(12) UK Patent Application (19) GB (11) 2 401 053 (13) A

(43) Date of A Publication 03.11.2004

(21) Application No: 0407436.5

(22) Date of Filing: 01.04.2004

(30) Priority Data:
(31) 0308367 (32) 11.04.2003 (33) GB

(71) Applicant(s):
Ravi Kumar Khetrapal
6 Canterbury Close, BROADSTAIRS, Kent,
CT10 2SF, United Kingdom

(72) Inventor(s):
Ravi Kumar Khetrapal

(74) Agent and/or Address for Service:
T M Gregory & Co
26 Cyril Street, NORTHAMPTON, NN1 5EL,
United Kingdom

(51) INT CL[7]:
A61B 17/17

(52) UK CL (Edition W):
A5R REP RX4

(56) Documents Cited:
DE 003205404 A
US 5403321 A
US 4803976 A
US 5728128 A
US 5031203 A
US 4625718 A

(58) Field of Search:
UK CL (Edition W) A5R
INT CL[7] A61B
Other:

(54) Abstract Title: **An apparatus to facilitate locking of intramedullary fixation devices using radiographic visualisation**

(57) An apparatus to facilitate locking to a bone of a patient an intramedullary fixation device and comprises an intramedullary fixation device with apertures 2 to receive locking screws, a support means 1 locatable on or around a body member adjacent a bone fracture with an elongate radiolucent drill guide 4, extending outwardly from the support means. An aiming means 3 associated with the drill guide which contrasts radiologically with the support means and is alignable under radiographic visualisation with the apertures to direct the locking screw into correct engagement with a locking aperture of the device. The drill guide means may be a rigid radiolucent plastics material with a contrasting aiming means which may be a thin metal ring or other radiopaque material concentrically surrounding the end of the drill guide means or which may be mounted to the support means. The support means may be a sheet of malleable material which can be wrapped around a limb of a patient.

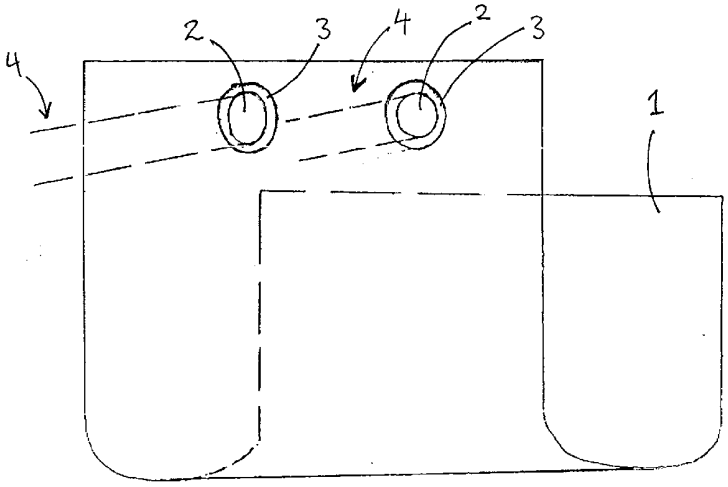

Fig 1A

GB 2 401 053 A

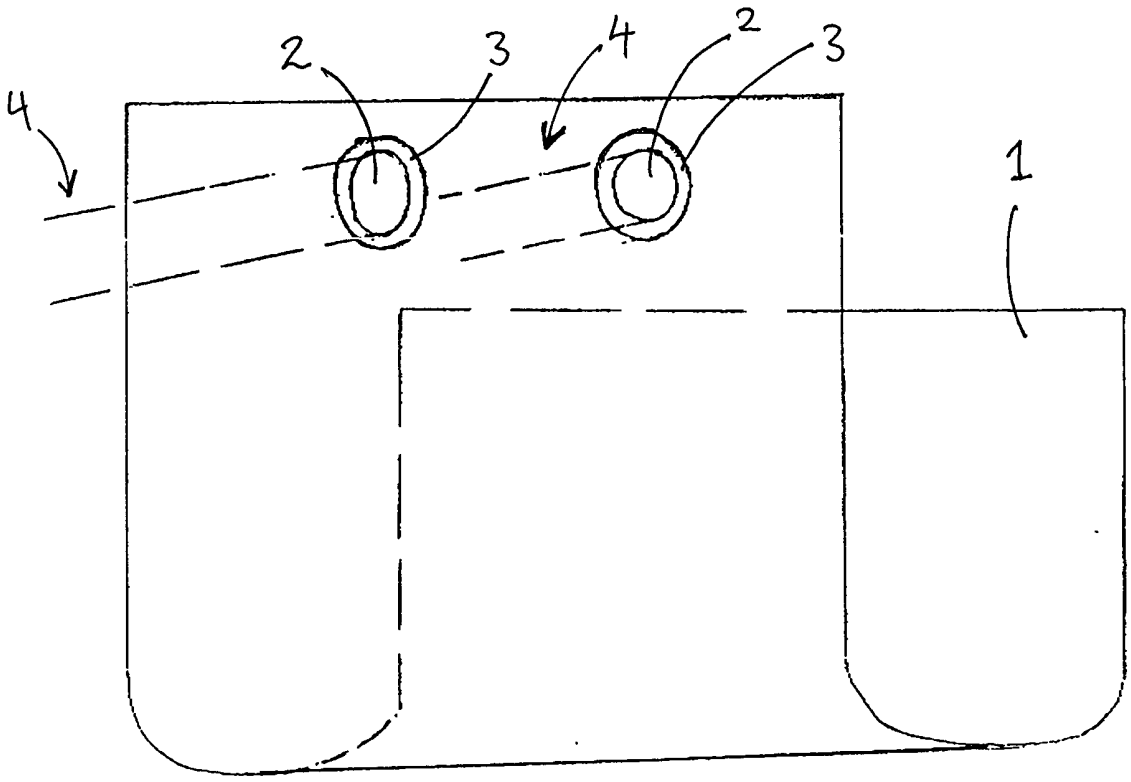

Fig 1A

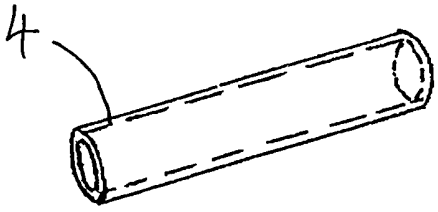

Fig 1B

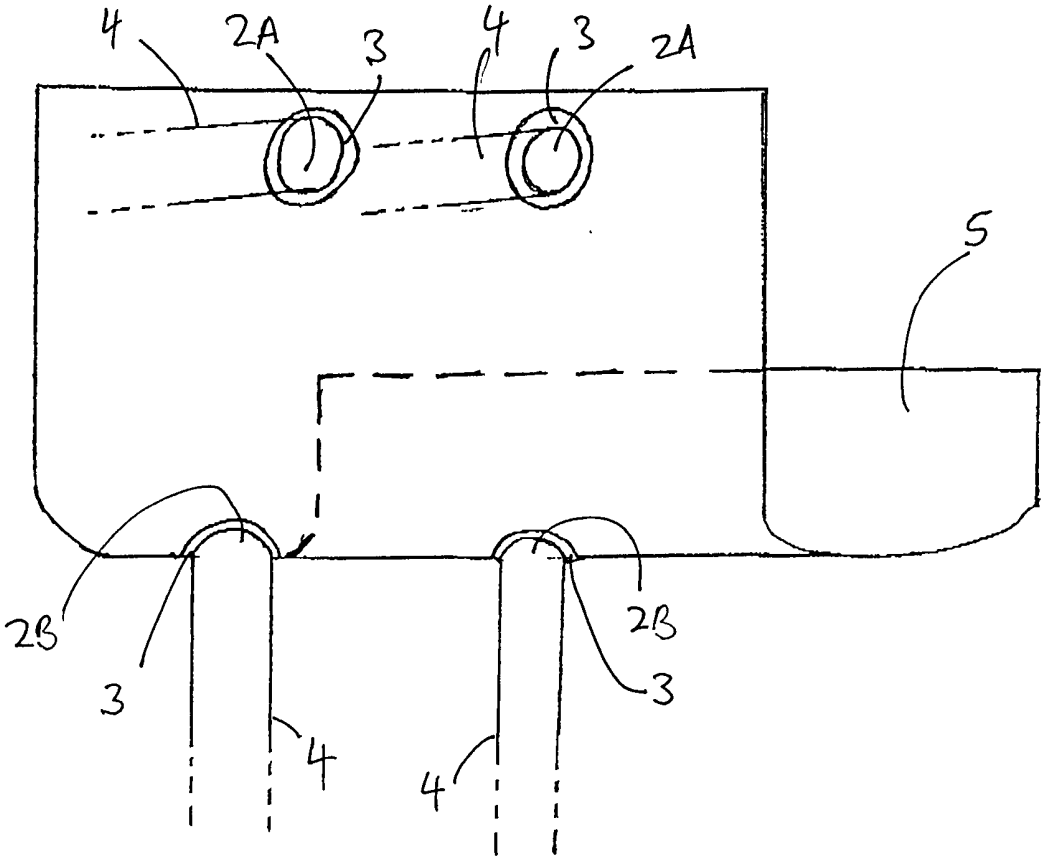

Fig 2

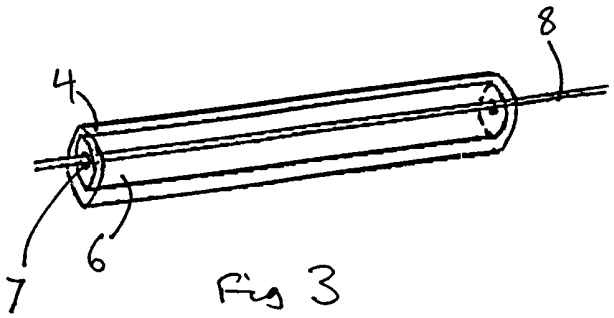

Fig 3

Fig 4

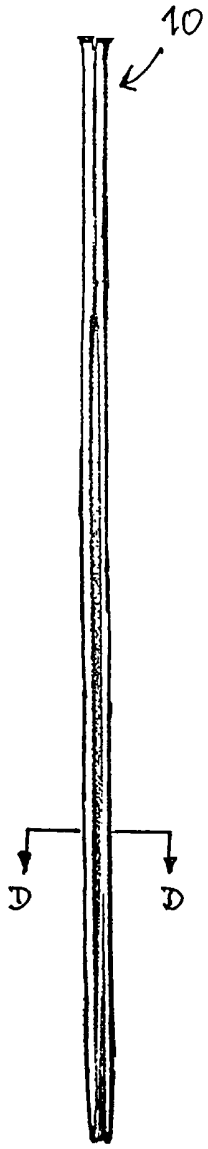

Fig 5A

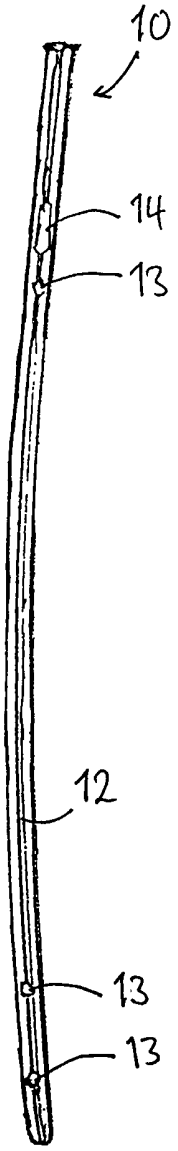

Fig 5B

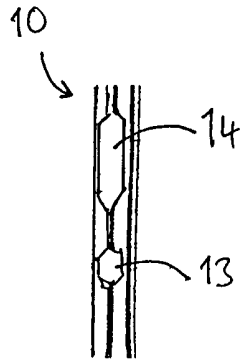

Fig 5C

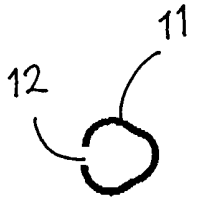

Fig 5D

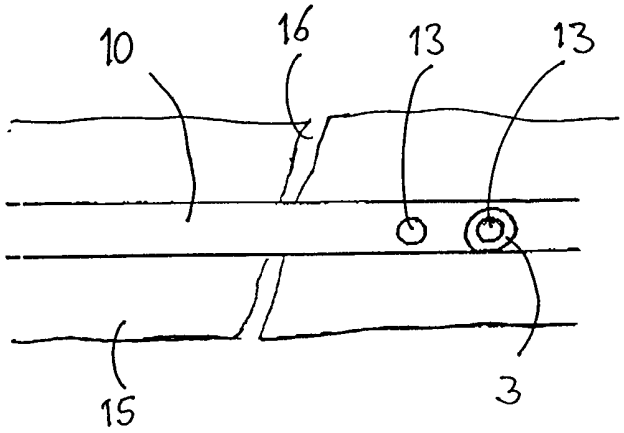

FIG 6

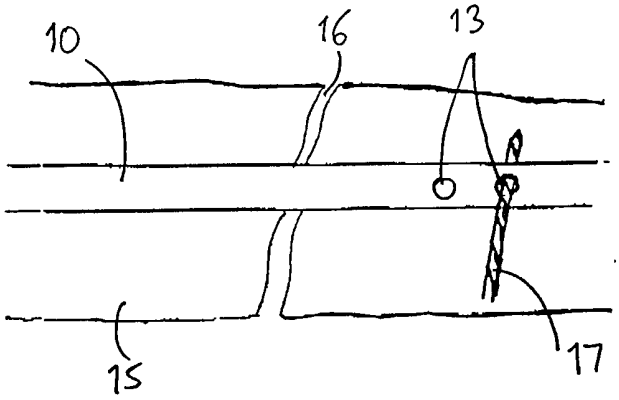

FIG 7

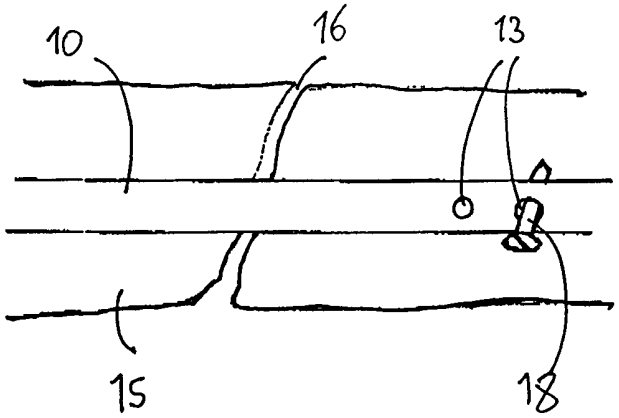

FIG 8

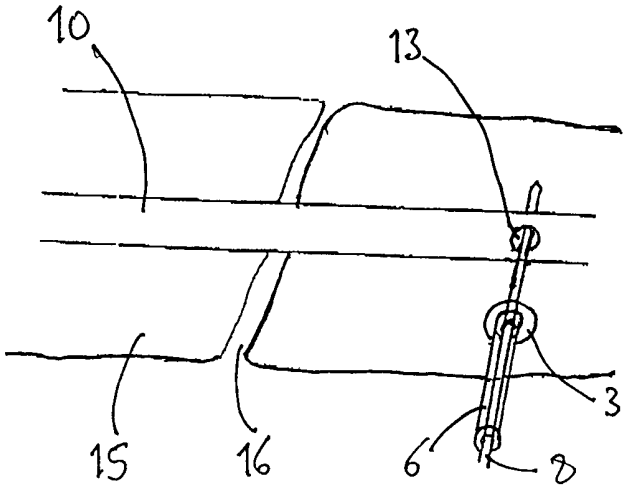

FIG 9

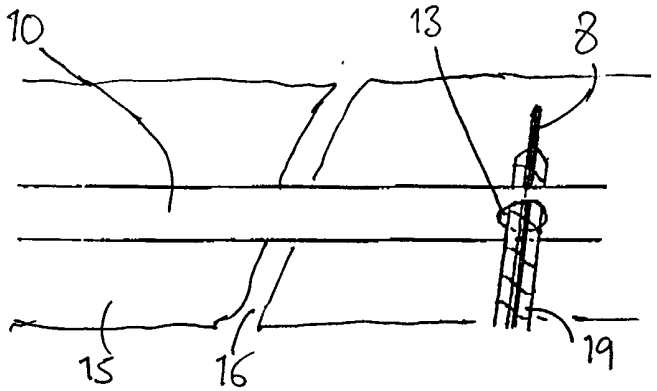

FIG 10

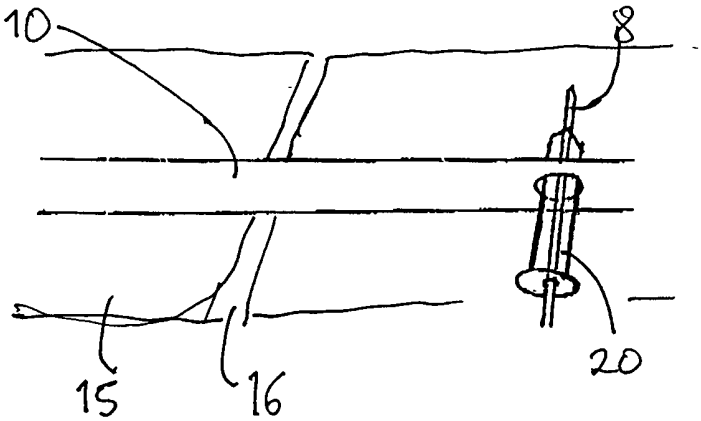

FIG 11

IMPROVED LOCKING OF INTRAMEDULLARY FIXATION DEVICES

The invention relates to apparatus to improve and expedite the locking of intramedullary fixation devices such as nails used for stabilisation of fractures, impending fractures, arthrodeses and osteotomies. More particularly but not exclusively, it relates to apparatus for guiding the distal locking of such nails. It also relates to a method for locking such nails.

There is a plethora of different intramedullary nails currently available for treating traumatic or pathological fractures of different long bones such as the tibia, femur and humerus or for the arthrodesis of joints, such as the ankle. These can be locked to the bone in different configurations and modes, statically or dynamically and in one or more planes. This depends on the different demands to be placed on the limb, whether it is going to be weight bearing or load bearing and the fracture stability and comminution.

The nails can be locked both proximally and distally using screws or bolts extending transversely through apertures provided in the nail and the bone to either side thereof.

Proximal locking can be carried out with the help of a guide attached to the jig for the actual passage of the nail and is usually expeditious and not especially demanding.

Distal locking, however, is currently usually performed largely unguided and may be time consuming and challenging, sometimes being the lengthiest part of the entire operation.

Multiple attempts may be required before a hole to receive a screw, etc, can be drilled accurately traversing both the bone and the aperture provided in the nail. This leads to undesirable additional trauma to the bone, and to adjacent soft tissues penetrated en route to the bone.

The procedure is carried out under X-ray visualisation, so it is desirable that it should be as brief as possible, to minimise radiation exposure to the limb of the patient and the hands of the surgeon. A shorter procedure would also reduce the time that the patient spends under general anaesthesia.

Inaccurate boring can also lead to damage to a drill bit if it is not properly aligned to pass through the aperture in the nail. The nail can also be weakened if the drill bit hits a margin of the aperture, or even misses the aperture entirely. This has been known to lead to fatigue and deformation or even fracture of the nail adjacent the aperture(s) at a later date.

It is hence an object of the present invention to provide apparatus which obviates the above problems and facilitates more rapid and convenient locking of intramedullary fixation devices. It is also an object of the present invention to provide a method for carrying out locking using such apparatus.

According to the present invention, there is provided apparatus to facilitate locking to bone of an intramedullary fixation device having aperture means to receive locking screw means, the apparatus comprising support means locatable on or around a body member adjacent a bone fracture, elongate drill guide means extending outwardly from the support means, and aiming means associated with said drill guide means contrasting radiologically with the support means and alignable under radiographic visualisation with said aperture means.

Preferably, the drill guide means comprises a hollow cylinder adapted to receive and guide drill means extending therethrough into the body member.

Advantageously, the drill guide means comprises rigid radiolucent plastics material.

The drill guide means may be dimensioned to receive drill means of a preselected size.

In a first embodiment, the support means is substantially radiolucent, and the contrasting aiming means is radioopaque.

Preferably, the aiming means comprises one or more radioopaque elements mounted to the support means or the drill guide means adjacent an end of the drill guide means locatable adjacent a surface of the body member.

Said one or more radioopaque elements may be adapted to indicate a longitudinal axis of the drill guide means.

The aiming means may comprise an annular radioopaque element concentrically surrounding the end of the drill guide means locatable adjacent the surface of the body member.

The aiming means may comprise metal.

In a second embodiment, the support means is substantially or partially radioopaque, and the contrasting aiming means is radiolucent.

Preferably, the aiming means comprises an aperture through the radioopaque support means adjacent an end of the drill guide means locatable adjacent a surface of the body member.

In either embodiment, the aiming means may comprise a plurality of elongate indicia extending towards the longitudinal axis of the drill guide means.

Preferably, the support means comprises flexible sheet means adapted to be wrappable around a substantial portion of said body member.

The drill guide means may then be so mounted to the flexible sheet means as to extend substantially normally to adjacent portions thereof.

The flexible sheet means is advantageously capable of substantially retaining a configuration into which it is wrapped.

The sheet means may be flexible only when warmed to a temperature above body temperature.

The support means may alternatively be substantially rigid and configured to fit around a substantial proportion of a body member of preselected dimensions.

Optionally, the support means may be provided with means to affix it detachably to the surface of the body member, for example adhesive means.

The apparatus may be provided with at least two drill guide means, each having respective aiming means associated therewith.

Said at least two drill guide means may be spaced to correspond with spacing between the aperture means of a preselected fixation device having a plurality thereof.

The apparatus may be provided with elongate wire guide means removably insertable within the or each drill guide means and provided with axially-extending passage means adapted to receive directing wire means.

The wire guide means thus permits accurate implantation through aperture means of the fixation device of directing wire means adapted to lead cannulated drill means and, subsequently, cannulated locking screw means through the aperture means.

The wire guide means may comprise a substantially cylindrical body of rigid radiolucent plastics material dimensioned to fit closely within a hollow cylindrical drill guide means and provided with an axially-extending passage therethrough, dimensioned to receive a preselected size of wire.

A method for locking an intramedullary fixation device comprises the steps of inserting the fixation device within a fractured limb bone, providing an apparatus as described above, positioning the apparatus around the limb such that aiming means of the apparatus is substantially aligned with an aperture through the fixation device provided to receive locking screw means, inserting drill means along a drill guide means of the apparatus associated with said aiming means, drilling a bore through the bone aligned with said aperture and inserting locking screw means into said bore and said aperture through the fixation device.

Preferably, the method also comprises the steps of aligning aiming means of the apparatus with a further aperture through the fixation device, drilling a further bore aligned with said further aperture and inserting further locking screw means through said further bore and said further aperture.

Advantageously, the method comprises the step of aligning simultaneously a plurality of aiming means of the apparatus with respective apertures through the fixation device.

The method may comprise the step of aligning aiming means of the apparatus with a plurality of apertures through the fixation device, at least one of said plurality of apertures extending through the device transversely to a remainder thereof, optionally substantially orthogonally to a remainder thereof.

The method may optionally comprise the additional step of passing guide wire means through guide means of the apparatus and the respective aperture in the fixation device.

The method then comprises the step of providing wire guide means as described above, inserting it into drill guide means of the apparatus and passing directing wire means along axial passage means of the wire guide means.

The method may then comprise the steps of inserting cannulated drill means over the directing wire means, passing the cannulated drill means along the drill guide means and drilling a bore through the bone therewith, and inserting cannulated locking screw means over the directing wire means into said bore and said aperture.

The method may comprise subsequently removing said directing wire means.

Embodiments of the present invention will now be more particularly described by way of example and with reference to the accompanying drawings, in which:

Figure 1A is a schematic perspective view of a limb surround embodying the invention;

Figure 1B is a perspective view of a drill guide mountable to the limb surround of Figure 1A;

Figure 2 is a schematic perspective view of an alternative limb surround embodying the invention;

Figure 3 is a perspective view of the drill guide of figure 1B with an obturator and a guide wire in place therewithin;

Figure 4 is a cross-sectional profile of an alternative targeting ring;

Figure 5A is an elevation of a conventional interlocking nail;

Figure 5B is an elevation of the interlocking nail of Figure 5A, viewed from an orthogonal direction;

Figure 5C is an enlarged view of part of the nail of Figure 5B;

Figure 5D is a cross-section of the nail of figure 5A, taken along the line D-D;

Figures 6 to 8 show, schematically, the use of the limb support in the distal fixation of a nail; and

Figures 9 to 11 show, schematically, the use of the limb support fitted with the obturator of Figure 3 in the distal fixation of a nail, using a guide wire.

Referring now to the figures and to Figure 1A in particular, a limb surround 1 comprises a generally rectangular sheet of malleable, radiolucent material, which can be wrapped around a limb of a patient, maintaining the selected wrapped conformation until deliberately unwrapped after use. In a particularly convenient embodiment, the material is flexible when warmed above body temperature, but substantially rigid once permitted to return to ambient temperature.

In Figure 1A, the limb surround 1 is shown in a partially wrapped conformation. Such limb surrounds 1 are dimensioned to fit a particular part of a limb, substantially or completely encircling the limb when fully wrapped. For example, for use in locking a femoral fixation device, a limb surround fifteen centimetres wide and from forty-five to sixty-five centimetres long is envisaged. For tibial locking, a limb surround approximately fifteen centimetres wide and twenty five centimetres long is appropriate, and for use with a humeral fixation device, a limb surround about ten centimetres wide and thirty centimetres long is planned.

The limb surround 1 is provided adjacent a shorter edge thereof with two circular apertures 2, each of which is concentrically encircled by a targeting ring 3. The targeting rings 3 each comprise a thin ring of metal or other radioopaque material, such that they stand out clearly from a remainder of the limb support 1 under X-ray visualisation. The targeting rings 3 can also be embedded in an end of a respective drill guide 4 which extends from the limb surround 1.

A hollow cylindrical drill guide 4, as shown in Figure 1B, extends orthogonally outwardly away from each aperture 2 of the limb surround 1, the two drill guides 4 extending substantially parallelly, one to the other. The internal diameter of the drill guide 4 is dependent on the diameter of the drill to be used; for example, a 4.5 millimetre drill bit is accommodated sufficiently snugly by a drill guide 4 having an internal diameter of six millimetres. Each drill guide 4 is around five centimetres long and comprises rigid radiolucent plastics material.

In an alternative limb support 5, a first and second pair of circular apertures 2A, 2B are provided, each surrounded by a targeting ring 3, and having a drill guide 4 extending outwardly therefrom. The drill guides 4 mounted to a first pair of apertures 2A extend substantially parallel one to the other, and the drill guides 4 mounted to a second pair of apertures 2B also extend substantially parallelly one to the other. This limb support 5 allows locking to be carried out in more than one plane.

It is sometimes necessary, particularly for large or swollen limbs, to pass a guide wire through the bone and the nail, to be followed by a cannulated drill and subsequently by a cannulated screw (see below for details). So as to allow a guide wire to be passed accurately,

an elongate cylindrical obturator 6 is provided, which fits closely within the drill guide 4, as shown in Figure 3. The obturator 6 has an axial passage 7 extending longitudinally therethrough, dimensioned to receive a selected guide wire 8 (for example, a two-millimetre K wire). The guide wire 8 is thus aligned with a centre of the respective targeting ring 3. The obturator 6 is removed once the guide wire 8 is in position.

An alternative targeting guide 9 having an elongate cross-sectional profile, as shown in Figure 4, is used for dynamic locking.

A typical nail 10 for fixation of a long bone is shown in Figures 5A to 5D. It comprises an elongate tube of stainless steel with a generally trefoil cross-sectional profile 11 along a majority of its length. A slot 12 extends along substantially its entire length. Locking apertures 13, 14 extend through the nail 10 adjacent each end, adapted to receive screws, bolts, or the like, passing through the nail 10 and the bone of the limb to either side of the nail 10, to lock the nail 10 in position.

As shown in Figure 5C, the locking apertures 13, 14 can be substantially circular 13, for static locking of the nail 10, or can be elongate 14, for dynamic locking, in which a degree of longitudinal relative movement of the nail 10 and the bone is allowed, but relative rotation is still prevented.

Alternative nails 10 are provided with further locking apertures, adjacent those shown, but extending through the nail 10 orthogonally thereto. These allow passage of locking screws along multiple axes, where especially secure locking is required.

Nails for the fixation of fractures of the humerus or femur are of broadly similar design, appropriately dimensioned.

In each case, a jig of conventional form is used to guide insertion of the nail along the bone and across the fracture or fractures to be fixed, and this jig can be used to guide locking of a proximal end of the nail to the bone. The main problem, as described above, concerns locking of a distal end of the nail, to prevent rotation of a distal fragment of the bone relative to a proximal fragment.

In some procedures, nails are passed retrogradely, for example supracondylar femoral nails, retrograde humeral nails, and ankle arthrodesis nails. Here, the end of the nail distal from the insertion jig is actually embedded within the anatomically proximal bone fragment. The term "distal" locking should thus be understood herein as referring to the distal end of the nail and not necessarily as referring to the distal end of the corresponding bone.

The procedure for locking a nail 10 distally using the limb surround 1 is shown in Figures 6 to 8. For simplicity, only the radioopaque parts of the limb surround 1 are shown, Similarly, only the bone 15 of the patient's leg is shown, and not any surrounding tissues. The limb surround 1 can be wrapped around the limb in a generally correct disposition either before the nail 10 is inserted into the bone 15 across a fracture 16, or subsequently. To assist the distal locking of the nail 10, the disposition of the limb surround 1 is adjusted relative to the limb until the targeting ring 3 (and its associated drill guide 4) is aligned coaxially with a selected locking aperture 13 through the nail 10. Under X-ray visualisation, the targeting ring 3 and nail 10 are opaque, while the bone 15 is semi-opaque and surrounding tissues and remainder of the limb surround are substantially invisible.

It is desired that the aperture 2, targeting rings 3 and drill guides 4 of the limb surround 1 be so spaced that each targeting ring 3, etc, can be aligned with a respective locking aperture 13 of the nail 10 simultaneously. However, only one targeting ring 3 is shown here, for clarity.

Once the targeting ring(s) 3 is correctly aligned, the limb surround 1 is substantially immobilised relative to the limb, for example using a sterile adhesive band or bandage. Strips of hook and loop repositionable fastening fabric, or strips of malleable metal, may also be employed. If a second limb surround 1 is to be used, to facilitate locking using further locking apertures extending through the nail 10 transversely to those shown, this is preferably also aligned at this stage. The two limb surrounds 1 may then be fastened together if desired. (Alternatively, of course, the limb surround 5 of Figure 2 may be used in this situation).

A drill bit 17 is then passed along the drill guide 4 and through the targeting ring 3, bores through the bone 15, passes through the locking aperture 13 in the nail 10 and bores again into the bone 15 on an opposite side of the nail 10. The drill guide 4 ensures that the drill bit 17 passes substantially concentrically through the locking aperture 13 on a first attempt, saving time and avoiding unnecessary damage to the nail 10, the bone 15 or surrounding tissues.

The drill bit 17 is then withdrawn and a locking screw 18 is inserted into the bore created, securing the nail 10 to the bone 15. Further screws 18 may then be inserted in the same manner as required.

When the patient's limb is particularly large or swollen (e.g. due to trauma associated with a fracture), and so the separation between the targeting ring 3 and the nail 10 is relatively large, the above method may still not be sufficiently accurate. In such a case, it is helpful first to pass a guide wire 8 through the bone 15 and the locking aperture 13 before drilling a bore to receive a locking screw.

For this procedure, the obturator 6 of Figure 3 is placed within the respective drill guide 4 of the limb surround 1, before the limb surround 1 is accurately aligned with the limb under X-ray visualisation. (Note: the obturator 6 is radiolucent, but is shown in Figure 9 for illustrative purposes). Once the limb surround 1 has been affixed to the limb, the guide wire 8 is introduced along the axial passage 7 of the obturator 6, centrally through the targeting ring 3, through the soft tissue and bone 15 of the limb and through the locking aperture 13 of the nail 10 back into the bone 15. Its positioning within the locking aperture 13 can be checked radiographically.

Once the guide wire 8 is in position, the obturator 6 is withdrawn from the drill guide 4, and a cannulated drill bit 19 is inserted over the guide wire 8 and down the drill guide 4.

A cannulated drill 19 is one provided with a elongate axial passage extending inwardly from its tip, dimensioned to receive a preselected size of guide wire 8. Thus, as it bores through soft tissue and bone 15, the drill 19 is constrained to follow the guide wire 8, and so will pass substantially centrally through the locking aperture 13. The cannulated drill 19 is then withdrawn, and a cannulated screw 20 is inserted along the guide wire 8 into the bore made by the drill 19 and through the locking aperture 13, locking the nail 10 to the bone 15. The

drill support guide will need to be removed or incised before the head of the locking bolt can pass completely across the nail. The guide wire 8 is then withdrawn.

The limb surround 1 thus allows a surgeon to drill a bore to receive a locking screw that is accurately aligned with an aperture in an intramedullary nail or the like, rapidly and without the need for multiple attempts. The shorter procedure results in less tissue damage to the patient, a shorter time under anaesthesia, and a shorter exposure to X-ray for both the patient and the surgeon. The increased accuracy in drilling reduces damage to drills and nails alike due to inadvertent contacts therebetween.

A further advantage of the malleable limb surround 1 is that when wrapped around the limb, it will aid with the reduction of the fracture 16, and will also help to maintain this reduction, with the fragments of the bone 15 accurately aligned, while the nail 10 is locked in position. This is particularly beneficial in the case of comminuted fractures.

In some situations, a rigid limb surround could be beneficial. A range of limb surrounds would then be provided, sized and shaped to fit different portions of each limb and different limb sizes. A particular limb surround would be chosen so as to be easily repositionable around the limb during alignment with a respective aperture 13 in the nail 10. Once correctly aligned, it would be substantially immobilised with a sterile adhesive band or bandage, as described for the flexible limb surround, above.

In an alternative to the radiolucent limb surrounds described above, limb surrounds of radioopaque material may be employed instead, comprising for example sheets of malleable metal. In this case, instead of a radioopaque targeting ring 3, as shown above, a radiolucent

targeting arrangement is used. In its simplest form, this will comprise an aperture through the limb surround, cooperating with a respective end of the or each drill guide.

CLAIMS

1. An apparatus to facilitate locking to bone of an intramedullary fixation device having aperture means to receive locking screw means, the apparatus comprising support means locatable on or around a body member adjacent a bone fracture, elongate substantially radiolucent drill guide means extending outwardly from the support means, and aiming means associated with said drill guide means contrasting radiologically with the support means and alignable under radiographic visualisation with said aperture means.

2. An apparatus as claimed in claim 1, wherein the drill guide means comprises a hollow cylinder adapted to receive and guide drill means extending therethrough into the body member.

3. An apparatus as claimed in either claim 1 or claim 2, wherein the drill guide means comprises rigid radiolucent plastics material.

4. An apparatus as claimed in any one of the preceding claims, wherein the support means is substantially radiolucent, and the contrasting aiming means is radioopaque.

5. An apparatus as claimed in claim 4, wherein the aiming means comprises one or more radioopaque elements mounted to the support means or the drill guide means adjacent an end of the drill guide means adjacent a surface of the body member.

6. An apparatus as claimed in claim 5, wherein said one or more radioopaque elements are adapted to indicate a longitudinal axis of the drill guide means.

7. An apparatus as claimed in either claim 5 or claim 6, wherein the aiming means comprises an annular radioopaque element concentrically surrounding the end of the drill guide means locatable adjacent the surface of the body member.

8. An apparatus as claimed in any one of claims 1 to 3, wherein the support means is partially or substantially radioopaque, and the contrasting aiming means is radiolucent.

9. An apparatus as claimed in claim 8, wherein the aiming means comprises an aperture through the radioopaque support means adjacent an end of the drill guide means adjacent a surface of the body member.

10. An apparatus as claimed in any one of claims 4 to 9, wherein the aiming means comprises a plurality of elongate indicia extending towards the longitudinal axis of the drill guide means.

11. An apparatus as claimed in any one of the preceding claims, wherein the support means comprises flexible sheet means adapted to be wrappable around a substantial portion of said body member.

12. An apparatus as claimed in claim 11, wherein the drill guide means is so mounted to the flexible sheet means as to extend substantially normally to adjacent portions thereof.

13. An apparatus as claimed in either claim 11 or claim 12, wherein the flexible sheet means is capable of substantially retaining a configuration into which it is wrapped.

14. An apparatus as claimed in any one of claims 11 to 13, wherein the sheet means is flexible only when warmed to a temperature above body temperature.

15. An apparatus as claimed in any one of claims 1 to 10, wherein the support means is substantially rigid and is configured to fit around a substantial proportion of a body member of known dimensions.

16. An apparatus as claimed in any one of the preceding claims, wherein the support means is provided with means to affix it detachably to the surface of the body member, for example adhesive means.

17. An apparatus as claimed in any one of the preceding claims, provided with at least two drill guide means, each having respective aiming means associated therewith.

18. An apparatus as claimed in claim 17, wherein said at least two drill guide means are spaced to correspond with the spacing between aperture means of a fixation device.

19. An apparatus as claimed in any one of the preceding claims, provided with elongate wire guide means removably insertable within the or each drill guide means and provided with axially-extending passage means adapted to receive directing wire means.

20. An apparatus as claimed in claim 19, wherein the wire guide means comprises a substantially cylindrical body of rigid radiolucent plastics material dimensioned to fit closely within a hollow cylindrical drill guide means and provided with an axially-

extending passage therethrough, dimensioned to receive a wire of predetermined diameter.

21. An apparatus to facilitate locking of bone to an intramedullary fixation device having aperture means to receive locking means, substantially as described herein and with reference to the Figures of the accompanying drawings.

Application No:	GB0407436.5	**Examiner:**	Mr Haydn Gupwell
Claims searched:	1-20	**Date of search:**	27 August 2004

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	None	US 5728128 A (CRICKENBERGER et al).
A	None	US 5403321 A (DIMARCO).
A	None	US 5031203 A (TRECHA).
A	None	US 4803976 A (FRIGG et al).
A	None	US 4625718 A (OLERUD et al).
A	None	DE 3205404 A (KLUGER).

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{W} :

A5R

Worldwide search of patent documents classified in the following areas of the IPC^{07}

A61B

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI, JAPIO