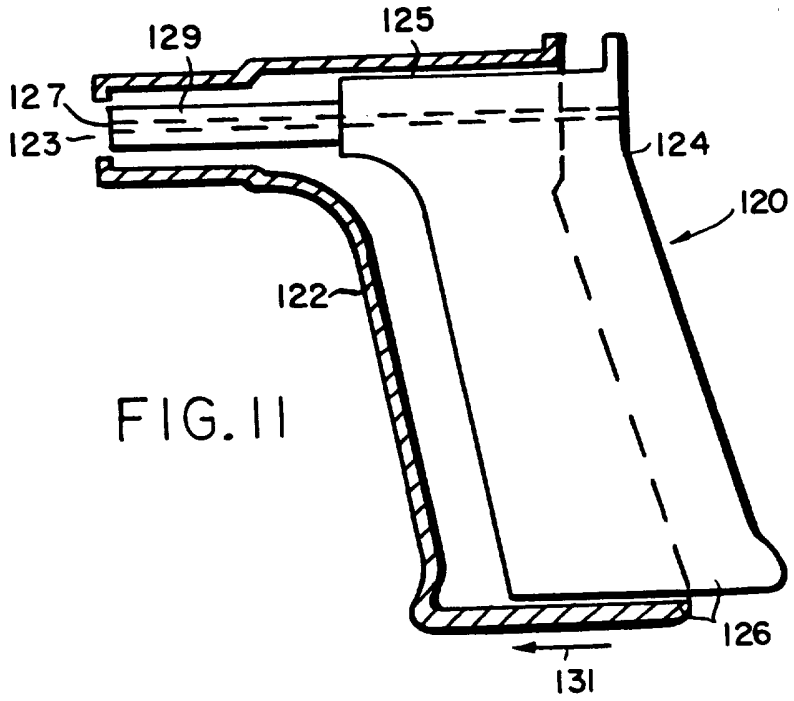
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FIG. 11

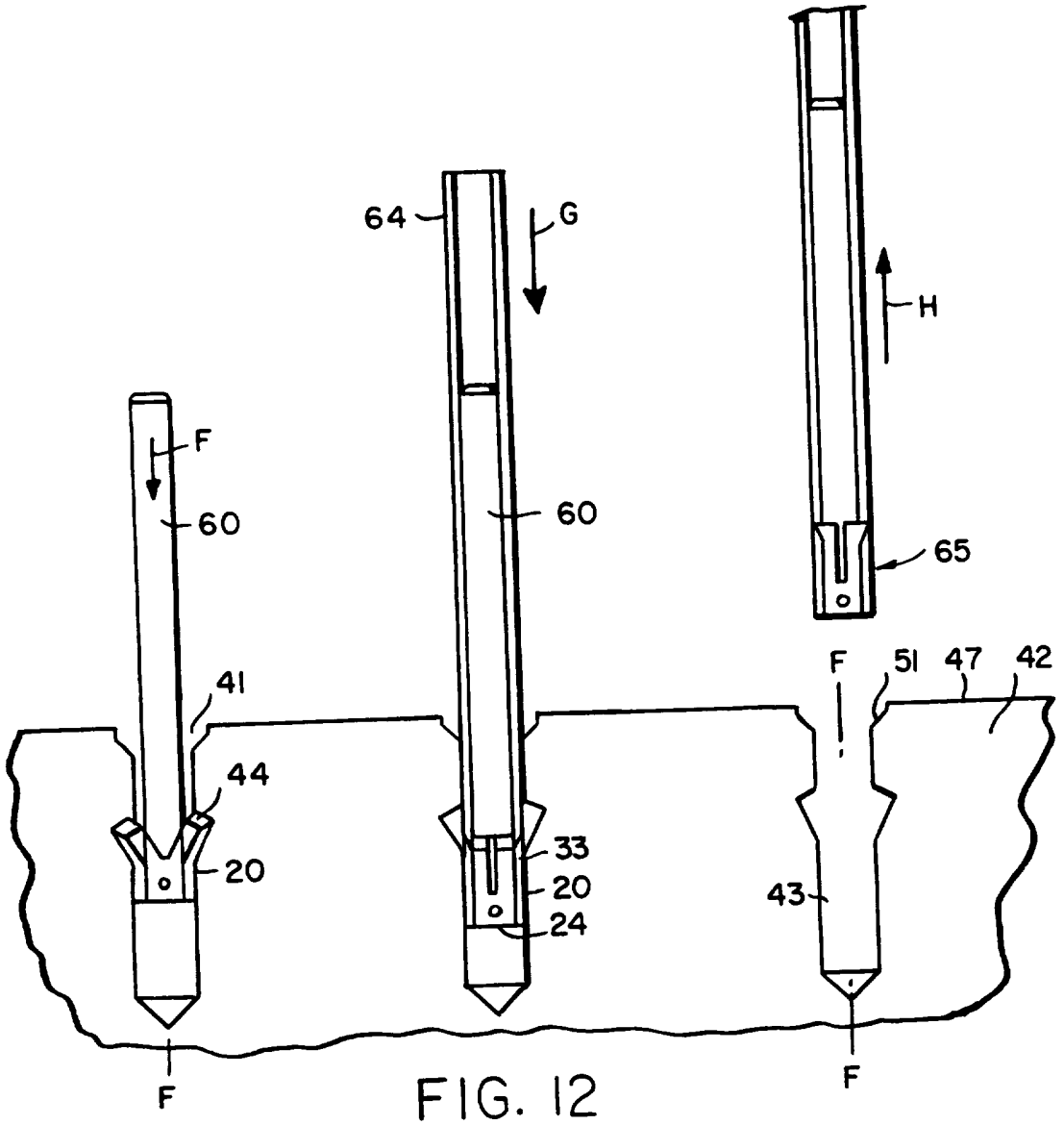
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FIG. 12

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 95/14724

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/04

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 6 A61B A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP,A,0 611 551 (USSC) 24 August 1994 see figures 4,5 ---	6 1-4,8-11
X A	US,A,5 176 682 (CHOW) 5 January 1993 see claims 10,11 ---	1 12,14
Y A	WO,A,92 04874 (NICHOLSON) 2 April 1992 see figures 2,4,7,11,12 ---	1-4,8-11 14
A	EP,A,0 251 583 (PFIZER) 7 January 1988 see column 15, paragraph 4 - column 17, paragraph 1; figures 1-5 ---	1-3,6-8, 10-14
A	FR,A,2 622 430 (LABOUREAU) 5 May 1989 see figures 1,4 --- -/--	7

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 1996	12. 04. 96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	**Authorized officer** Barton, S

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

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 95/14724

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US,A,5 372 604 (TROTT) 13 December 1994 see figure 8	1
A	EP,A,0 238 223 (3M) 23 September 1987 see figure 4	7
A	EP,A,0 270 704 (LUTZE) 15 June 1988 see figures 4,6	9
A	US,A,5 141 520 (GOBLE) 25 August 1992 see column 5, line 9 - line 10; figures 7,10	5

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

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/US95/14724

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

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

1. [X] Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT.

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

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

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

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

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

2. [ ] As all searchable claims could be searches 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

Inte onal Application No
PCT/US 95/14724

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int onal Application No
PCT/US 95/14724

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