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(54) Title: **FIXATION DEVICE FOR USE IN SURGERY**

(57) Abstract: A fixation device (10) for use as an anchor on a bone site, and which comprises: a shank (11) having a core diameter, and provided with first and second ends (12, 13); an external screw thread (14) on the shank (11), located between the first and second ends (12, 13); a socket (19) in the shank (11); and an aperture which is capable of receiving at least one strand of suture which extends transversely from a first opening on the exterior of the shank (11), through the socket, to a second opening on the opposite side of the shank. There is also disclosed an insertion instrument (20) for use with the fixation device.



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FIXATION DEVICE FOR USE IN SURGERY

This invention relates generally to fixation devices and insertion instruments for use in surgery, and in particular, but not exclusively, to instruments for inserting fixation devices used in implant surgery.

5 Fixation devices are presently used, amongst other things, to anchor suture which is to be tied to soft tissue (e.g. ligament or skin) that has become detached from the bone due to trauma or surgery. The suture will securely hold the soft tissue adjacent to the bone so that the healing process can occur and allow the soft tissue to become reattached to the bone.

 To insert fixation devices, a tool or insertion instrument is needed. There is no
10 generic insertion instrument as they are generally specific to the fixation device being used. Many different embodiments of fixation devices and insertion instruments exist.

 The present invention seeks to provide a fixation device and insertion instrument that provides an increase in the fixing strength of the fixation device in the bone over the prior art. It also seeks to make the process of inserting fixation devices into bone easier and include
15 features that provide an improved technique of attaching soft tissue to suture.

 The invention seeks preferably to achieve one or more of the following objectives:

1. to provide a fixation device with increased length thread for bone engagement;

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2. to provide a fixation device with an increasing thread thickness for increased bone engagement strength;
3. to provide a fixation device that provides improved techniques of attaching suture to the fixation device, thus allowing an improved technique for anchoring soft tissue to bone, and increasing the number of anchor points per thread which in turn increases the strength of the anchor;
4. to provide an insertion instrument that can be coupled with the fixation device, which makes the process of inserting the fixation device into a bone site and the attachment of suture to soft tissue easier;
5. to provide a fixation device that has a shank with as small as inner core diameter as practically possible, thus increasing the depth and pitch of the thread for increased bone engagement strength, while still allowing the above objectives to be met; and
6. to provide a fixation device and insertion instrument that allows the fixation device to be inserted into a bone site first axially, and then rotationally.

According to a first aspect of the present invention there is provided a fixation device for use as an anchor on a bone site, said fixation device comprising: a shank having a core diameter, and having first and second ends, the first end of said shank forming a point; an external screw thread on said shank, located between said first end and said second end, said

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external screw thread having an outer diameter; a socket in said shank, extending axially from said second end toward said first end; and an aperture which is capable of receiving at least one strand of suture or other flexible elongate connecting member, proximal to said second end, extending transversely from a first opening on the exterior of said shank, through said socket, to a second opening on the opposite side of said shank.

According to a second aspect of the present invention there is provided an insertion instrument for inserting fixation devices in a bone site, said insertion device comprising: an elongate gripping portion for manipulation of the instrument; and an elongate nose; in which: a first section of said elongate nose has a polygonal, star or turbine profile section that is fixed to a first end of said gripping portion; a second section of said elongate nose, distal to said gripping portion, forms a point which may be used to pierce a hole in soft tissue through which at least one strand of suture may be passed through; between said first and said second sections, a middle section is formed and is generally cylindrical with a diameter less than the width of said first section at its widest point; and an aperture, for receiving at least one strand of suture or other flexible elongate connecting member, is formed transversely through said middle section.

According to a third aspect of the present invention there is provided a fixation tool assembly for use in forming an anchor point on a bone site for at least one strand of suture or

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other flexible elongate connecting member to hold soft tissue adjacent to the bone site, the assembly comprising a fixation device and an insertion instrument adapted to be coupled together to allow the fixation device to enter the bone site, in which; an elongate nose fixed to a gripping portion of said insertion instrument is receivable by a socket of said fixation device; apertures exist in said elongate nose and said fixation device which are capable of being aligned when said elongate nose is coupled with said fixation device enabling said suture to be received by said apertures; and a first end of said fixation device allows initial driving of the fixation device into the bone site, and an external screw thread on said fixation device further drives the device into the said bone site upon rotation of the said fixation device by said insertion instrument.

Preferred embodiments of fixation devices and insertion instruments according to the invention will now be described in detail, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is an axial view of a first embodiment of the fixation device according to the invention.

Figure 2(a) illustrates a schematic axial cross-section of the first embodiment of the fixation device, coupled with a preferred embodiment of the insertion instrument according to the invention.

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Figure 2(b) illustrates a schematic axial cross-section of an alternative embodiment of the fixation device, coupled with an alternative embodiment of the insertion instrument according to the invention.

Figure 3 illustrates a schematic perspective view of the first embodiment of the fixation device, coupled with a preferred embodiment of the insertion instrument which is being pulled out of the fixation device.

Figure 4 illustrates an enlarged detail of the first embodiment of the fixation device with the back section cut-away and the insertion instrument not shown, showing the suture arrangement within the fixing device.

Figure 5 illustrates another perspective view of the first embodiment of the fixation device coupled with a preferred embodiment of the insertion instrument which is being pulled out of the fixation device.

Figure 6 illustrates the manner in which the fixation device may be inserted into the bone of a patient and the manner in which soft tissue may be tied to the fixation device using the anchored suture.

Figure 7 illustrates a schematic perspective view of a second embodiment of the fixation device according to the invention with the increase in depth and pitch of the thread.

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Figure 8 shows a schematic axial cross-section of the second embodiment of the fixation device according to the invention when coupled with a preferred embodiment of the insertion instrument.

Figure 9 illustrates two axial views of the second embodiment of the fixation device, showing the stepped profile, and also showing the increase in width of the thread along its path.

The same items in different Figures share common reference numerals.

Referring now to Figure 1 of the drawings, a preferred embodiment of the fixation device is shown, designated generally by reference 10. The fixation device 10 has a smooth cylindrical shank 11, a point 12 at one end of the shank 11, a flat end 13 at the opposite end of the shank 11, and a threaded portion 14 which starts at the end of the smooth part of the shank 15 and continuing to flat end 13 of fixation device 10. There exists a recess 11a extending axially from the point 12, through the shank 11 to the threaded portion 14. Recess 11a helps cut the nose and thread of the fixation device into the bone, so providing a self tapping action when inserting the fixation device into a bone site. Fixation device 10 incorporates a transverse hole 17, and recess 18 on the outside of the fixation device 10, which takes form of an axially extending slot connecting transverse hole 17 to flat end 13. Another recess (not shown) similar to recess 18 exists on the opposite side of fixation device 10,

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starting from transverse hole 17 and extending parallel to the axis to flat end 13. The inner core diameter 19 of the shank 11 is constant along the length of the fixation device. The outer thread diameter 19a is also constant along the length of the fixation device.

Referring now to Figure 2(a), a bore 19 is formed in the fixation device 10 which
5 extends axially from flat end 13 towards point 12 and is of sufficient length to enable an elongate nose 21 of an insertion instrument 20 (and a following block 22) to be inserted inside the fixation device 10, with flat end 13 fitting flush against a handle 24 of the insertion instrument. Bore 19 and block 22 may be of any shape that allows block 22 to interlock with bore 19 and provide a rotational coupling to rotate the fixing device 10 around its axis when
10 handle 24 is rotated. By way of example and not limitation, bore 19 has a hexagonal profile which allows a hexagonal block 22 of the elongate nose 21 of the insertion instrument to interlock with bore 19. Elongate nose 21 of the insertion instrument 20 contains a transverse hole 23 through which a suture 30 is able to pass through. When transverse hole 23 is appropriately lined up with transverse hole 17, suture 30 is able to pass through the fixation
15 device 10 and elongate nose 21. Once threaded, each end of suture 30 is fixed to handle 24 of the insertion instrument 20 to pull it taut.

Referring now to Figure 2(b), an alternative embodiment of the fixation device and insertion instrument as described in Figure 2(a) is shown. In this embodiment, bore 19'

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extends through the fixation device as shown. Insertion instrument 20 couples with the fixation device in the same manner as described in relation to Figure 2(a) above, with elongate nose 21' extending along the length of bore 19', protruding from the end of the fixation device ending at point 25'. Point 25' and exposed portion 11' of elongate nose 21' of the insertion instrument correspond to point 12 and smooth shank 11 in Figure 2(a) and provide the same properties of aiding the insertion of the fixation device into a bone site by impaction as discussed in relation to Figure 6 below. As illustrated in Figure 2(a), there exists gap 26 above transverse hole 23 for which its use is described below in relation to Figure 3. As illustrated in Figure 2(b) no gap exists above transverse hole 23. This is by no way limiting and it will be appreciated that preferred embodiments of the insertion instrument provide that elongate nose 21 or 21' may or may not contain gap 26 above transverse hole 23.

Referring now to Figure 3, this shows another preferred embodiment of the invention, and in particular a method of removing the insertion instrument 20. Once fixation device 10 has been inserted into a bone, insertion instrument 20 needs to be removed. Insertion instrument 20 is pulled axially in the direction shown by arrow X. Once the ends of suture 30 are detached from handle 24, insertion instrument 20 can be detached from suture 30. Suture loop 31 can be un-hooked through gap 26 in elongate nose 21, leaving a loop of suture 31 as shown in Figure 4. Figure 4 shows an enlarged cut-away detail of fixation device 10, once

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insertion instrument 20 has been removed. Alternatively, as discussed above, transverse hole 23 may be closed, i.e. gap 26 may not exist. In this instance the suture may then be removed from the transverse hole 23 by cutting the suture at loop 31.

Figure 5 illustrates an alternative perspective view of the fixation device 10, suture 30 and insertion instrument 20 as they are in Figure 3.

Referring now to Figure 6, this shows another preferred embodiment of the invention and successive steps in the fixation of an anchoring device to bone. By way of example and not limitation, there is shown a method of inserting fixation device 10 into bone 40 using the insertion instrument and anchoring a soft tissue 50. Fixation device 10 is pre-loaded on insertion instrument 20 with suture 30 already threaded through the fixation device and nose of the insertion instrument as described above, and attached to handle 24. Fixation device 10 is impacted into the bone by use of insertion instrument 20 as shown in Figure 6(a), until it reaches a specified depth such that the thread begins to engage as shown in Figure 6(b). The fixation device is then screwed into the bone as shown by arrow Y in Figure 6(b) until it is fully inserted as shown in Figure 6(c). The insertion instrument is removed by pulling handle 24 in the axial direction as shown by arrow X in Figure 6(d). Point 25 of elongate nose 21 of the insertion instrument 20 may be used to pierce a hole in soft tissue 50 that is to be attached to bone 40 as shown in Figure 6(e). Loop 31, created by the removal of insertion instrument

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20, may be released from the insertion instrument by unhooking it through gap 26 as described above, producing an arrangement as shown in Figure 6(f). The ends of suture 30 are threaded through loop 31 as shown in Figure 6(g), and the ends of the suture are pulled to pull the ligament or soft tissue 50 into position as shown in Figure 6(h). A knot 60 is created with the
5 ends of suture 30 through the ligament or soft tissue 50 as shown in Figure 6(i). If more than one fixation devices are used, it is possible to link the loops of sutures together from adjacent anchors to produce a running stitch.

Referring now to Figures 7, 8 and 9, another preferred embodiment of the fixation device is shown, designated generally by 70. The properties of fixation device 70 can be taken
10 to be the same as fixation device 10, apart from the differences described below. In order to maximise fixation strength of the fixation device in the bone, the depth and pitch of the thread is required to be increased. This is achieved by reducing the inner core diameter and by increasing the depth of the thread and pitch. In order to accommodate the insertion instrument, the inner core diameter of the shank 11 is required to be increased at the rear of the fixation
15 device 70 (towards flat end 13). The inner core diameter of the shank 11 of the fixation device 70 is therefore not uniform along the threaded portion 14 of the shank 11, but instead has a stepped profile. The diameter of the threaded portion 14 of the shank 11 is smaller towards point 12 of the fixation device than it is towards flat end 13 of the fixation device 70 as shown

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in Figure 7. Figure 8 shows a schematic axial cross-section of fixation device 70 coupled with insertion instrument 80. As shown, the inner core diameter of the threaded portion 14 of the shank 11 of fixation device 70 towards point 12 is less than the inner core diameter of the threaded portion 14 of the shank 11 of fixation device 70 towards the flat end 13. Diameter 73 is smaller than diameter 74, where diameter 74 is of sufficient measurement to enable a bore to extend axially into fixation device 70 which will accommodate elongate nose 81 of insertion instrument 80.

Figure 9 illustrates an axial profile of the stepped profile as described above and illustrates another preferred embodiment of the invention. To further increase the fixation strength of the fixation device within the bone the thread increases in thickness along its path, as illustrated in relation to fixation device 70. The thickness of the thread at 75 (proximal to point 12) is smaller than the thickness of the thread at 76, which in turn is smaller than the thickness of the thread at 77, (proximal to flat end 13). Due to the outer thread diameter 19a remaining constant along the length of the fixation device, the thread goes from having a V shaped profile as at 75, to a flat topped profile as shown at 77.

Advantages in use of examples according to the preferred embodiments of the invention include allowing the thread of the fixation device to extend to the end of the fixation device, thereby providing an increased length of thread for bone engagement over the prior art.

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Moreover, due to the manner in which the suture is threaded through the fixation device, and pulled into a loop on the removal of the insertion device, this allows two fixation points on the soft tissue to be produced from a single suture. With the prior art, it is only possible to produce this number of fixation points when using two sutures per fixation device. Also, to
5 maximise fixation strength of the fixation device in the bone, the depth of the thread and the pitch has been increased by reducing the diameter of the shank and increasing the pitch along the front of the fixation device. A stepped profile is needed to accommodate the insertion instrument, allowing the aforementioned features and advantages to still be incorporated into the design. To further increase the fixation strength, the thread of the fixation device
10 uniformly increases in width, thereby increasing the compression force on the bone allowing a tighter grip to be achieved.

CLAIMS

1. A fixation device for use as an anchor on a bone site, said fixation device comprising:
 - a shank having a core diameter, and having first and second ends;
 - an external screw thread on said shank, located between said first end and said second end, said external screw thread having an outer diameter;
 - a socket in said shank, extending axially from said second end toward said first end;and
 - an aperture which is capable of receiving at least one strand of suture or other flexible elongate connecting member, proximal to said second end, extending transversely from a first opening on the exterior of said shank, through said socket, to a second opening on the opposite side of said shank.
2. A fixation device according to claim 1, in which the first end of said shank forms a point.
3. A fixation device according to claim 1, in which said socket extends from said second end to said first end forming a bore through said shank.
4. A fixation device according to claim 1 or 2, in which there exists a generally smooth cylindrical section between said first end and said external screw thread.
5. A fixation device according to claim 4, in which said thread extends from said smooth cylindrical section to said second end.
6. A fixation device according to any of the preceding claims, in which a receiving section of said socket proximal to said second end has a polygonal, star or turbine profile.
7. A fixation device according to any of the preceding claims, in which a first recess capable of receiving at least one strand of suture extends axially, and externally, from said first

opening to said second end, and a second recess capable of receiving at least one strand of suture extends axially, and externally, from said second opening to said second end.

8. A fixation device according to any one of the preceding claims, in which said core diameter is non-uniform along the length of said shank.

9. A fixation device according to claim 8, in which said core diameter towards said second end is larger than the diameter towards said first end.

10. A fixation device according to claim 9, in which said core diameter does not taper, but has stepped increments forming a stepped profile.

11. A fixation device according to claim 10, in which there is at least one stepped increase in diameter.

12. A fixation device according to claim 11, in which there are more than one stepped increases in diameter.

13. A fixation device according to any of the preceding claims, in which the thickness of said thread is non-uniform along its path.

14. A fixation device according to claim 13, in which the thickness of said thread is larger toward said second end than the thickness of said thread toward said first end.

15. A fixation device according to claim 14, in which said outer diameter of said thread is constant and thickness of the outer edge of the thread therefore increases, changing the profile of said thread from a V shape to a wider flat topped edge.

16. An insertion instrument for inserting fixation devices in a bone site, said insertion device comprising:

an elongate gripping portion for manipulation of the instrument; and

an elongate nose;

in which:

a first section of said elongate nose has a polygonal, star or turbine profile section that is fixed to a first end of said gripping portion;

a second section of said elongate nose, distal to said gripping portion, forms a point ;

between said first and said second sections, a middle section is formed and is generally cylindrical with a diameter less than the width of said first section at its widest point; and

an aperture, for receiving at least one strand of suture or other flexible elongate connecting member, is formed transversely through said middle section.

17. An insertion instrument as in claim 16, in which there exists a gap in said middle section, for passing at least one strand of suture or other flexible elongate connecting member through, providing an opening to said aperture forming a hook profile.

18. An insertion instrument as in claim 16 or 17, in which a recess is formed in said middle section and said first section extending axially from said aperture to a distance along said first section, and on the opposite side a second recess extending axially from said aperture to a distance along said first section.

19. An insertion instrument as in any of the preceding claims in which said gripping portion contains, a first recess extending axially from said first end towards second end distal to said elongate nose, and a second recess extending axially from first end proximal to said elongate nose towards second end distal to said elongate nose on opposite side of said gripping portion to said first recess.

20. An insertion instrument as in any of the preceding claims in which means are provided to secure suture proximal to said second end of said gripping portion.

21. A fixation tool assembly for use in forming an anchor point on a bone site for at least one strand of suture or other flexible elongate connecting member to hold soft tissue adjacent to the bone site, the assembly comprising a fixation device and an insertion instrument adapted to be coupled together to allow the fixation device to enter the bone site, in which;

an elongate nose fixed to a gripping portion of said insertion instrument is receivable by a socket of said fixation device;

apertures exist in said elongate nose and said fixation device which are capable of being aligned when said elongate nose is coupled with said fixation device enabling said suture to be received by said apertures; and

a first end of said fixation tool assembly, distal to said gripping portion of said insertion instrument, allows initial driving of said fixation tool assembly into the bone site, and an external screw thread on said fixation device further drives the device into the said bone site upon rotation of the said fixation device by said insertion instrument.

22. A fixation tool assembly as in claim 21 in which a first end of said fixation device distal to said gripping portion of said insertion instrument, allows said initial driving of said fixation tool assembly into the bone site.

23. A fixation tool assembly as in claim 21 in which said elongate nose of said insertion instrument extends through said fixation device and a first end of said elongate nose distal to said gripping portion allows said initial driving of said fixation tool assembly into the bone site.

24. A fixation tool assembly as in any of the preceding claims arranged such that, upon removal of said insertion instrument from said fixation device, the insertion instrument pulls said suture through said aperture on said fixation device, to form a loop of suture extending axially from a second end of said fixation device with the ends of said suture still passing through opposite ends of said aperture on said fixation device.

25. A fixation tool assembly as in claim 24 in which a first end of said elongate nose distal to said gripping portion allows the creation of a hole in said soft tissue, in which said loop of suture may be passed through said hole to form an anchor point.

26. A fixation tool assembly as in claim 25 in which said ends of said suture may be passed through said loop of suture and pulled tight to bring said soft tissue adjacent to said bone site.

27. A fixation tool assembly as in claim 26 in which said ends of said suture may form a knot through a second hole in said suture to form a second anchor point for said suture and said soft tissue.

28. A fixation tool assembly as in any of the preceding claims in which a multiple of said fixation devices may be used to form a running stitch of sutures.

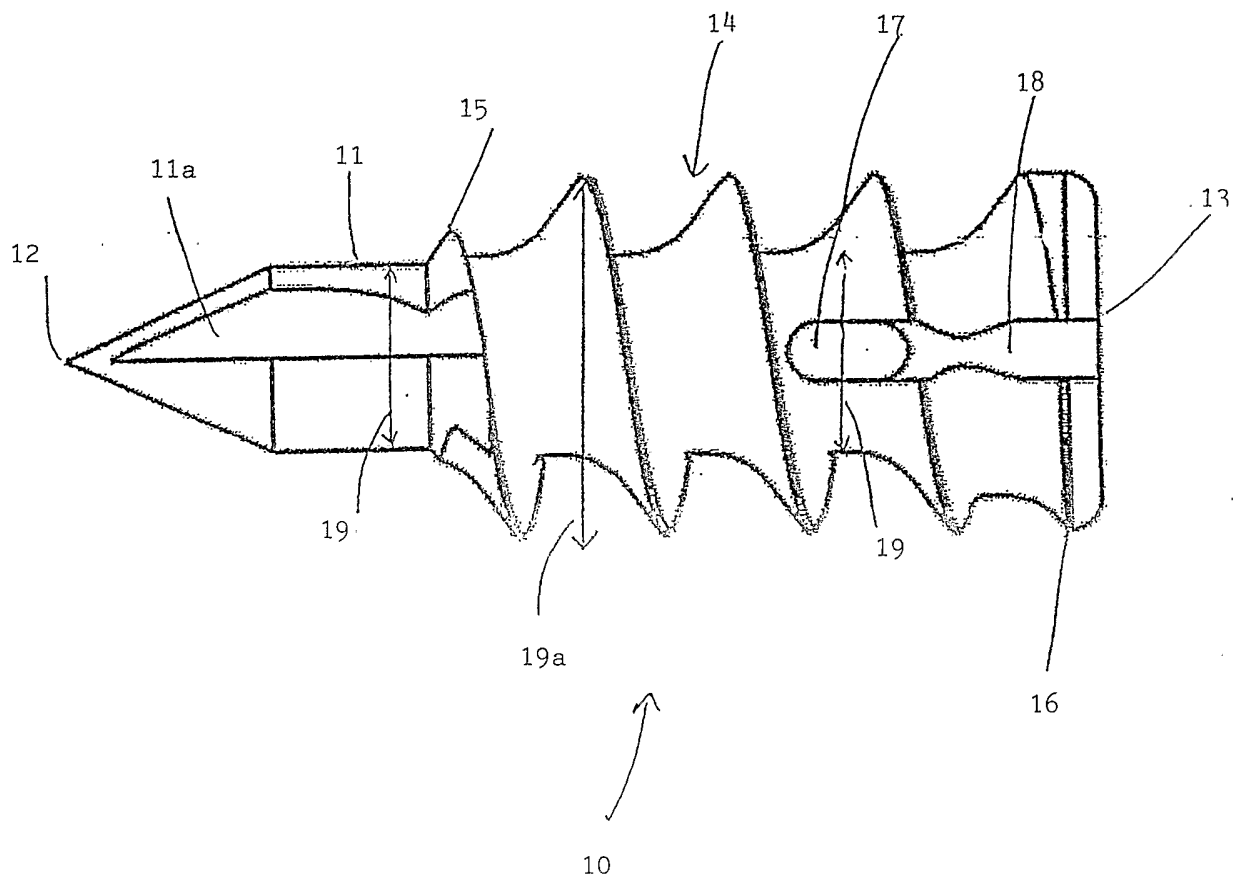
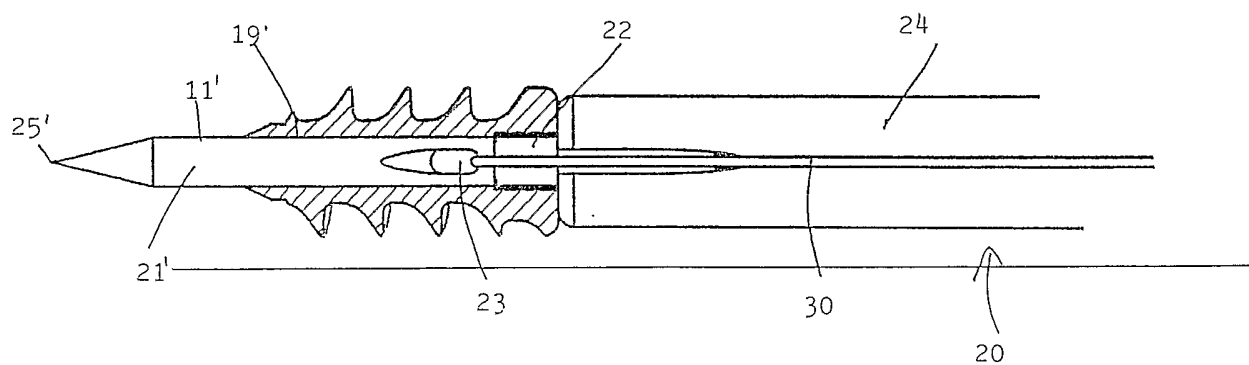
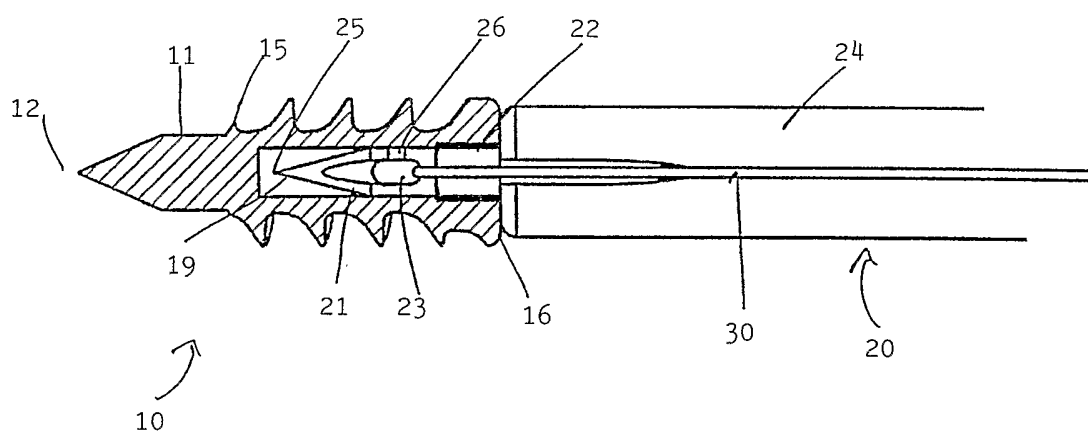


FIGURE 1



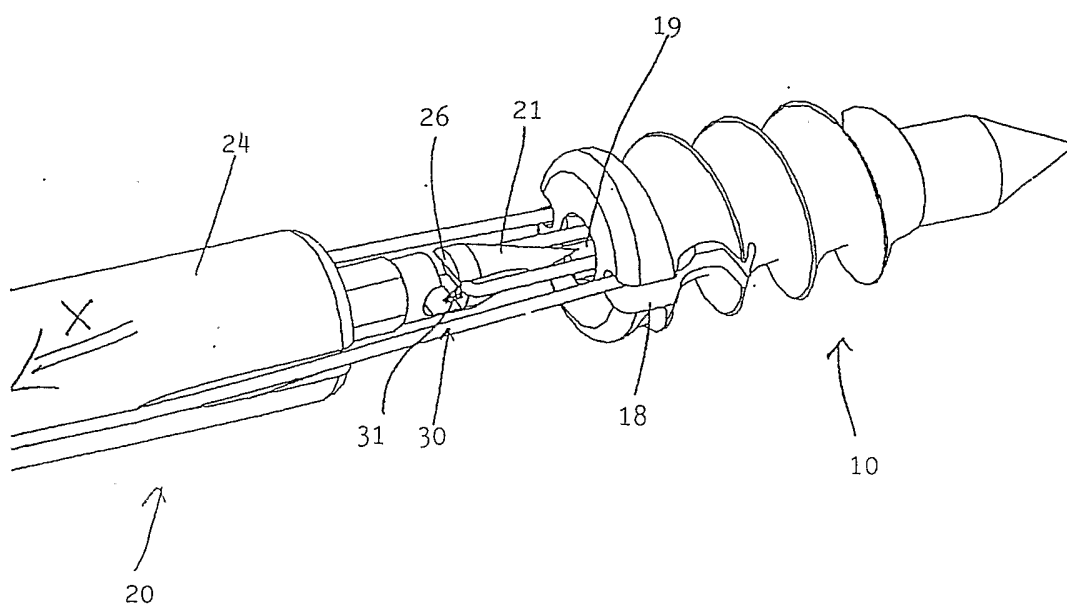


FIGURE 3

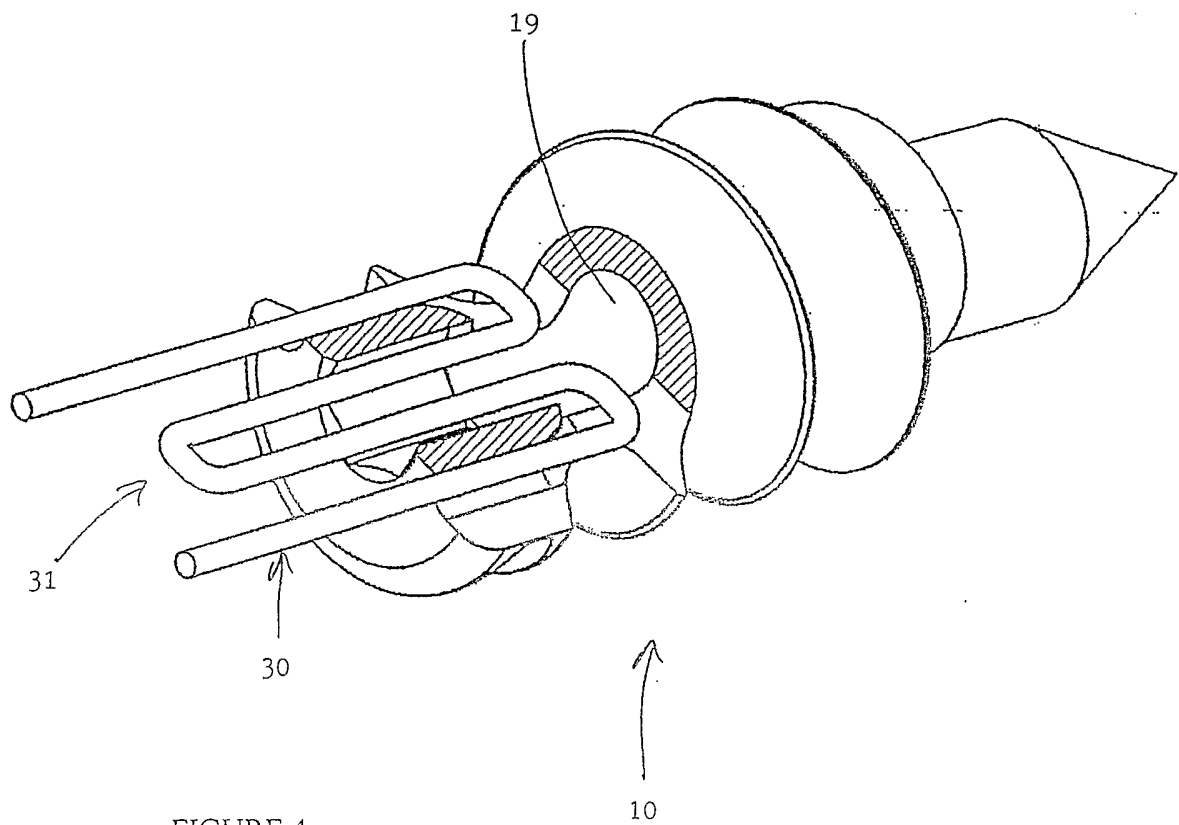


FIGURE 4

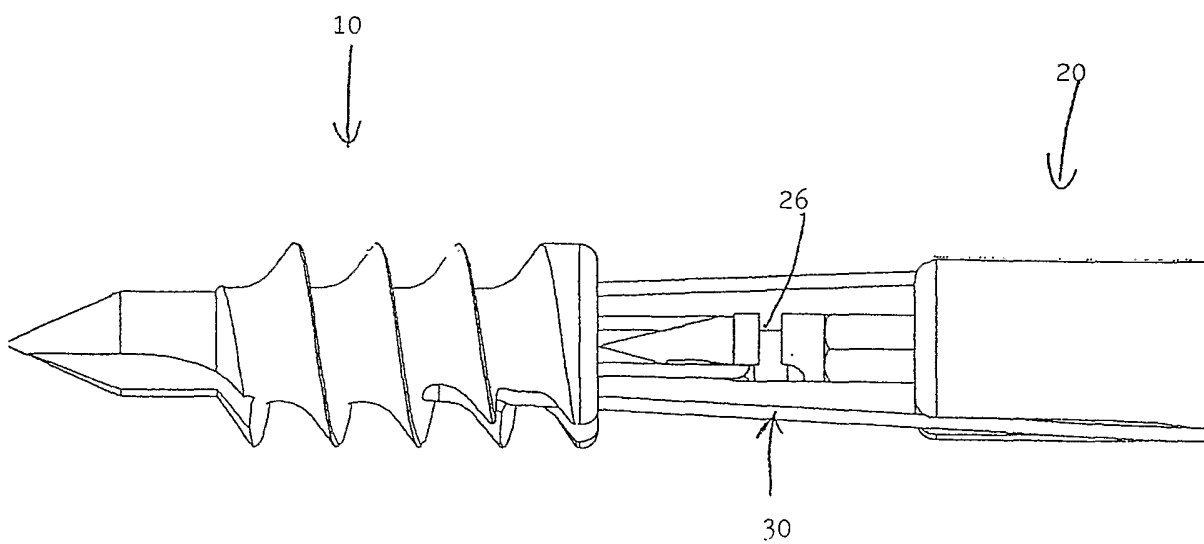


FIGURE 5

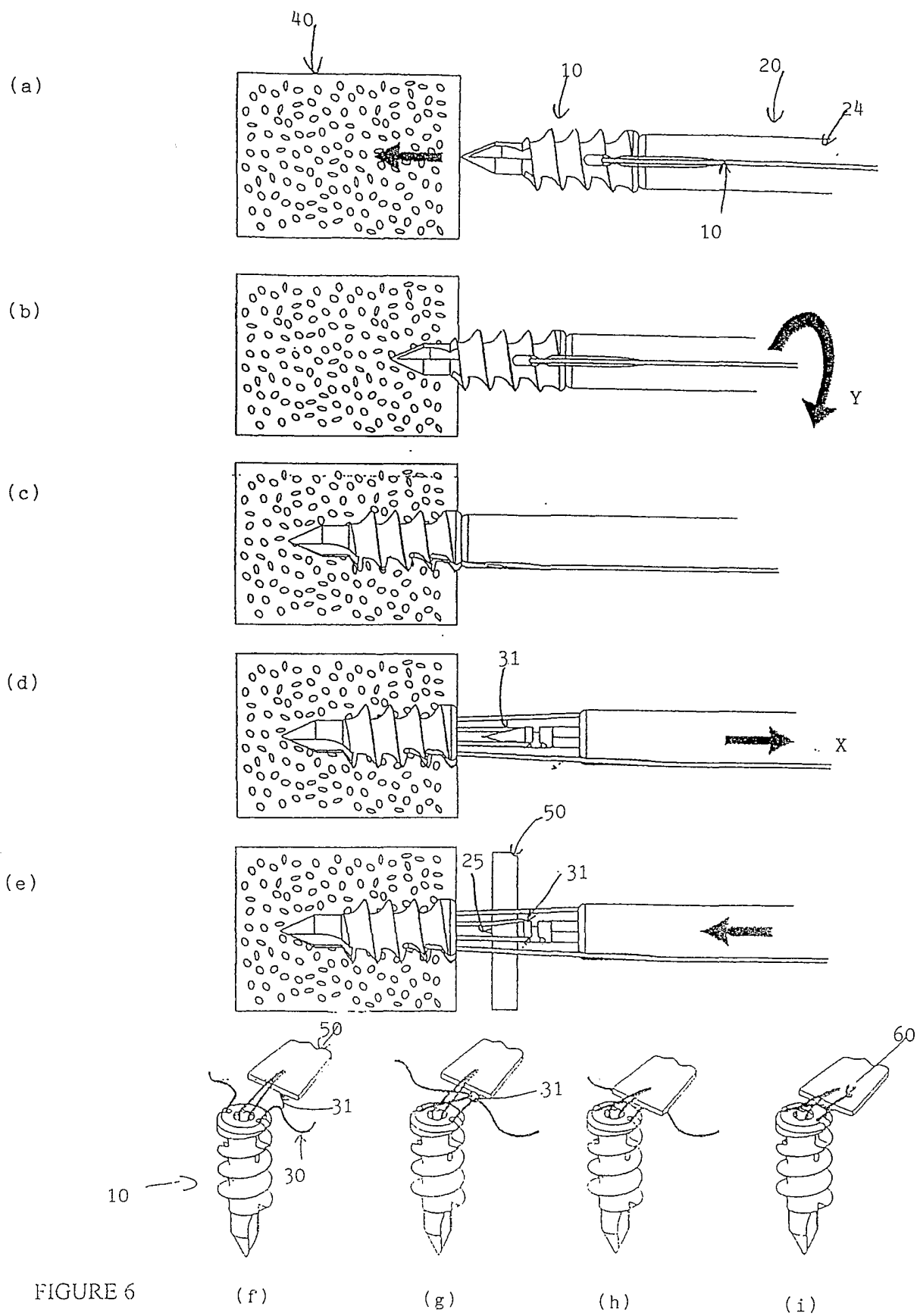


FIGURE 6

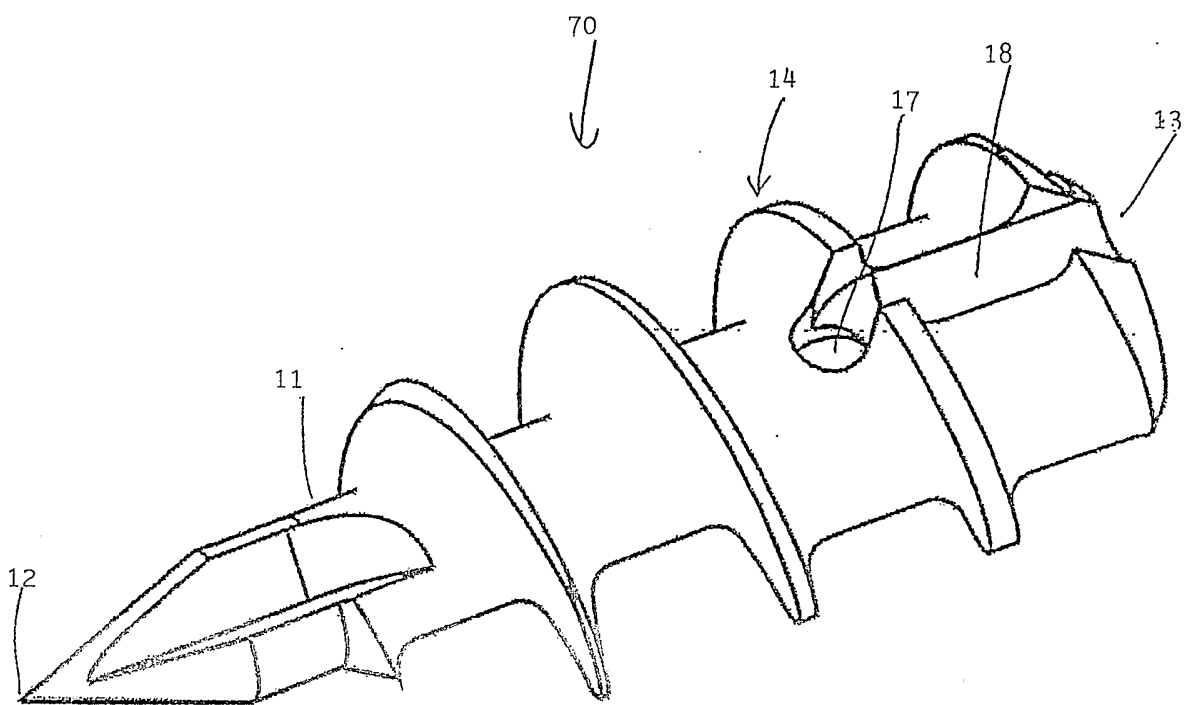


FIGURE 7

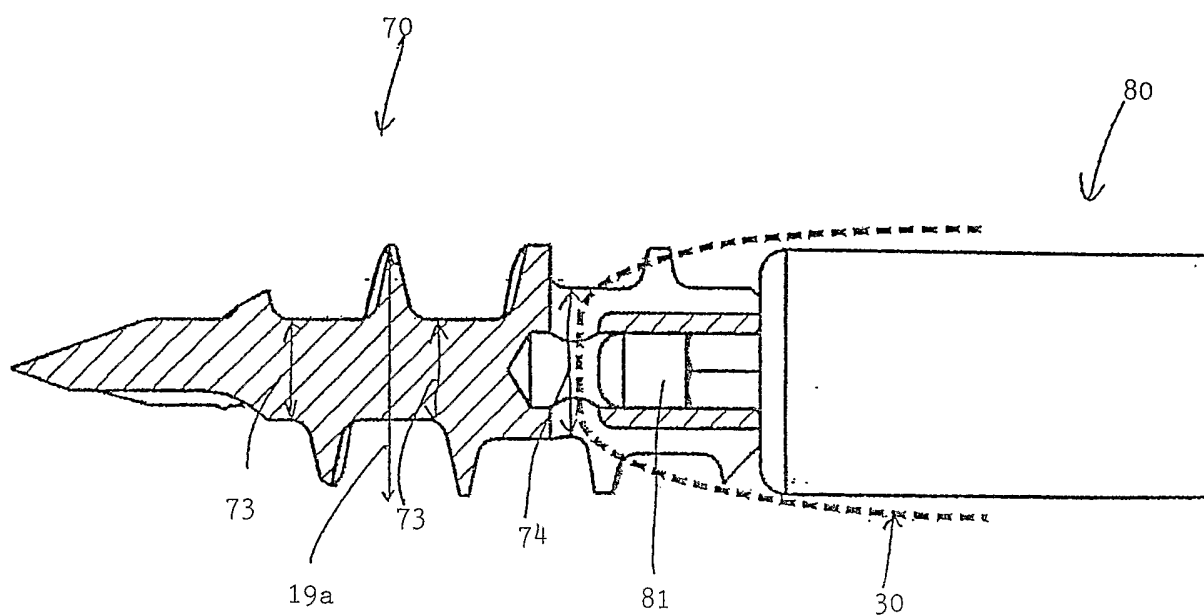


FIGURE 8

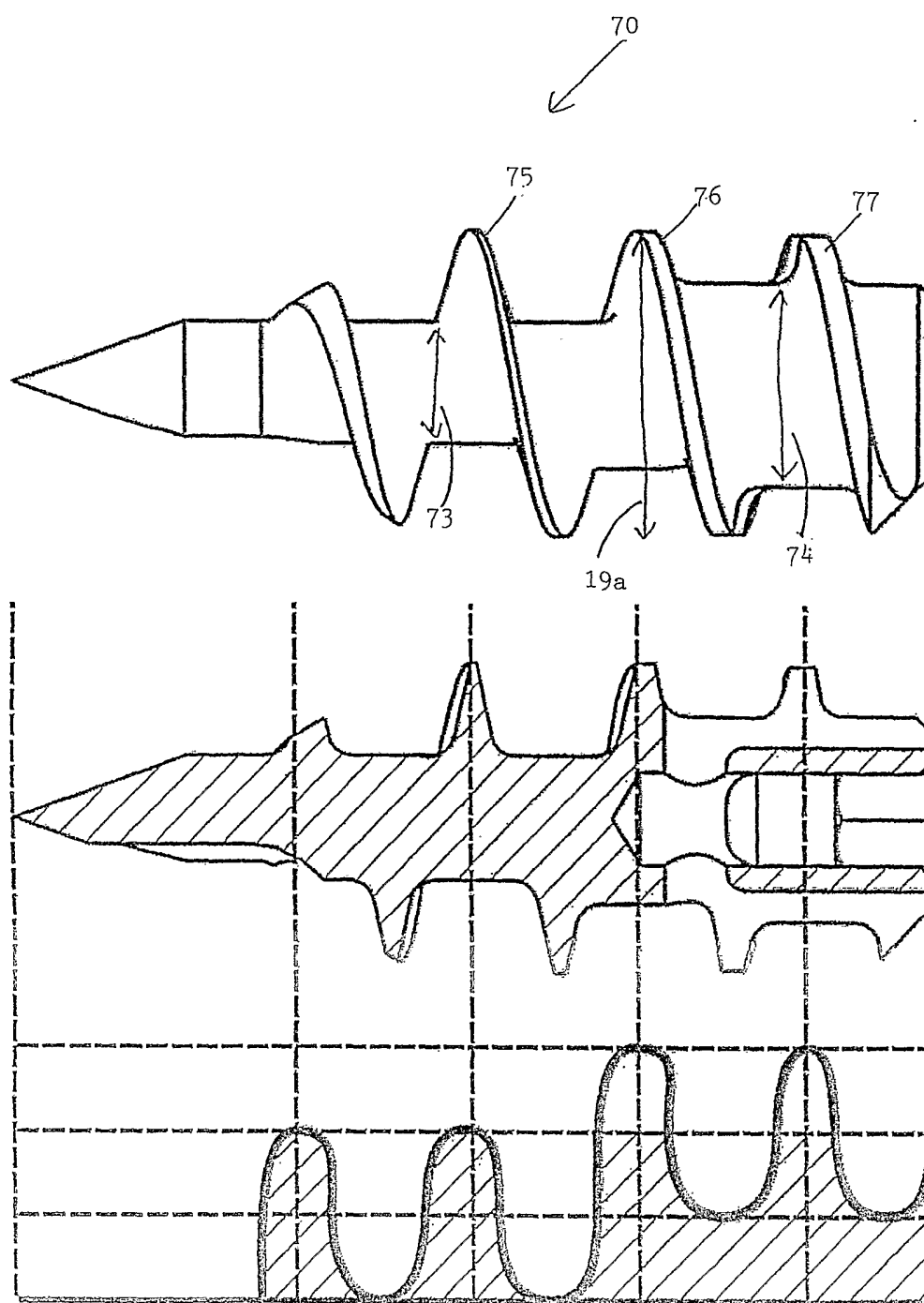


FIGURE 9