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US 5092866 A US 4790303 A

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UK CL (Edition L) A5R RAM RFB
INT CL[5] A61B , A61F
Online database: WPI

(54) Surgical implants,tensioning tools and anchorage inserter

(57) A surgical implant (20) comprises a hank formed from a single strand (21) of flexible biocompatible material (such as polyester) with at least one bight (22) at each end of the hank and a tail (25) extending from at least one end, and a crimpable sleeve (26) encircling at least overlapping end lengths (27) of the strand. The implant (20) can be used for stabilising the spine, the bights (22) being applied directly to adjacent vertebrae or to pedicle screws (28) or to hooking members anchored to adjacent vertebrae, the strand material (21) being tensioned by pulling the tail (25) before crimping the sleeve (26). The implant may also be used in the replacement or augmentation of knee or ankle ligaments and in the reduction of bone fractures.

A capstan (Figure 5 not shown) for tensioning the strand comprises a shank with a co-axial spigot or socket at one end for engagement with a hole or spigot on a surgical implant, eg one of the hooking members, a handgrip at the after end of the shank for rotating the capstan and means on the shank for holding a tail end of the strand so that the strand is wound on the shank as the capstan is turned.

The hooking members can be applied by a tool (Figure 14 not shown) having a forted end, engageable with a bollard shaped portion of the hooking member, and having a striking portion at its other end.

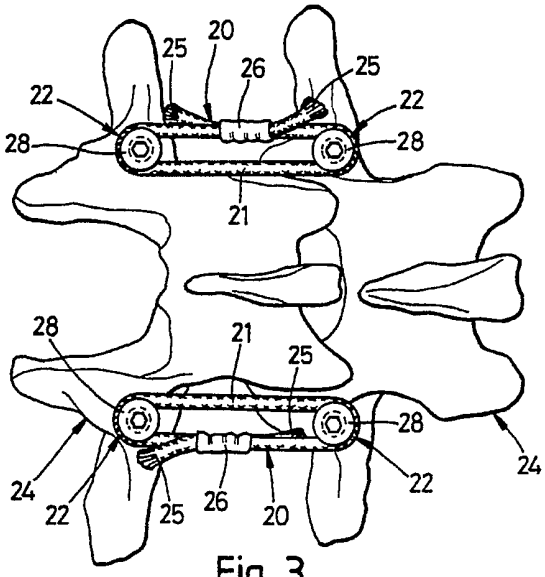

Fig. 3

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

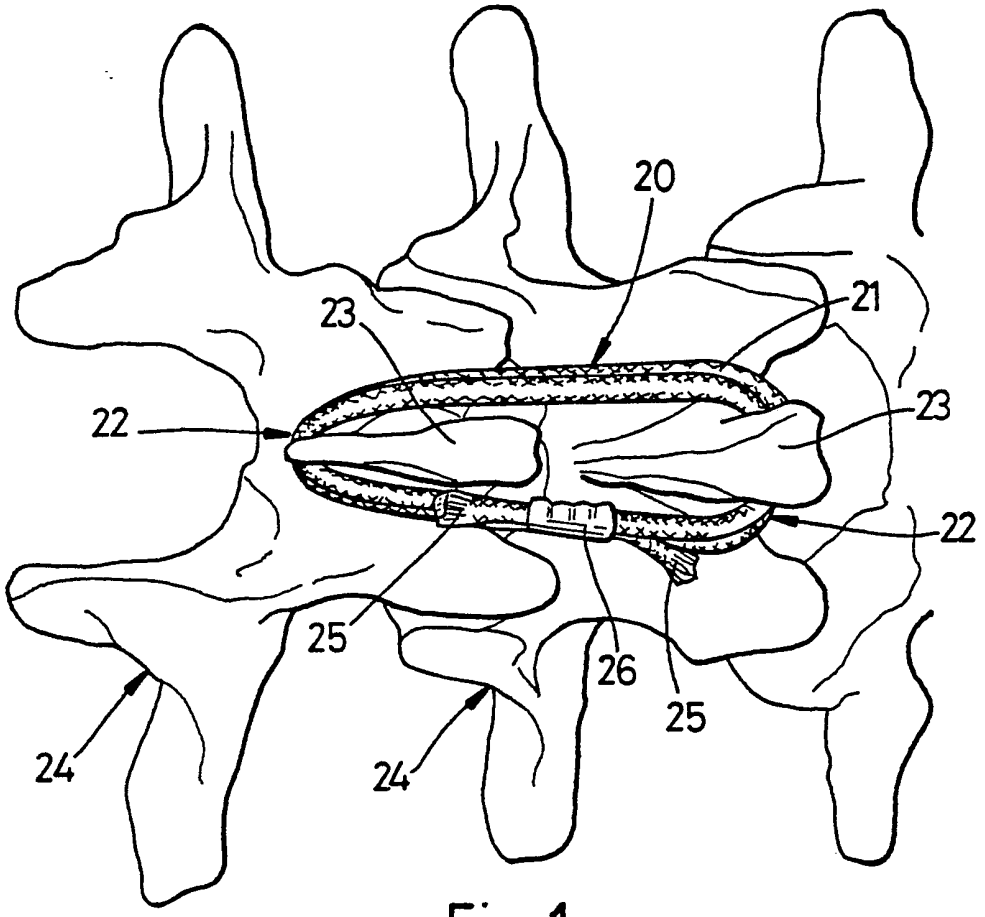

Fig. 1

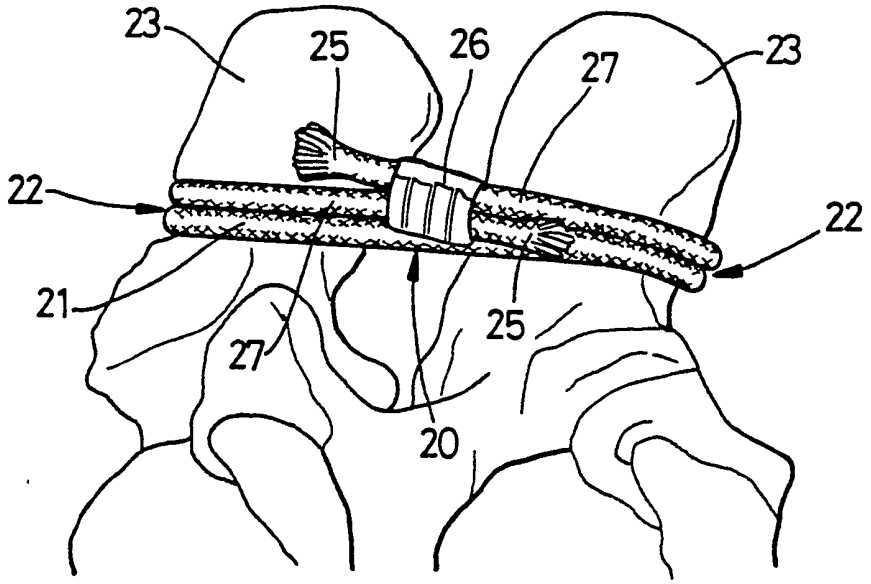

Fig. 2

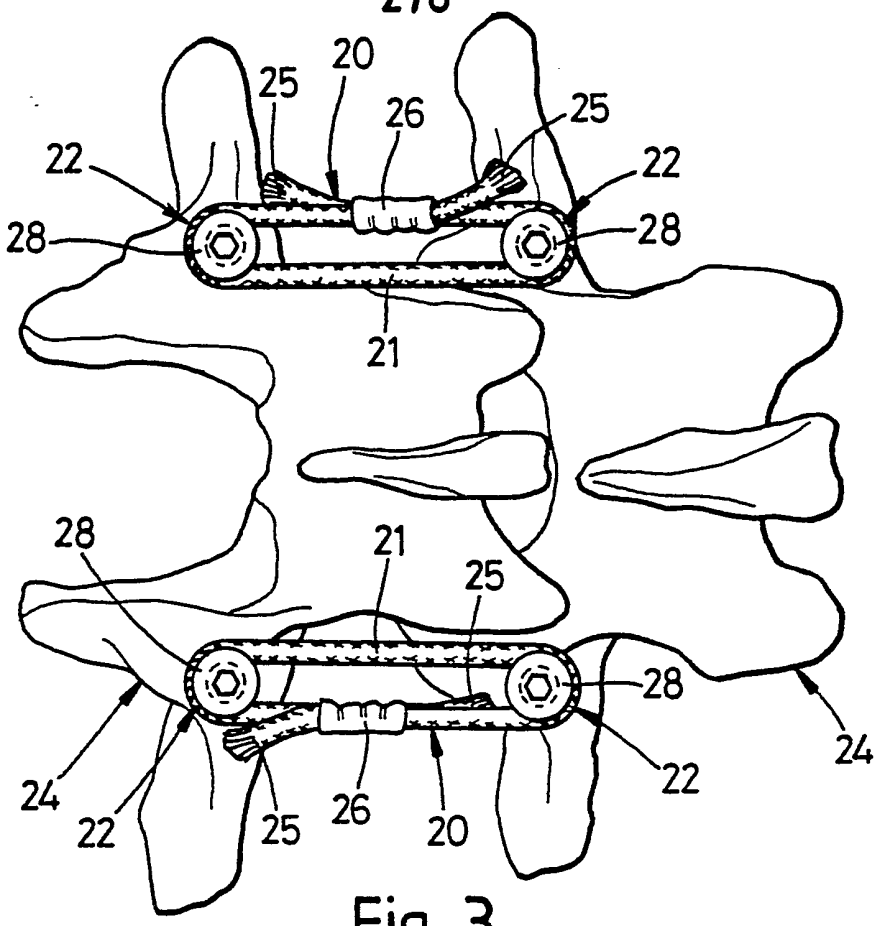
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Fig. 3

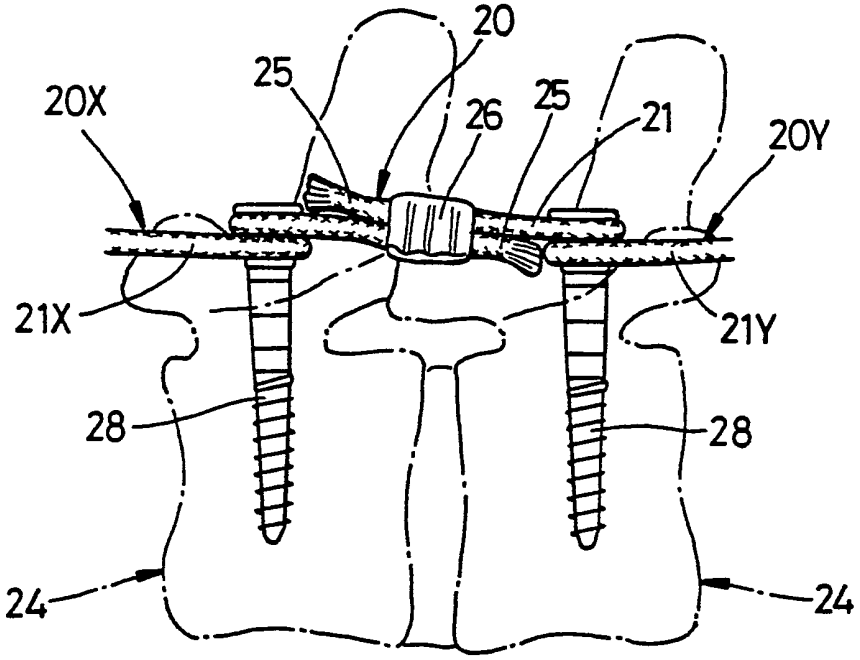
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Fig. 4

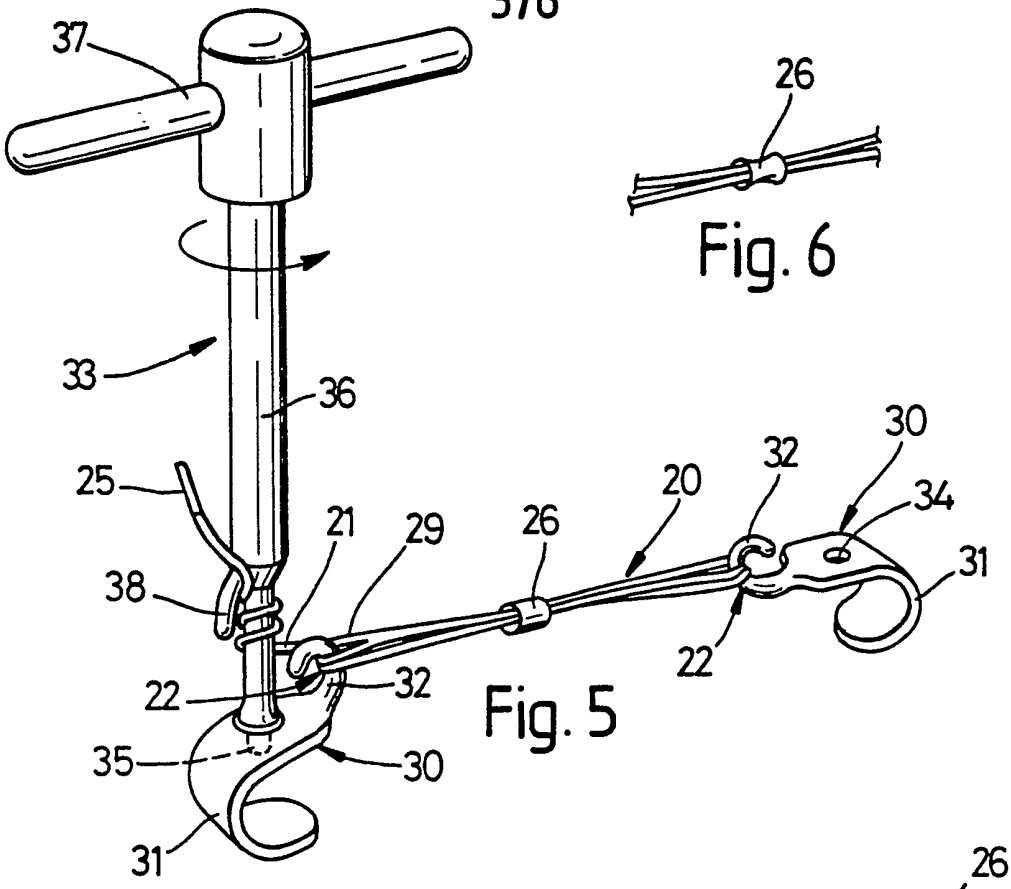

Fig. 5

Fig. 6

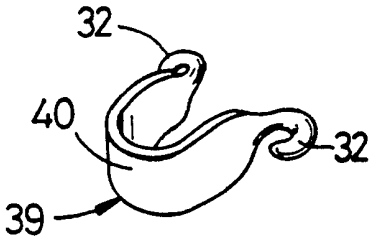

Fig. 7

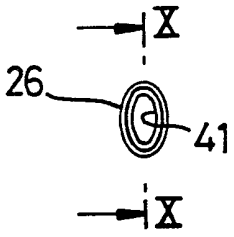

Fig. 9

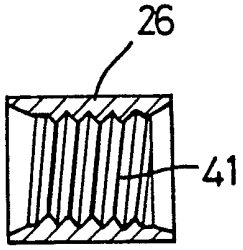

Fig. 10

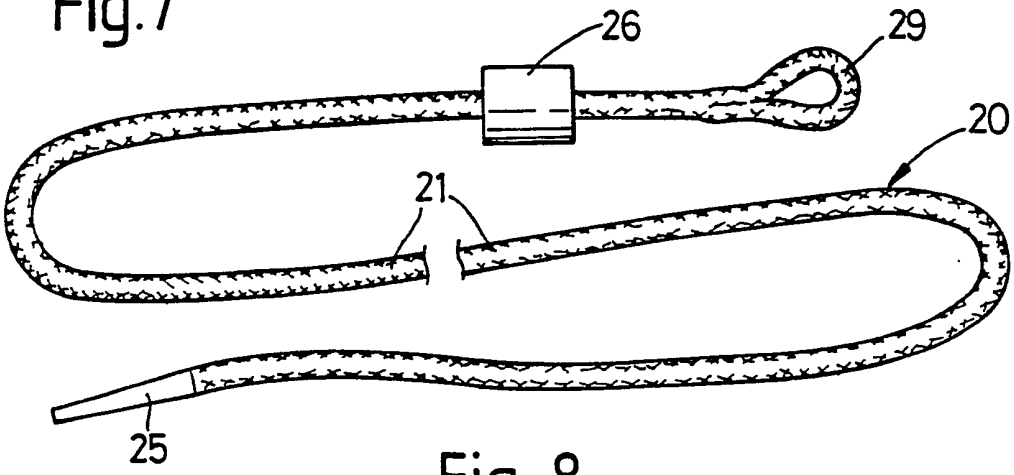

Fig. 8

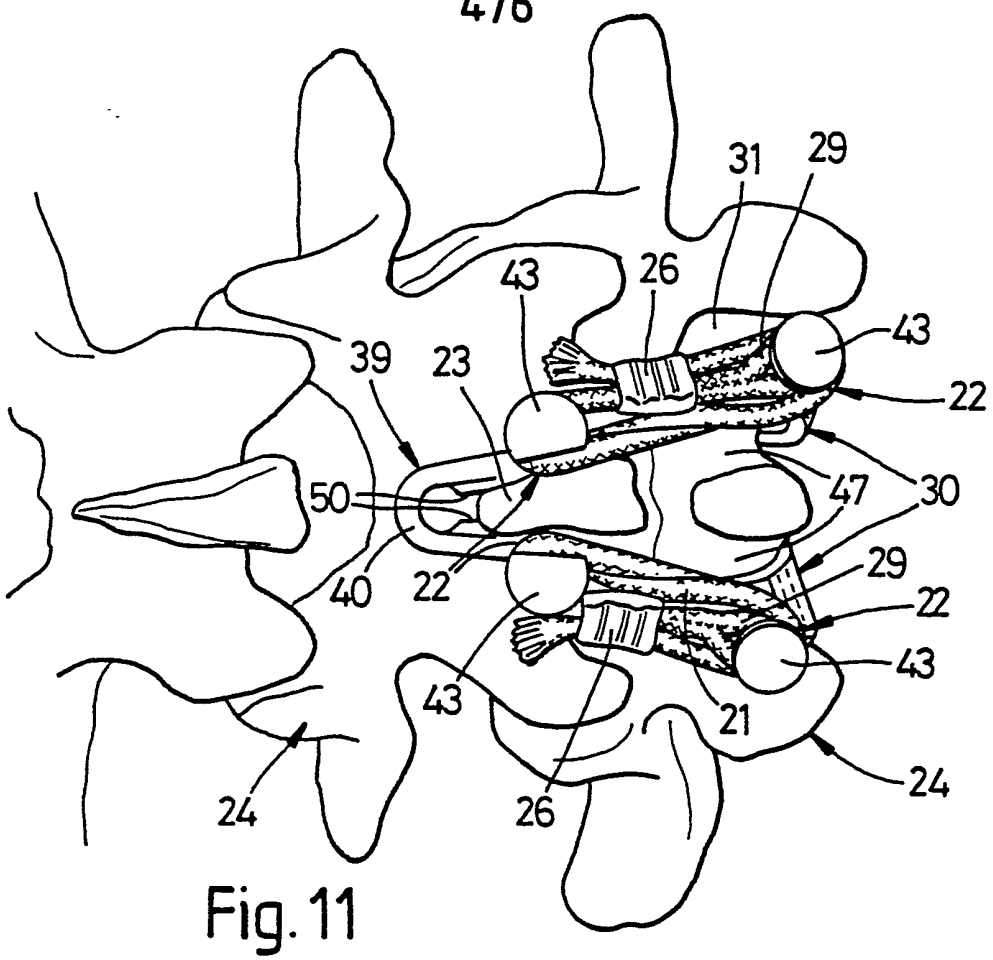
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Fig. 11

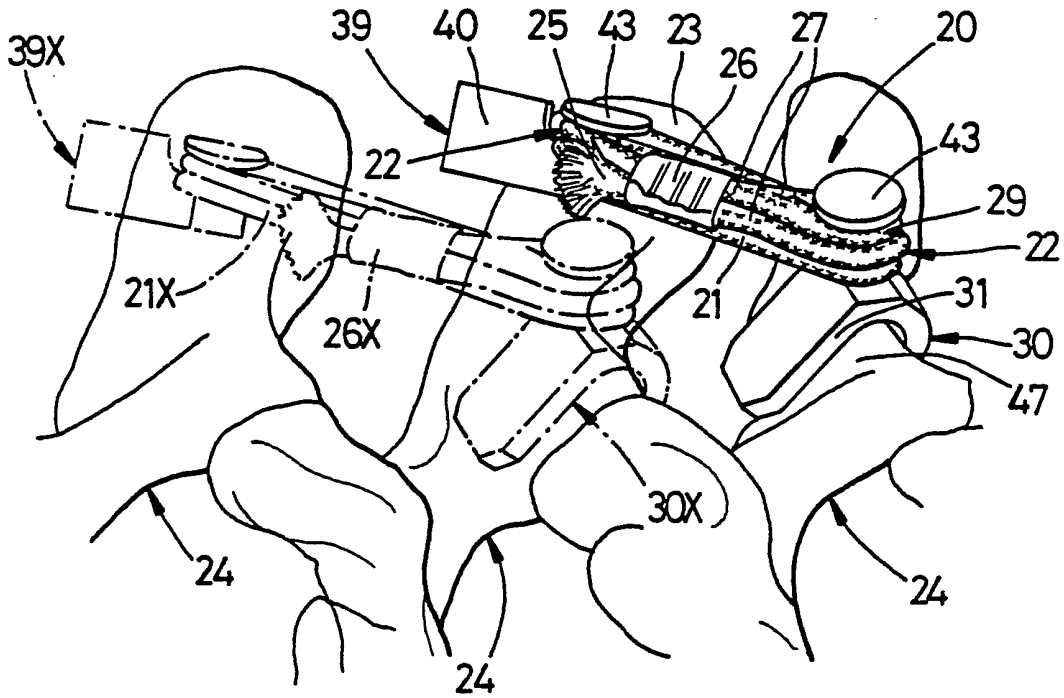
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Fig. 12

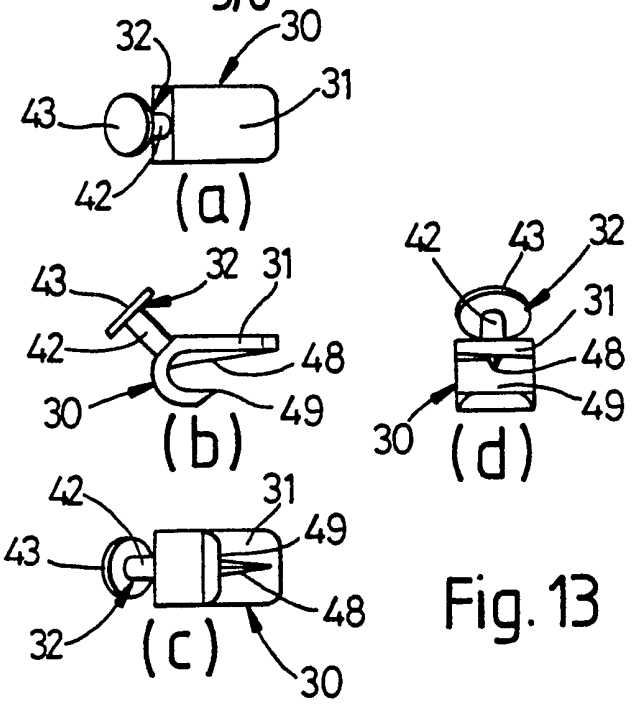


Fig. 13

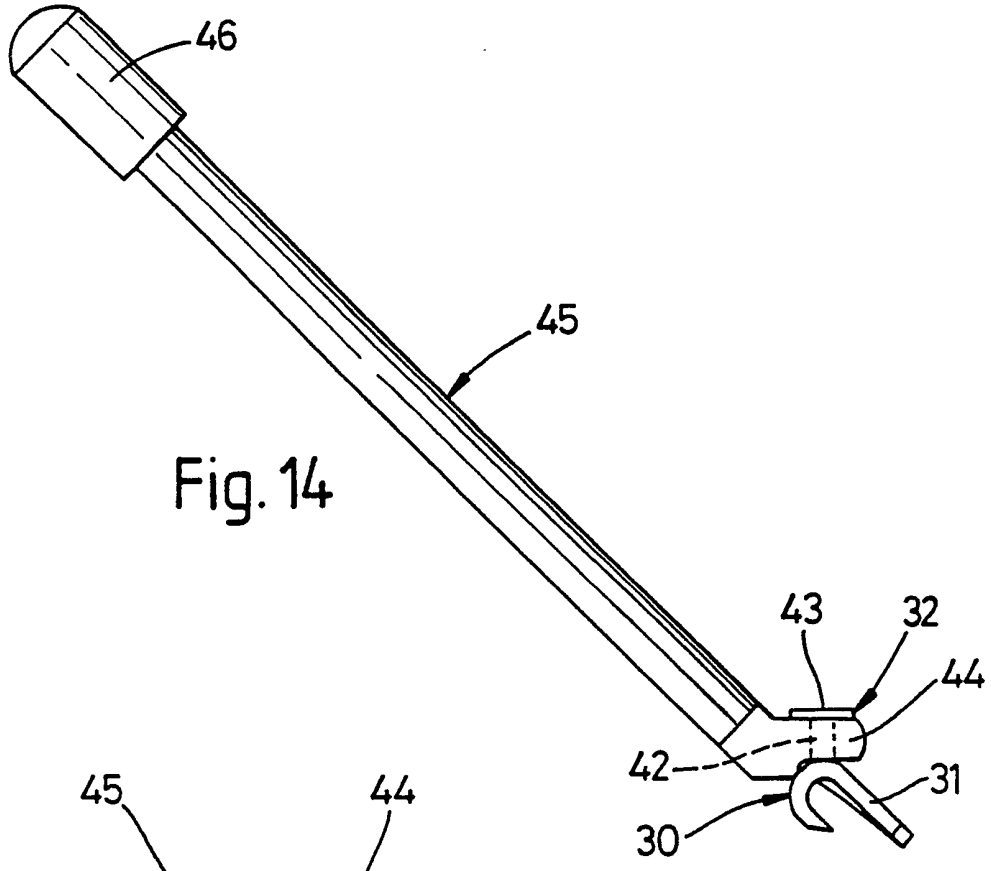


Fig. 14

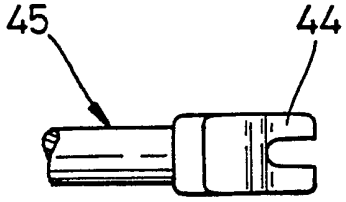
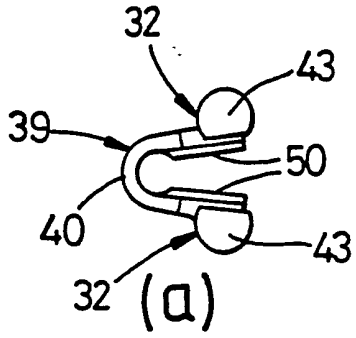
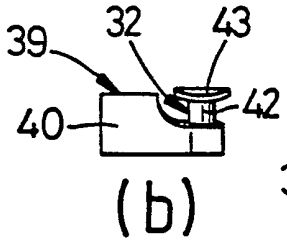
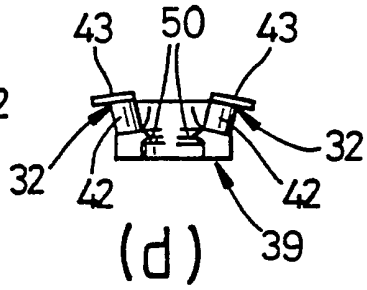


Fig. 15







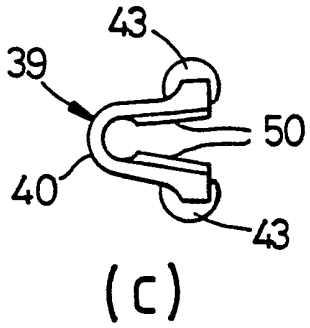


Fig. 16

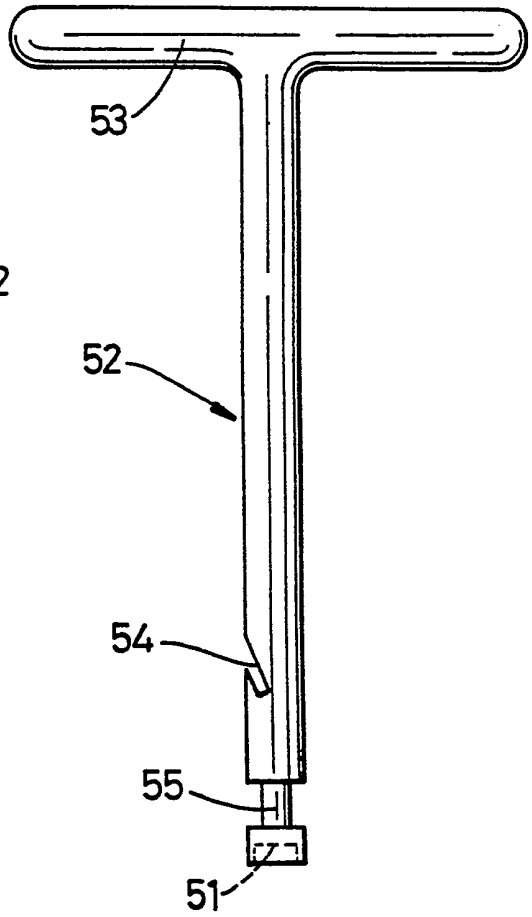


Fig. 17

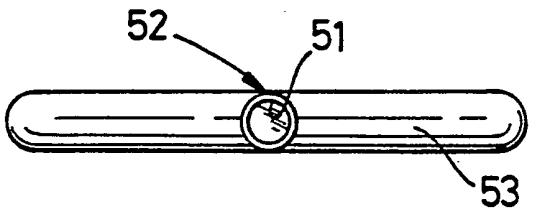


Fig. 18

SURGICAL IMPLANTS, ETC.

This invention relates to surgical implants, etc., more particularly - but not exclusively - for the stabilization of the spine, but also applicable to other indications, such as the replacement or augmentation of knee or ankle ligaments, and also possibly applicable to the reduction of fractured bones.

Various forms of spinal stabilization are in use, including fixation devices such as Harrington, Hartshill (see EP-A-0 146 347 and EP-A-0 269 268), Luque, and Knodt, which comprise solid rods hooked on to the vertebrae or held thereto by wires.

More recently there have been introduced flexible stabilisation systems, such as inextensible strips between pedicle screws (See Burton US-A-4 743 260 and Graf et al EP-A-0 381 588) or inextensible bands of predetermined lengths round pedicle screws (see also EP-A-0 381 588).

However, in order to avoid failure of these anchorages in pedicles it has been proposed (in EP-A-0 381 588) to loop inextensible flexible members directly round the spinous processes; Senegas has an inextensible member wound in a figure of eight or multiples thereof round the spinous processes and through spacers therebetween, while Cremascoli (see EP-A-0 322 334) has semi-elastic flat lacing looped round the spinous processes and in between passed through small tubular cushions of the same material.

The winding or looping of flexible members, whether inextensible or semi-elastic, round the spinous processes and

through spacers or cushions is a time-consuming operation, and it is also difficult to tension the flexible members to adjust the load between vertebrae spanned by the flexible members, because of friction of the flexible members with themselves and with the bones and spacers or cushions.

One object of the present invention is to provide a surgical implant that can be quickly and surely applied, particularly for spinal stabilization but also for ligament augmentation or replacement or for reduction of fractured bones, and that can be easily tensioned to adjust the load between vertebrae spanned.

A secondary object of the invention is to adapt the surgical implant for alternative methods of engagement with the spine or with other bones in the body.

According to one aspect of the present invention, a surgical implant comprises a hank formed from a single strand of flexible biocompatible material with at least one bight at each end of the hank and a tail extending from at least one end, and at least one crimpable sleeve-like element encircling at least the overlapping end lengths of the strand.

With this simplest form, the two bights can be quickly and surely applied one over each of two spinous processes (or anchoring means such as pedicle screws secured in two vertebrae), any slack being taken up by pulling the tail, further pulling of which makes use of the purchase of the looped strand material to adjust the load between the vertebrae, then the crimpable sleeve-like element is squeezed (using any suitable, e.g., proprietary crimping tool) on to

the lengths of strand passing therethrough to secure the strand in its tensioned state.

The at least one crimpable sleeve-like element may encircle all the strands of the hank intermediate its ends, or only all the lengths of strand at one side of the hank, and more than one crimpable sleeve-like element may be applied to the hank.

For other indications, such as ligament augmentation or replacement, the bights are simply applied over suitable heads of anchorages in the relevant bones.

Conveniently, the at least one bight at one end of the hank comprises an eye formed at the end of the strand material remote from the tail, while the at least one bight at the other end of the hank is formed by the strand material looping from the corresponding end of the crimpable sleeve-like element. It will be evident that the eye will be of a size adequate to fit over a spinous process or the head of a pedicle screw or other anchorage.

The hank may consist of a plurality of loops of the single strand of flexible biocompatible material, so as to increase the purchase when pulling the tail to adjust the load between vertebrae or other bone parts. Thus the hank will have at each end a corresponding plurality of coincident bights.

In order to adapt the surgical implant for alternative engagement with the lamina or transverse processes on either side of the spine and/or to distribute the load over a greater edge area of the spinous processes (or the lamina or

transverse processes) than is afforded to the strand material when applied directly thereto, the surgical implant according to another aspect of the present invention also comprises a pair of hooking members, each having a broad flat hook portion for engaging one part of the spinal column, integrated with an oppositely directed and reverse facing round hook portion engageable with the bight or bights at one end of the hank. For symmetrical loading of vertebrae, two implants in accordance with the invention and each comprising a hank, a crimpable sleeve-like element, and two hooking members, all as defined above, may be applied to the lamina or transverse processes at both sides of the spine. Alternatively, two hooking members, each in the form of a broad flat yoke with a round hook portion integrated with and oppositely directed to each end of the yoke, are combined with two hanks and two crimpable sleeve-like elements as defined above, the yokes being hooked on to spinous processes and the hanks lying one to each side of the spinous processes. Again, one yoke may be applied to the spinous process of one vertebra, and two hooking members, as defined above, may be applied to the lamina at both sides of the spinous process of other vertebra, and combined with two hanks and two crimpable sleeve-like elements as defined above, the bights of the hanks being applied to respective round hook portions on the yoke and the corresponding hooking members.

At least one of the hooking members preferably has abutment means for a tensioning tool for pulling the tail of the strand material, which abutment means may take the form of

a hole (or a spigot) located between the flat and round hook portions (or between the yoke and the round hook portions).

Each round hook portion is preferably formed by a bollard having a cylindrical body and a flat circular head, which aids retention of an eye at one end of the strand material. The bollard is also conveniently engageable by a forked end of an applicator tool having a striking portion at the other end; and the flat circular head of the bollard may also serve as a spigot for engagement by a socket in a tensioning tool.

A selection of hooking members is preferably made available with a variety of widths and radii of the broad flat hook portions and/or of the yoke portion, so that the surgeon can select hooking members appropriate to the size and shape of parts of the spinal column.

The hooking members, when used on the spine, may be attached to the cranial or caudal border of the lamina, the cranial base of the transverse processes, or the caudal edge of the sacral foramen.

The insides of the broad flat hook portions and/or of the broad flat yokes are preferably provided with sharp-ridged ribs extending in the direction of application of the hooking members, to enhance the grip on engaged bone parts; and a leading end of each broad flat hook portion is preferably provided with a chisel edge, to effect some shaving of an engaged bone part, if necessary, to achieve a good fit.

The strand material may be made of polyester or any other suitably strong flexible inert or biocompatible

material, and the crimpable sleeve-like element may be made from any suitably ductile inert material.

The inside of the crimpable sleeve-like element is preferably provided with circumferentially extending ribs, to enhance the grip on the strand material; thus, this element may be conveniently manufactured as an initially cylindrical and, preferably, internally screwthreaded sleeve, which is then flattened slightly, so as to accommodate a pair of overlapping end lengths of strand material in an element having minimal cross-sectional dimensions.

The hooking members may be made from any suitable implant material (e.g., stainless steel, titanium, ceramic) and may be coated with hydroxyapatite to encourage ingrowth of bone tissue, which will assist in reducing edge loading, while a plurality of turns of strand material in the hank will encourage ingrowth of body tissue.

According to a further aspect of the present invention, of independent significance, a capstan for tensioning a flexible surgical strand comprises a shank with a co-axial spigot or socket at one end for engagement with a hole in or spigot on a surgical implant, handgrip means at the other end of the shank for rotating the capstan after engagement with the spinal implant, and means on the shank (such as a cleat thereon or a notch or aperture therein), for securing a flexible surgical strand to the shank for winding thereon upon rotation of the capstan.

The handgrip means may comprise a crossbar secured to the shank, or it may comprise a knurled knob, which may be

coupled to the shank through a torque-setting device, for indicating or limiting the load applied to a flexible surgical strand secured to the shank as aforesaid.

Embodiments of the invention and manner of application thereof will now be described, by way of example only, with reference to the accompanying drawings in which:-

Figure 1 is a plan view of one of the simplest forms of surgical implant in accordance with the invention shown applied to the spinous processes of adjacent vertebrae;

Figure 2 is a side elevation of parts of Figure 1, as seen from the lower side of Figure 1;

Figure 3 corresponds to Figure 1 but shows two of the simplest forms of implant applied to pairs of pedicle screws secured in both sides of a pair of adjacent vertebrae;

Figure 4 is a side elevation of one of the implants of Figure 3 and its associated pedicle screws, with an indication (in chain-dotted lines) of the pair of adjacent vertebrae, and with an indication how further similar implants can extend from those pedicle screws;

Figure 5 is a perspective view of a basic concept for a surgical implant in accordance with the invention provided with hooking members, one of which is engaged by a tensioning tool;

Figure 6 is a fragmentary perspective view showing the crimpable sleeve-like element of Figure 5 after crimping on to the lengths of strand passing through it;

Figure 7 is a perspective view of alternative form of hooking member to those shown in Figure 5;

Figure 8 is a plan view of components of a preferred form of surgical implant in accordance with the invention;

Figure 9 is an end view of the crimpable sleeve-like element of Figure 8;

Figure 10 is an enlarged section taken from the line X-X of Figure 9;

Figure 11 is a plan view showing the two sets of components as in Figures 8 to 10, together with a preferred form of yoke and a pair of other hooking members of preferred form applied to adjacent vertebrae;

Figure 12 is a side elevation of parts of Figure 11, with an indication of similar surgical implants, yoke and other hooking members extending from one of the vertebrae to the next;

Figures 13 (a), (b), (c) and (d) are respective plan, side, underneath and end views of one of the hooking members shown in Figures 11 and 12;

Figure 14 is a side elevation of a tool for use in driving into place a hooking member as in Figures 13 (a) to (d) and shown engaged therewith;

Figure 15 is a fragmentary underneath view of the lower end of the tool of Figure 14, without the hooking member;

Figures 16 (a), (b), (c) and (d) are respective plan, side, underneath and end views of the other hooking member shown in Figures 11 and 12;

Figure 17 is a side elevation of a tensioning tool for engagement with one of the hooking members shown in Figures 11

and 12; and

Figure 18 is an underneath view of the tensioning tool shown in Figure 17.

In Figures 1 and 2, a surgical implant 20 comprises a hank formed from a single strand 21 of flexible biocompatible material with bights 22 at both ends, applied over each of two spinous processes 23 on adjacent vertebrae 24 with tails 25 projecting from a crimpable sleeve-like element 26 encircling the overlapping end lengths 27 of the strand, the element 26 being shown as having been crimped to secure the strand 21 after tensioning by pulling the tails 25 in opposite directions.

In Figure 3, two similar implants 20 are applied to pairs of pedicle screws 28 secured in both sides of a pair of adjacent vertebrae 24, the crimpable sleeve-like elements 26 being shown as having been crimped after tensioning the strands 21 to provide symmetrical loading of the vertebrae. In Figure 4, strands 21X, 21Y of further implants 20X, 20Y are indicated as extending to further adjacent vertebrae which are not shown or indicated.

The strand 21 shown in Figure 5 has one bight at one end of the hank comprising an eye 29 formed at the end of the strand material remote from the tail 25, and the hank consists of a plurality of loops with all the lengths of strand between the bights 22 encircled by the crimpable sleeve-like element 26. Hooking members 30 each have a broad flat hook portion 31 for engaging one part of the spinal columnm, e.g., the lamina or transverse processes (not shown) on one side of the

spine and to distribute the load over a greater edge area thereof, and an oppositely directed and reverse facing round hook portion 32 engaged by the bights 22 at one end of the hank of flexible biocompatible material 21. Abutment means for a tensioning tool 33, for pulling the tail 25 of the strand material, takes the form of a hole 34 located between the flat and round hook portions 31, 32, which hole is engaged by a spigot 35 at one end of a shank 36 of the tensioning tool. This tool 33 is in the form of a capstan with handgrip means 37 at the other end of the shank for rotating the capstan, a cleat 38 being provided on one side of the shank for securing the tail 25 of the strand material 21 to the shank for winding thereon upon rotation of the capstan. Figure 6 shows the crimpable sleeve-like element 26 crimped on to the hank.

Figure 7 shows a hooking member 39 having a broad flat yoke 40 with a round hook portion 32 integrated with and oppositely directed to each end of the yoke. Two such hooking members may have their yokes hooked on to spinous processes (not shown) of adjacent vertebrae, and two hanks and two crimpable sleeve-like elements combined therewith by hooking the bights 22 of the hanks on the round hook portions 32, with one hank on each side of the spinous processes, and the elements 26 crimped on to the hanks after they have been tensioned. Alternatively, one such hooking member 39 may have its yoke hooked on a spinous process of one vertebra while two hooking members 30 have their broad flat hook portions hooked on the lamina of an adjacent vertebra, and

combined with two hanks and two crimpable sleeve-like elements by hooking the bights of the hanks on respective round hook portions on the hooking members 30, 39.

It will be appreciated that because the crimpable sleeve-like element 26 in Figures 5 and 6 encircles four lengths of the strand material 21, its bore must be of an adequate diameter for easy feeding of the tail 25 repeatedly therethrough, and - in consequence - the outside diameter will be commensurately larger. Preferably, therefore, as shown in Figures 1 and 2, Figures 3 and 4, and Figures 11 and 12, the crimpable sleeve-like element 26 encircles only the overlapping end lengths 27 of the strand 21, thus minimising the cross-sectional dimensions of the element 26. Thus the element 26 may be manufactured as an initially cylindrical and, preferably, internally screwthreaded sleeve, which is then flattened slightly to give the preferred form shown in Figures 8 to 10 with the turns of the internal screwthread 41 constituting circumferentially extending ribs, to enhance the grip on the strand material 21 upon crimping of the element 26 thereon.

The preferred forms of crimpable sleeve-like element 26 and strand material 21 with eye 29 are shown in Figures 11 and 12 in use in combination with preferred forms of hooking members, details of which will be described with reference to Figures 13(a) to (d) and 16(a) to (d). In these preferred forms of hooking members the round hook portions 32 are formed by bollards having cylindrical bodies 42 and flat circular heads 43, and the heads on the hooking members 30 are shown in

Figures 11 and 12 aiding retention of the eyes 29 of hanks of strand material hooked on the bollards.

In Figure 14 the bollard 32 of one of the hooking members 30 is shown engaged by a forked end 44 of an applicator tool 45 having a striking portion 46 at the other end, which enables the hooking member 30 to be hammered into place on the lamina 47 at one side of the spinous process 23 of one vertebra 24, and - as shown in Figure 11 - another hooking member 30 is hammered into place on the lamina 47 at the other side of that spinous process 23. As can be seen in Figures 13(a) to (d), the inside of each broad flat hook portion 31 is provided with a sharp-ridged rib 48 extending in the direction of application of the hooking member 30, to enhance the grip on the engaged bone part. A leading end 49 of each broad flat hook portion 31 is provided with a chisel edge, to effect some shaving of the engaged bone part, if necessary, to achieve a good fit.

In Figures 16(a) to (d) a hooking member 39 can be seen to be provided with sharp-ridged ribs 50 extending along the insides of the arms of the yoke portion 40 in the direction of application to the spinous process 23 of an adjacent vertebra 24 in Figures 11 and 12, to enhance the grip on this engaged bone part.

Referring again to Figures 11 and 12 the bights 22 of the hanks are applied to respective bollard type round hook portions on the yoke 39, 40, with the crimpable sleeve-like elements 26 encircling the overlapping end lengths 27 of the strands, and after tensioning of the strands (as by means of

the tool shown in Figures 17 and 18, and which will be described presently) the elements 26 are crimped on to the lengths of strand passing therethrough to secure the strands in their tensioned state.

Any suitable one of the heads 43 of the bollard type round hook portions of the hooking members 30, 39 may serve as a spigot engageable by a socket 51 in one end of the tensioning tool 52 shown in Figures 17 and 18, the other end of which has a handgrip 53 enabling the tool to be rotated with the socket 51 thus engaged with a head 43. The tool 52 has a notch 54 into which the tail 25 of a hank can be jammed, and a neck 55 round which the strand material 21 can be wound as the tool is rotated to tension the strand material.

Further hooking members 30X, 39X, a hank of strand material 21X and crimped element 26X are indicated in chain dotted lines Figure 12 providing further stabilisation between the vertebra carrying the hooking member 39 and the next adjacent vertebra.

CLAIMS

1. A surgical implant comprising a hank formed from a single strand of flexible biocompatible material with at least one bight at each end of the hank and a tail extending from at least one end, and at least one crimpable sleeve-like element encircling at least the overlapping end lengths of the strand.

2. A surgical implant as in Claim 1, wherein the at least one crimpable sleeve-like element encircles all the strands of the hank intermediate its ends.

3. A surgical implant as in Claim 1, wherein the at least one crimpable sleeve-like element encircles all the lengths of strand at one side of the hank.

4. A surgical implant as in any one of Claims 1 to 3, wherein more than one crimpable sleeve-like element is applied to the hank.

5. A surgical implant as in any one of Claims 1 to 4, wherein the at least one bight at one end of the hank comprises an eye formed at the end of the strand material remote from the tail, while the at least one bight at the other end of the hank is formed by the strand material looping from the corresponding end of the crimpable sleeve-like element.

6. A surgical implant as in any one of Claims 1 to 5, wherein the hank consists of a plurality of loops of the single strand of flexible biocompatible material.

7. A surgical implant as in any one of Claims 1 to 6, also comprising a pair of hooking members, each having a

broad flat hook portion for engaging one part of the spinal column, integrated with an oppositely directed and reverse facing round hook portion engageable with the bight or bights at one end of the hank.

8. A surgical implant as in any one of Claims 1 to 6, also comprising two hooking members, each in the form of a broad flat yoke with a round hook portion integrated with and oppositely directed to each end of the yoke, combined with two hanks and two crimpable sleeve-like elements as defined above.

9. A surgical implant as in any one of Claims 1 to 6, also comprising one hooking member in the form of a broad flat yoke with a round hook portion integrated with and oppositely directed to each end of the yoke and a pair of hooking members, each having a broad flat hook portion for engaging one part of the spinal column, integrated with an oppositely directed and reverse facing round hook portion engageable with the bight or bights at one end of the hank.

10. A surgical implant as in any one of Claims 7 to 9, wherein at least one of the hooking members has abutment means for a tensioning tool for pulling the tail of the strand material.

11. A surgical implant as in Claim 10, wherein the abutment means takes the form of a hole located between the flat and round hook portions.

12. A surgical implant as in any one of Claims 7 to 10, wherein each round hook portion is formed by a bollard having a cylindrical body and a flat circular head.

13. A surgical implant as in any one of Claims 7 to

12, wherein a selection of hooking members is made available with a variety of widths and radii of the broad flat hook portions and/or of the yoke portion.

14. A surgical implant as in any one of Claims 7 to 13, wherein the insides of the broad flat hook portions and/or of the broad flat yokes are provided with sharp-ridged ribs extending in the direction of application of the hooking members, to enhance the grip on engaged bone parts.

15. A surgical implant as in Claim 7 or Claim 9, wherein a leading end of each broad flat hook portion is provided with a chisel edge, to effect some shaving of an engaged bone part.

16. A surgical implant as in any one of Claims 1 to 15, wherein the strand material is made of polyester

17. A surgical implant as in any one of Claims 1 to 16, wherein the inside of the crimpable sleeve-like element is provided with circumferentially extending ribs, to enhance the grip on the strand material.

18. A surgical implant as in Claim 17, wherein the crimpable sleeve-like element is manufactured as an initially cylindrical and internally screwthreaded sleeve, which is then flattened slightly, so as to accommodate a pair of overlapping end lengths of strand material in an element having minimal cross-sectional dimensions.

19. A surgical implant as in any one of Claims 7 to 9, wherein the hooking members are coated with hydroxyapatite to encourage ingrowth of bone tissue.

20. Surgical implants substantially as hereinbefore

described with reference to the accompanying drawings.

21. A capstan for tensioning a flexible surgical strand comprising a shank with a co-axial spigot or socket at one end for engagement with a hole in or spigot on a surgical implant, handgrip means at the other end of the shank for rotating the capstan after engagement with the spinal implant, and means on the shank for securing a flexible surgical strand to the shank for winding thereon upon rotation of the capstan.

22. A capstan as in Claim 21, wherein the means on the shank for securing a flexible strand thereto is a cleat on the shank.

23. A capstan as in Claim 21, wherein the means on the shank for securing a flexible strand thereto is a notch in the shank.

24. A capstan as in any one of Claims 21 to 23, wherein the handgrip means comprises a crossbar secured to the shank.

25. A capstan as in any one of Claims 21 to 23, wherein the handgrip means comprises a knurled knob.

26. A capstan as in Claim 24 or Claim 25, wherein the crossbar or knurled knob is coupled to the shank through a torque-setting device, for indicating or limiting the load applied to a flexible surgical strand secured to the shank as aforesaid.

27. A capstan or tensioning tool substantially as hereinbefore described with reference to Figure 5 or Figures 17 and 18 of the accompanying drawings.

28. A tool for applying a hooking member as defined

in Claim 7 in combination with Claim 12, the tool comprising a forked end engageable with the bollard of the hooking member and a striking portion at the other end.

29. A tool as in Claim 28 and substantially as hereinbefore described with reference to Figures 14 and 15 of the accompanying drawings.

Examiner's report to the Comptroller under Section 17 (The Search report)

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Relevant Technical Fields

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Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASE : WPI

Documents considered relevant following a search in respect of Claims :-
1-20

Categories of documents

X: Document indicating lack of novelty or of inventive step.

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Category	Identity of document and relevant passages		Relevant to claim(s)
E,X	WO 93/15680 A	(HILLWAY SURGICAL LTD) - see eg page 5 lines 2-5	1,3
P,X	WO 93/03681 A	(HOWMEDICA INC) - see eg page 5 line 34 - page 6 line 3	1,3
X	US 5116340	(SONGER ET AL) - see eg Figure 6	1,3
Y	US 5092866	(BREARD ET AL) - see column 3 lines 30-40	16
X Y	US 4790303	(STEFFE) - see column 3 lines 49-66 and Figure 5	X: 1,3 Y: 16

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