

Title

AN INTRAMEDULLARY NAIL SYSTEM

Field of the Invention

- 5 This invention relates to a nail system. In particular, this invention relates to a cephalomedullary nail.

Background to the Invention

- 10 Hip fractures, *i.e.* fractures of the proximal femur, are among the most serious long bone fractures due to their potential for non-union, mal-union, and long-term dysfunction, as well as their propensity for open injury. Intramedullary nails have been in use for some time as aids in healing bone fractures and are the gold standard treatment option for such fractures.

- 15 Intramedullary nailing acts as an internal splint and permits early weight bearing along with fracture healing. Examples of nail systems used for fixation of bones include an intramedullary nail described in (a) WO 2012/107056 having a coupling unit with a cylindrical pin engaging a bone fastener; (b) US 9295504 having an anti-rotation shaft fixed in position by nails and a lag screw lock; (c) EP 2779927 which describes a bone
20 fixation implant comprising an elongated implant shaft having a first channel extending from a proximal end to a side opening in a side wall of an implant shaft along a first axis and a second channel extending longitudinally through the implant shaft from the proximal end to the distal end along a second axis, characterized in that the first and second channel axes enclose an angle of one of 5°, 6°, 7.5° and 8°; (d) EP 1663037
25 which describes an apparatus for treating a bone fracture that comprises a compression member that cooperates with an engaging member to preclude rotation of the engaging member relative to the implant; and (e) EP 3079614 which describes one flexible screw with an internal thread for attachment of a compression screw and/or driver to change it from a flexible to a rigid conformation, *i.e.* a single screw fixation element, which in
30 practice can be flexible or rigid, for stiffening the fixation screw so that it can be compressed into a proximal femur.

- Current intramedullary nailing systems may not have adequate rotational, construction and fixation stability. Having a nailing system with better stability will assist in fracture
35 healing.

It may also be beneficial to provide a nail system that can be placed in different configurations depending on the anatomy, fracture pattern and surgeon preference to assist with better fixation and recovery.

- 5 It is an object of the invention to address at least one of the above-mentioned problems or to at least provide an alternative solution.

Furthermore, although the invention has specific applicability in intramedullary nailing it may be more broadly used in other general orthopaedic procedures as a system with
10 improved fixation and stability.

Summary of the Invention

The majority of hip fracture nails only include the option to place one screw or fastener. While multiple devices do offer two screw or fastener options, and even options where
15 the two fasteners mechanically interact, no device includes two offset locking screws or screws which mechanically interact together as set out in the claimed invention. The nail and nail system of the claimed invention sets the placement of the second locking screw offset from and within the first locking screw at an angle such that the mechanical interaction between the two locking screws, the nail and a clamping mechanism or set
20 screw provides improved fixation and overall stability (both rotationally and in terms of translation) relative to other contemporary devices. The outcome of this improved stability is a reduction in post operative complications such as non-union, malunion, cutout, cut-through and limb shortening. Additionally, the functionality that allows the user to select between two distinct trajectories using one set of implants is advantageous.
25 This provides pre-operative and intra-operative flexibility and allows tailoring of the implant system to provide a more idealized fixation setup for each patient's needs.

The invention relates to a nail for a cephalomedullary nail system as set out in the appended claims.
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The invention also relates to a cephalomedullary nail system as set out in the appended claims.

In an aspect of the present invention, there is provided a nail (1) for use with a
35 cephalomedullary nail system (100,101). The nail (1) comprising a proximal end (4) and a distal end (40), and having a substantially elongate cylindrical body member (45). The

proximal end (4) further comprises a non-circular nail stem (11) comprising a first end (6) located further from the distal end (40), a second end (60) located closer to the distal end (40). The non-circular nail stem (11) is typically a fluted nail stem (11) comprising a plurality of protrusions (12) extending radially outwards from an outer surface (5) thereof
5 and a plurality of grooves (13) formed between the protrusions (12). The axis of the nail stem (11) and the axis of the body member (45) are offset from each other by between about 2° to about 5°, and preferably by about 4°. That is to say that the nail stem (11) is bent at between about 2° to about 5° relative to the body member (45).

10 In an example, the protrusions (12) are equally sized and spaced around the circumference of the nail stem (11).

In an example, the grooves (13) have a substantially semi-circular cross-sectional shape.

In an example, the grooves (13) have a substantially square cross-sectional shape.

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The non-circular nail stem (11) is intended to be inserted into a circular entry portal in a bone. The entry portal is typically of a smaller size than the non-circular nail stem (11) diameter. The interference level between the non-circular nail stem (11) and the entry portal in the bone (femur) allows for insertion of the nail (1). The interference level
20 compresses bone at the nail stem-to-bone interface, providing axial and rotational stability.

In an example, the cross-sectional shape of the flute nail stem (11) is constant along at least a length of the fluted nail stem (11).

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In an example, wherein at least a portion of the nail stem (11) is tapered in the direction of the first end (6) to the second end (60).

In an example, the longitudinal axis of the nail (1) is curved.

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In an example, the fluted nail stem (11) has a diameter, measured between the grooves (13), of between 14mm and 16mm.

In an example, the fluted nail stem (11) has a diameter, measured between the grooves
35 (13), of between about 12mm to about 18mm; or between about 13mm to about 17mm; or between about 14mm to about 16mm; or substantially 15mm. Preferably, the fluted

nail stem (11) has a diameter, measured between the grooves (13), of 15mm, 15.1mm, 15.2mm, 15.3mm, 15.4mm, 15.5mm, 15.6mm, 15.7mm, 15.8mm, or 15.9mm. Ideally, the diameter is 15.4mm.

- 5 In an example, the fluted nail stem (11) has a diameter, measured between the protrusions (12), of between 16mm and 19mm, or between about 16.5mm and 18.5mm, or between about 17mm and about 18mm. Preferably, the fluted nail stem (11) has a diameter, measured between the protrusions (12), of 17mm, 17.1mm, 17.2mm, 17.3mm, 17.4mm, 17.5mm, 17.6mm, 17.7mm, 17.8mm, or 17.9mm. Ideally, the diameter is
10 17.5mm.

- In an example, the fluted nail stem (11) has a diameter, measured between the protrusions (12), of substantially 17.5mm. The fluted nail stem (11) is designed to allow rotation during insertion into the bone but to prevent rotation once fully seated. The
15 dimensions of the fluted nail stem (11) allow rotational adjustment up until the point where the fluted nail stem, and hence the nail (1) itself, is fully seated and at the point of fully seating, it is rotationally locked.

- In a further aspect of the present invention, a cephalomedullary nail system (100,101) is
20 provided. The system comprising a or the nail (1) described above which has a proximal end (4) and a distal end (40), and having a substantially elongate cylindrical body member (45,45a), wherein the proximal end (4) further comprises a non-circular nail stem (11); a first locking screw (2) (the lag screw), and a second locking screw (3) (the diverging screw), comprising a threaded portion (17,18), respectively, configured to
25 engage with bone. The first locking screw (2) has a greater diameter than the second locking screw (3). The first locking screw (2) comprises an aperture (7) configured to accommodate the second locking screw (3) within and through the structure of the first locking screw (2). The nail (1) comprises an aperture (8) having an entry point (15) and an exit point (16) configured to accommodate the first locking screw (2) and the second
30 locking screw (3) when the second locking screw (3) is fitted within and through the structure of the first locking screw (2); and wherein the first locking screw (2) further comprises one or more radiographic markings (29) configured to indicate rotational alignment of the first locking screw (2) and at least two radial notches (30) configured to indicate the correct depth of the first locking screw (2) in the nail stem (11). The second
35 locking screw (3) fits within and passes through the structure of the first locking screw

(2) via the aperture (7), and both first and second locking screws (2,3) fixate onto bone (the head of a femur, for example).

In one aspect, the non-circular nail stem (11) comprises a first end (6) located further
5 from the distal end (40), and a second end (60) located closer to the distal end (40).
Preferably, the non-circular nail stem (11) is a fluted nail stem comprising a plurality of
protrusions (12) extending radially outwards from an outer surface (5) thereof; and a
plurality of grooves (13) formed between the protrusions (12). More preferably, the
10 protrusions (12) are equally sized and spaced around the circumference of the nail stem
(11).

In one aspect, the grooves (13) have a substantially square or substantially semi-circular
cross-sectional shape.

15 In one aspect, the fluted nail stem (11) has a diameter, measured between the grooves
(13), of between 14mm and 16mm. Preferably, the fluted nail stem (11) has a diameter,
measured between the grooves (13) of 15.4mm.

In one aspect, the fluted nail stem (11) has a diameter, measured between the
20 protrusions (12), of between 16mm and 19mm. Preferably, the fluted nail stem (11) has
a diameter, measured between the protrusions (12) of substantially 17.5mm.

In one aspect, the cross-sectional shape of the nail stem (11) is constant along at least
a length of the nail stem (11).

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In one aspect, the at least a portion of the nail stem (11) is tapered in the direction of the
first end (6) to the second end (60).

In one aspect, the first locking screw (2) further comprises a partial internal thread (21)
30 which corresponds to the threaded portion (18) of the second locking screw (3).
Preferably, the length of the threaded portion (18) of the second locking screw (3) limits
the depth that the second locking screw (3) can be placed within the first locking screw
(2).

35 In one aspect, the longitudinal axis of the nail (1) is curved.

In an example, in a first configuration the second locking screw (3) is inferior to the first locking screw (2) when in use.

5 In an example, in a second configuration the second locking screw (3) is superior to the first locking screw (2) when in use.

10 In one aspect, the first locking screw (2) further comprises at least one radiographic marking (29), wherein when viewed on the inferior side of the first locking screw (2) indicates that the second locking screw (3) can be placed in the superior configuration.

In one aspect, the first locking screw (2) further comprises at least one radiographic marking (29), wherein when viewed on the superior side of the first locking screw (2) indicates that the second locking screw (3) can be placed in the inferior configuration.

15 In one aspect, when the at least one radiographic marking (29) is visible the first locking screw (2) is in an incorrect rotation.

20 In one aspect, if no radiographic markings (29) are visible, the first locking screw (2) is in a correct rotation.

In one aspect, the first locking screw (2) further comprises at least one radial notch (30), wherein the interaction between the at least one radial notch (30) and the entry point (15) in the non-circular nail stem (11) indicates the correct depth placement window (31) for the first locking screw (2). Preferably, if one radial notch (30) is visible the depth of the first locking screw (2) is acceptable.

25 In one aspect, if two radial notches (30) are visible the depth of the first locking screw (2) is too lateral.

30 In one aspect, if no radial notches (30) are visible the depth of the first locking screw (2) is too medial.

35 In an example, the aperture (7) has an axis offset from the axis of the first locking screw (2) by between 0° and 90°. Preferably, the aperture (7) has an axis offset from the axis of the first locking screw (2) by between 5° and 15°.

In an example, the aperture (8) has a substantially circular cross-section.

In an example, the aperture (8) has a longitudinal axis offset from the longitudinal axis of the nail (1) by between about 115° and about 140°. Preferably, the aperture (8) has a longitudinal axis offset from the longitudinal axis of the nail (1) by between about 120° and about 130°.

In an example, the aperture (8) comprises a first indentation (22) on the exit point (16). In an example, the first indentation (22) is located on a proximal side (50) of the aperture (8).

In an example, the aperture (8) comprises a second indentation (23) on the entry point (15). In an example, the second indentation (23) is located on a distal side (52) of the aperture (8).

In one aspect, the first indentation (22) and the second indentation (23) limit the axial movement of the first locking screw (2) and the second locking screw (3) when both are conjoined in the nail stem (11). This means that the second locking screw (3) is fitted within the structure of the first locking screw (2). This is referred to as "slide limitation". Slide limitation refers to the way in which the size of the indentations (in particular the first indentation (22)) are configured to limit slide to a maximum level, *i.e.* the point at which the second locking screw interacts with the indentation is calibrated to be at 1mm to 20 mm of slide. In an example, the point at which the second locking screw interacts with the indentation may be calibrated to be at 10mm of slide.

In one aspect, the cephalomedullary nail system (100,101) further comprises a targeting arm (300) configured to engage with the first locking screw (2) and the second locking screw (3), the targeting arm (300) comprising an aiming arm (302) and a positioning element (306) having at least one hole (301a,301b) adapted to accommodate placement of the second locking screw (3) within an aperture (7) in the first locking screw (2) and a hole (303) adapted to accommodate and position the first locking screw (2).

In one aspect, the nail (1) further comprises a set screw (24) to hold the first locking screw (2) and the second locking screw (3) in place when inserted inside the aperture (8). Preferably, the set screw (24) is located in a bore (42) of the fluted nail stem (11).

In one aspect, the set screw (24) comprises:

- a threaded member (24a) configured to engage with a complementary threaded portion (25) located within the bore (42); and
- an engaging member (26) connected to the threaded member (24a);
- 5 wherein the engaging member (26) comprises up to two wings (27) configured to engage the first locking screw (2) when inserted inside the aperture (8);
- wherein when the threaded member (24a) is tightened the engaging member (26) moves in a direction towards the first locking screw (2) such that the up to two wings (27) engage the first locking screw (2); and
- 10 wherein when the threaded member (24a) is loosened the engaging member (26) moves in a direction away from the first locking screw (2) such that the up to two wings (27) disengage the first locking screw (2).

15 In one aspect, the first locking screw (2) has at least one flat side (28) configured to engage the up to two wings (27).

In one aspect, there is provided a kit of parts for use in repairing a bone fracture, the kit comprising the cephalomedullary nail system (100,101) described above.

20 The kit further comprises a first locking screw (2) and second locking screw (3). The kit further comprises a locking mechanism or set screw (24).

In one embodiment, the material of construction of the nail system (100,101) is suitably a durable, rigid and biocompatible material, for example, implant-grade titanium alloys
25 (such as titanium-aluminium-vanadium (Ti-6AL-4V ELI64) or titanium-aluminium-niobium (Ti-6Al-7Nb)), stainless steel (316L or 316LVM), or any other metal alloy, composite, polymer material or combination thereof that is suitable for load-bearing application as an *in vivo* implant.

30 In one aspect, there is provided a method of repairing a femur fracture using the cephalomedullary nail system (100,101) described above, the method comprising the steps of:

- i. positioning the affected limb of the patient;
- ii. reducing the bone fracture;
- 35 iii. opening a portal to the medullary canal, at the proximal femur and drilling a short entry passage;

- iv. optionally reaming the medullary canal;
- v. inserting the nail (1) into the entry passage to an initial position;
- vi. rotational alignment of the non-circular nail stem (11) with the bone;
- vii. advancement of the nail (1) to its final position;
- 5 viii. placing the first locking screw (2);
- ix. placing the second locking screw (3) in the intended configuration in the cephalomedullary nail system (100,101);
- x. optionally inserting at least one fixing screw (10); and
- xi. closing all soft tissue.

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In one aspect, the method further comprises the step of confirming the correct rotation of the first locking screw (2) by determining before step ix. by observing whether at least one radiographic marking (29) is visible or not. Preferably, when the at least one radiographic marking (29) is visible the first locking screw (2) is in an incorrect rotation.

- 15 Preferably, when the at least one radiographic marking (29) is not visible the first locking screw (2) is in a correct rotation.

- 20 In one aspect, the method further comprises the step of confirming whether the first locking screw (2) is at the correct depth prior to step ix., the step comprising determining the interaction between at least one radial notch (30) on the first locking screw (2) and the entry point (15) in the non-circular nail stem (11). Preferably, if one radial notch (30) is visible at or before the entry point (15), the depth of the first locking screw (2) is acceptable. Preferably, if two radial notches (30) are visible at or before the entry point (15), the depth of the first locking screw (2) is too lateral. Preferably, if no radial notches
- 25 (30) are visible at or before the entry point (15), the depth of the first locking screw (2) is too medial.

- 30 In one aspect, the method further comprises the step of adjusting the set screw (24) to assert downward pressure on the conjoined and already inserted first locking screw (2) and the second locking screw (3). Preferably, when the downward pressure of the set screw (24) is optionally relieved by turning the set screw (24) by at least one quarter turn anti-clockwise.

Definitions

- 35 In the specification, the term "cephalomedullary" should be understood to mean interacting with both the medulla, that is, the hollow part of bone that contains bone

marrow and the head of the femur. Cephalomedullary nails are specific to the proximal end (hip end) of the femur. All cephalomedullary nails are intramedullary nails. However, not all intramedullary nails are cephalomedullary nails.

- 5 In the specification, the term “intramedullary” should be understood to mean situated or occurring within the medulla, that is, the hollow part of bone that contains bone marrow. An intramedullary nail is any nail which is placed into the medullary canal of a long bone (tibia, femur, humerus).
- 10 In the specification, the term “press fit” should be understood to mean the fastening of two parts that is achieved by normal force or friction. For example, when a shaft is inserted tightly into a slightly smaller hole in another part, with the interference holding both parts in place.
- 15 In the specification, the term “non-circular nail stem” should be understood to mean a nail stem, being defined by an outer wall, where the surface has features that lend to the nail stem having a non-circular appearance. For example, the nail stem could be fluted, have spikes, have teeth or protrusions, be triangular, square, trapezoidal or polygonal or have a combination of any these features.
- 20 In the specification, the term “fluted” should be understood to mean where the surface of an object has many curves or protrusions that go in and out, such as, for example, a fluted standing column.
- 25 In the specification, the term “protrusion” or “protrusions” should be understood to mean a bulge, a projection or protuberance that is an extension beyond the normal line or surface of an object or thing. The protrusions may also be teeth. In this instance, the protrusion can be likened to a tooth on a cog.
- 30 In the specification, the term “rigid mode” should be understood to mean a locking mode of cephalomedullary nail systems whereby the fixation member(s) (the first (lag screw) or second locking screws) is rigidly locked within the stem of the nail thereby preventing any rotational or translational movement of the fixation member(s) relative to the nail.
- 35 In the specification, the term “sliding mode” should be understood to mean a locking mode of cephalomedullary nail systems whereby the fixation member(s) (first locking

screw or lag screw; or the second locking screw) is partially locked within the stem of the nail thereby preventing any rotational movement but allowing translational movement of the fixation member(s) relative to the nail.

- 5 In the specification, the term “locking screw” should be understood to mean the screws of the claimed invention that are placed through the nail stem and secure it to the femur. In this instance, the first locking screw has a diameter larger than the diameter of the second locking screw, which permits the second locking screw to pass through, at an angle, the structure of the first locking screw (the second locking screw being confined
10 within and by the first locking screw). Both first and second locking screws then fixate onto bone providing additional fixation to the head of the femur.

Brief Description of the Drawings

- The invention will be more clearly understood from the following description of an embodiment thereof, given by way of example only, with reference to the accompanying
15 drawings, in which:

Figure 1 shows a front view of a cephalomedullary nail system according to a first aspect of the invention and in a first configuration;

- 20 **Figure 2** shows a cross-section of the back view of the cephalomedullary nail system of Figure 1;

Figure 3 shows a perspective view of the cephalomedullary nail system of Figure 1;

- Figure 4** shows a front view of the cephalomedullary nail system of Figure 1 in a second configuration;

- 25 **Figure 5** shows a cross-section of the back view of the cephalomedullary nail system of Figure 4;

Figure 6 shows a perspective view of the cephalomedullary nail system of Figure 4;

- 30 **Figure 7** shows a front view of a cephalomedullary nail system according to a second aspect of the invention and in a first configuration;

Figure 8 shows a cross-section of the back view of the cephalomedullary nail system of Figure 7;

Figure 9 shows a perspective view of the cephalomedullary nail system of Figure 7;

- 35 **Figure 10** shows a front view of the cephalomedullary nail system of Figure 7 in a second configuration;

- Figure 11** shows a cross-section of the back view of the cephalomedullary nail system of Figure 10;
- Figure 12** shows a perspective view of the cephalomedullary nail system of Figure 10;
- 5 **Figure 13** shows a cross-section of the back view of the nail of the cephalomedullary nail system of Figure 1;
- Figure 14** shows a front view of the nail of Figure 13;
- Figure 15** shows a perspective view of the nail of Figure 13;
- Figure 16** shows a cross-section of the back view of the nail of the cephalomedullary nail system of Figure 7;
- 10 **Figure 17** shows a front view of the nail of Figure 16;
- Figure 18** shows a perspective view of the nail of Figure 16;
- Figure 19** shows a top view of the first locking screw of the cephalomedullary nail system of Figure 1;
- 15 **Figure 20** shows a side view of the first locking screw of figure 19;
- Figure 21** shows a second side view of the first locking screw of Figure 19;
- Figure 22** shows a bottom view of the first locking screw of Figure 19;
- Figure 23** shows a front view of the first locking screw of Figure 19;
- Figure 24** shows a back view of the first locking screw of Figure 19;
- 20 **Figure 25** shows a top view of a first locking screw according to a different embodiment;
- Figure 26** shows a side view of the first locking screw of Figure 25;
- Figure 27** shows a cross-sectional view of the first locking screw of Figure 26;
- 25 **Figure 28** shows a front view of the first locking screw of Figure 25;
- Figure 29** shows a back view of the first locking screw of Figure 25;
- Figure 30** shows a side view of the second locking screw of the cephalomedullary nail system of Figure 1;
- Figure 31** shows a front view of the second locking screw of Figure 30;
- 30 **Figure 32** shows a back view of the second locking screw of Figure 30;
- Figure 33** shows a front view of the set screw assembly of the cephalomedullary nail system of Figure 1;
- Figure 34** shows a bottom view of the set screw assembly of Figure 33;
- Figure 35** shows a side view of the set screw assembly of Figure 33;
- 35 **Figure 36** shows a back view of the set screw assembly of Figure 33;
- Figure 37** shows a side view of the set screw assembly of Figure 33;

- Figure 38** shows a top view of the first portion of the set screw assembly of Figure 33;
- Figure 39** shows a side view of the first portion of Figure 38;
- Figure 40** shows a cross-sectional view of the first portion of Figure 39;
- 5 **Figure 41** shows a bottom view of the first portion of Figure 38;
- Figure 42** shows a front view of the second portion of the set screw assembly of Figure 33;
- Figure 43** shows a bottom view of the second portion of Figure 42;
- Figure 44** shows a back view of the second portion of Figure 42;
- 10 **Figure 45** shows a front view of the second portion of Figure 42;
- Figure 46** shows a cross-section of a front view of the second portion of Figure 42;
- Figure 47** shows a bottom view of the second portion of Figure 42;
- Figure 48** shows a side (A) and rear (B) view of the targeting arm of the claimed invention.
- 15 **Figure 49** shows a side view of the targeting arm of Figure 48 engaged with the cephalomedullary nail system of the claimed invention during placement of the second fixation member of figure 30.
- Figure 50** shows a section view of Figure 49.
- 20 **Figure 51** shows (A) the minimum acceptable depth of the first locking screw (lag screw) in the nail stem of claimed invention and (B) the maximum acceptable depth of the first locking screw (lag screw) in the nail stem of claimed invention, and (C) is the central or nominal position of the first locking screw (lag screw) (in terms of depth). When placed at this depth, the aperture in the first locking screw
- 25 is aligned perfectly with targeting hole in the targeting arm.
- Figure 52** shows a cross-sectional view of a femur with the cephalomedullary nail system of Figure 1 implanted therein.

Detailed Description of the Drawings

- 30 Fixation using screws or other similar fixation members is commonplace in intramedullary nailing and more broadly in general orthopaedic procedures. The claimed nail and nail system provides improved fixation and improved stability which translates into improved patient outcomes. This nail and nail system has significant applications in the trauma space but could also more broadly be applied in general orthopaedics.

Referring to the figures, **Figures 1 to 6** illustrate an example of a cephalomedullary nail system 100. The cephalomedullary nail system 100 shown comprises a nail 1, a first locking screw 2, and a second locking screw 3.

5 **Figures 13 to 15** show the nail 1 of the cephalomedullary nail system 100. The nail 1 comprises a body member 45 having a proximal end 4 and a distal end 40. In use, the proximal end 4 is positioned near the top of a femur (given the reference number 200), while the distal end 40 is positioned towards the bottom half of the femur 200. The nail 1 may be substantially elongate and cylindrical in shape. The body member 45 of the nail
10 1 is substantially hollow and comprises a cylindrical bore 42 around a longitudinal axis as shown in **Figures 2 and 5**. The bore 42 typically extends along the entire length of the body member 45 of the nail 1, from the proximal end 4 to the distal end 40. The longitudinal axis of the body member 45 of the nail 1 may be non-linear or curved, as shown in **Figures 2, 3, 5, and 6**. The curved shape of the body member 45 of the nail 1
15 may follow the general shape of a femur 200.

The distal end 40 of the nail 1 may also comprise one or two apertures 9 through which a fixing screw 10 passes through each, and a slot 9a configured to accommodate a further fixing screw 10. The distal end 40 of the nail 1 is secured to the femur 200 when
20 in use.

The nail 1 may further comprise a non-circular nail stem 11 located at a proximal end 4 of the nail 1. The elongate body member 45 is connected to or integrally formed with the non-circular nail stem 11. In use, the body member 45 may be positioned along a shaft
25 201 of the femur 200 and the non-circular nail stem 11 may be positioned at least partly through the greater trochanter 202 of the femur 200, as shown in **Figure 52**. The non-circular nail stem 11 is configured to be press fit, e.g. configured to press fit into the femur 200.

30 The non-circular nail stem 11 comprises a first end 6 and a second end 60. Typically, the non-circular nail stem 11 is a fluted nail stem comprising a plurality of protrusions 12 extending radially outwards from an outer surface 5 of the non-circular nail stem 11. For ease of reference, the non-circular nail stem 11 shall be referred to as the fluted nail stem 11 hereinafter. The first end 6 of the fluted (non-circular) nail stem 11 is located further
35 from the distal end 40 of the nail 1 and the second end 60 is located closer to the distal end 40 of the nail 1. The protrusions 12 (which can also be referred to as teeth) may be

equally sized and spaced. In the examples shown, they are equally spaced around the circumference of the nail stem 11. Formed between the protrusions 12 are a plurality of grooves or flutes 13, which create a space within which becomes occupied by bone when the nail 1 is in use (*in situ* in the femur 200). The grooves 13 may have a substantially

5 semi-circular cross-sectional shape, for example, they may be crescent shaped, v-shaped, u-shaped, or arc-shaped. In other examples, the grooves 13 may have straight sides rather than forming a curved surface. The protrusions 12 may extend along the entire length of the fluted nail stem 11. In some examples the protrusions 12 extend along at least a part of the length of the fluted nail stem 11.

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The protrusions 12 are configured to interact with bone surrounding the fluted nail stem 11 when *in situ*. The protrusions 12 and their interaction with the surrounding bone of a femur provide an overall improved stability, including an improved construct and rotational stability. The protrusions 12 also increase the relative cross-sectional area of

15 the fluted nail stem 11 that interacts with the bone, therefore improving the fatigue life of the fluted nail stem 11. The radial design of the protrusions 12 may provide a relatively low force of insertion, *i.e.* be relatively easy to insert, whilst also providing a relatively high resistance to rotation once it has been implanted. Furthermore, the radial design of the protrusions 12 distributes any stresses (created in the bone during insertion) radially

20 around the circumference of the fluted nail stem 11, which may lead to lower levels of stress concentrated in the bone. In some examples, the protrusions 12 may be located on only some circumferential regions of the fluted nail stem 11. The semi-circular cross-sectional shape may increase the relative surface area of the grooves 13 which contacts the surrounding bone. During insertion of the nail stem 11, the protrusions 12 create

25 localized, radially outward deformations of the bone, which fills into the grooves 13. The design and shape of the protrusions 12 and the grooves 13 compress the bone in use to generate these localised deformations and create a tight fit (press fit) between the nail 1 and the bone of the femur 200.

30 At least a portion of the fluted nail stem 11 may be tapered, *i.e.* the diameter may reduce along the length of the fluted nail stem 11 in the direction of the first end 6 to the second end 60. The second end 60 of the fluted nail stem 11 typically has a smaller diameter than the first end 6 of the fluted nail stem 11. This may make insertion of the nail 1 easier and assist in reducing the insertion force required. The body member 45 of the nail 1

35 typically has substantially the same diameter as, and is continuous with, the second end 60 of the tapered fluted nail stem 11.

The fluted nail stem 11 typically has a diameter, measured between the grooves 13, of between 14mm and 16mm, and in some examples may be approximately 15mm, and in some examples may be approximately 15.4mm. The fluted nail stem 11 typically has a diameter, measured between the protrusions 12, of between 16mm and 19mm, and in
5 some examples may be approximately 17mm, and in some examples may be approximately 17.5mm.

In use, the fluted nail stem 11 may be placed into a reamed opening hole in the femur
200, with a size of the opening hole determined based on the desired outcome or fixation
10 strength. In some examples, the reamed opening hole may be between 14mm and 18mm, and in some examples may be approximately 15mm or 16mm, and in some examples may be either approximately 15.5mm or 16.5mm. This allows for generally between 0.5mm and 1.0mm of radial interference between the nail stem 11 and the bone of the femur 200. This interference couples the fluted nail stem 11 rigidly with the femur
15 200 with little or no relative rotation. The nail 1 is designed to allow rotation during insertion into the bone but to prevent rotation once fully seated. The fluted or non-circular nature of the nail stem 11 allows rotational adjustment up until the point where it is fully seated and at the point of fully seating, it is rotationally locked. At full seating, that is when the nail 1 is correctly inserted in the femur 200, the fluted or non-circular design
20 engages and compress the bone giving stability to the nail/bone construct.

The fluted nail stem 11 may provide an improved fixation and stability relative to alternative existing systems whilst having a minimal or no increase in the surgical time and/or procedure difficulty. The improved fixation and stability may reduce post operative
25 complications such as non-union, malunion, cutout, cut-through and limb shortening.

The fluted nail stem 11 further comprises an aperture 8 that extends from one side of the nail stem 11 at an entry point 15 through to an opposite side of the fluted nail stem 11 at an exit point 16, as shown in **Figures 13 and 14**. In some instances, the entry point 15 and the exit point 16 can be reversed, that is, the first locking screw 2 can enter the
30 aperture 8 through either the entry point 15 or the exit point 16, depending on the need of the user. The aperture 8 is configured to accommodate the first locking screw 2 and the second locking screw 3. The exit point 16 may be located closer to the first end 6 of the fluted nail stem 11 and the entry point 15 may be located closer to the second end
35 60 of the fluted nail stem 11. The longitudinal axis of the aperture 8 may be non-perpendicular and non-collinear to the longitudinal axis of the nail 1. The longitudinal axis

of the aperture 8 may be offset from the longitudinal axis of the nail 1 by between about 115° and about 140°, as best shown in **Figures 2** and **5**. In some instances, the longitudinal axis of the aperture 8 may be offset from the longitudinal axis of the nail 1 by between about 120° and about 130°, or between about 121° and about 126°, or is set at 5 121° or 126° relative to the nail stem 11, or 125° or 130° if relative to the body member 45 (where the nail stem 11 itself is bent at an angle of 4° relative to the longitudinal axis of the body member 45). The angle of the aperture 8 positions the first locking screw 2 and the second locking screw 3 to contact the femur 200, when in use, through a neck 203 and a head 204 thereof, as shown in **Figure 52**.

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Figures 19 to 24 show the first locking screw 2 of the cephalomedullary nail system 100,101. **Figures 30 to 32** show the second locking screw 3 of the cephalomedullary nail system 100,101. The first locking screw 2 also may be termed the lag screw and the second locking screw 3 may be termed the diverging screw. The first locking screw 2 15 and the second locking screw 3 may be substantially cylindrical in shape. As can be seen in these figures, the first locking screw 2 and the second locking screw 3 may each have a threaded portion 17,18 (respectively) and a non-threaded portion 19,20 (respectively). The threaded portions 17,18 are the leading ends of the first locking screw 2 and the second locking screw 3 (respectively) that are inserted into the femur 200. The threaded 20 portion 17 of the first locking screw 2 is typically shorter in length than the threaded portion 18 of the second locking screw 3. The first locking screw 2 and the second locking screw 3 may be substantially the same length. In some examples, the second locking screw 2 may be shorter than the first locking screw 2. The first locking screw 2 may have a larger diameter than the second locking screw 3. In the example shown in the figures, 25 the first locking screw 2 has a greater diameter than the second locking screw 3. The diameter of the first locking screw 2 may be between 8mm and 15mm, and in some examples is approximately 11mm, and in some examples is approximately 11.5mm. The diameter of the second locking screw 3 may be between 3mm and 9mm, and in some examples is approximately 6mm.

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The first locking screw 2 comprises an aperture 7 which is configured to accommodate the second locking screw 3 within the structure of the first locking screw 2, as shown in **Figures 1 to 6**. This assists in providing additional fixation in the head 204 of the femur 200 as shown in **Figure 52**. The dimensions of the aperture 7 may correspond to the 35 dimensions (size and shape) of the second locking screw 3. The aperture 7 has a substantially circular cross-section, which is adapted to receive the second locking screw

3. In alternative embodiments, the cross-sectional shape may be different for instance, square, oval, or rectangular. The aperture 7 may have an axis offset from the axis of the first locking screw 2. The axis of the aperture 7 may be non-perpendicular and non-colinear with the longitudinal axis of the first locking screw 2. In some examples like those
- 5 shown in **Figures 19 to 24** the angle of the aperture 7 is offset from the axis of the first locking screw 2 by between 0° and 90°, and in some examples is between 5° and 15°, and in some examples is approximately 10°. The angle of the aperture 7 positions the first locking screw 2 and second locking screw 3 relative to each other in the neck 203 and head 204 of the femur 200 in use. The angle between the first locking screw 2 and
- 10 the second locking screw 3 provides a wedge-shaped interaction between the locking screws 2,3 and the femur 200, which can prevent any movement, axial and/or rotational, of the fragment of the head 204 of the femur 200 along and/or around the axis of the first locking screw 2.
- 15 Within the structure of the first locking screw 2 is a partial internal thread 21, as shown in **Figures 19** and **20**. The partial internal thread 21 (or teeth) corresponds to the threaded portion 18 of the second locking screw 3. When the second locking screw 3 is placed into the aperture 7 and through the internal structure of the first locking screw 2, the threaded portion 18 threads into the partial internal thread 21. Once the second
- 20 locking screw 3 is in its final position, the threaded portion 18 reaches a hard stop in the first locking screw 2 and cannot advance any further. This forms a rigid coupling between the first locking screw 2 and the second locking screw 3. When the second locking screw 3 is accommodated in the aperture 7 of the first locking screw 2, a conjoining of the first locking screw 2 with the second locking screw 3 occurs. The conjoined first locking screw
- 25 2 and second locking screw 3 is accommodated in the aperture 8 of the nail stem 11 through the entry point 15, traversing the diameter of the bore 42 of the nail 1, and out through the exit point 16. The coupled or conjoined locking screws 2,3 now act as if one locking screw was being used and they move as one under force when *in situ*, and fixate onto bone.
- 30 The locking screws 2,3 can be placed in the nail stem 11 in one of two configurations. The surgeon or medical professional can choose between the two configurations depending on a number of different factors, for example, the patient's specific fracture pattern and/or anatomy. In the first configuration, or superior configuration, the second
- 35 locking screw 3 is placed superior to or above the first locking screw 2, as shown in **Figures 1 to 3**. In the second configuration, or the inferior configuration, the second

locking screw 3 is placed inferior to or below the first locking screw 2, as shown in **Figures 4 to 6**.

The aperture 8 may comprise a first indentation 22 on the exit point 16 of the aperture 8, as shown in **Figure 13**. The aperture 8 may comprise a second indentation 23 on the entry point 15 thereof, also shown in **Figure 13**. The first indentation 22 is typically located on a proximal side 50 of the first aperture 8. The second indentation 23 on the second end 16 of the first aperture 8 is typically located on a distal side 52 of the first aperture 8. These indentations 22,23 allow for placement of the first locking screw 2 and the second locking screw 3 in either of the first and/or second configurations. The indentations 22,23 provide at least two functions: (a) they are clearance cuts that allow placement of the second locking screw 3, *i.e.* if the indentations 22,23 were not present, placement of the second locking screw 3 is limited but still be possible (depending on the depth of the first locking screw 2); and (b) the indentations 22,23 limit any slide that the system 100,101 can achieve. The function of the second locking screw 3 is to provide stability, prevent rotation, and to spread load so there is less risk of losing fixation in the femur. If the system 100,101 is implanted in sliding mode, the first locking screw 2 and the second locking screw 3 can slide together through the nail stem 11. Slide is limited in either direction when the second locking screw 3 interacts with the indentations 22,23 in the nail stem 11. Now, this would also occur if the indentations 22,23 were not present as the second locking screw 3 would just hit the nail stem 11 itself.

The cephalomedullary nail system 100 may be implemented in one of two modes, either rigid mode or sliding mode. In the sliding mode, the first locking screw 2, and therefore the second locking screw 3 when conjoined with the first locking screw 2, may move or slide along the first aperture 8, *i.e.* tangentially in a direction along the axis of the first aperture to allow fracture compression. The angle between the first locking screw 2 and the second locking screw 3 means that the total possible slide of the locking screws 2,3 in use is limited by the interaction between the second locking screw 2 and the fluted nail stem 11. This interaction prevents excessive sliding of the locking screws 2,3 in either direction. Advantageously, as the second locking screw 3 is accommodated within and conjoined with the first locking screw 2, the conjoined locking screws 2,3 act as one body when sliding laterally through the first aperture 8 of the fluted nail stem 11. In the rigid mode, the position of the first locking screw 2, and therefore the second locking screw 3 when conjoined with the first locking screw 2, may be locked or fixed in place in the

aperture 8 of the nail 1. The method of implementing the rigid mode and sliding mode is described below.

The nail 1 may further comprise a set screw 24 to hold the first locking screw 2 and the second locking screw 3 in place when inserted into the first aperture 7. The set screw 24 can also be termed the clamping mechanism. **Figures 33 to 47** shows one example of a set screw 24. The set screw 24 may enable selection of either the rigid or the sliding mode. The set screw 24 is typically located in the bore 42 along the longitudinal axis of the nail 1 in the fluted nail stem 11, as shown in **Figures 2 and 5**. The set screw 24 comprises a threaded member 24a, shown in **Figures 38 to 41**, configured to engage a complementary threaded portion 25 located within the bore 42 of the nail stem 11. The set screw 24 may also comprise an engaging member 26, as shown in **Figures 42 to 47**, configured to connect to the threaded member 24a, as shown in **Figures 33 to 37**. The engaging member 26 comprises up to two wings 27 configured to engage with the first locking screw 2 when accommodated in the first aperture 8. When the threaded member 24a is rotated in either direction, it results in an axial translation of the engaging member 26. When the threaded member 24a is tightened, the engaging member 26 moves downwards, such that the up to two wings 27 engage with the first locking screw 2. When the threaded member 24a is loosened, the engaging member 26 moves upwards such that the up to two wings 27 disengage from the first locking screw 2.

The first locking screw 2 may further comprise one or more flat sides or regions 28 that are configured to engage the up to two wings 27 of the engaging member 26. In some forms, as shown in the figures, the first locking screw 2 has a plurality of flat sides or regions 28 around its circumference. This allows for the up to two wings 27 of the engaging member 26 to engage with the first locking screw 2 when it is in a number of different rotational positions when accommodated with the aperture 8 of the fluted nail stem 11. The up to two wings 27 may also have substantially flat surfaces which engage the flat sides or regions 28, which provides rotational control of the first locking screw 2 and therefore the second locking screw 3 when conjoined with the first locking screw 2.

If the rigid mode is required, the set screw 24 is moved to engage with the first locking screw 2, which rigidly and rotationally clamps the first locking screw 2 and therefore the second locking screw 3 when conjoined with the first locking screw 2, in place. If the sliding mode is required, the set screw 24 is moved so that the set screw 24 is not rigidly coupled to the first locking screw 2, but they remain very close together. This relationship

means that the first locking screw 2 and second locking screw 3 can slide, but, the interaction between the flat sides or regions 28 limits rotational movement of the first locking screw 2 and therefore the second locking screw 3 when conjoined with the first locking screw 2.

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In some examples, not shown, a spring member is positioned between the threaded member 24a and the engaging member 26. When the threaded member 24a is tightened, the spring member is compressed and provides a force on the engaging member 26 preventing it from loosening. This may assist in providing a constant force on the threaded member 24a and the first locking screw 2 in use, which may resist any movement of the threaded member 24a and/or the first locking screw 2. In some forms, the set screw 24 is pre-assembled and placed within the bore 42 of the fluted nail stem 11, to improve ease of use.

15 In order to have the correct interaction with the set screw 24, and therefore the fluted nail stem 11, the first locking screw 2 may have to be inserted in the aperture 8 in a correct orientation. For example, the first locking screw 2 may have to be assembled to an exact rotation within the aperture 8. To assist in positioning the first locking screw 2, the first locking screw 2 may comprise one or more radiographic markings 29, which are visible under x-ray, to guide the user on the correct rotation. For example, when no radiographic markings 29 are visible the first locking screw 2 has the correct rotation. When the first locking screw 2 is over-rotated, e.g. too far clockwise, one marking 29 may be visible, for example, as shown in **Figure 21**. When the first locking screw 2 is under-rotated, e.g. too far counter-clockwise, two markings 29 may be visible, for example, as shown in **Figure 20**. In other examples, different radiographic markings 29 or combinations of markings 29 may be used to show or indicate rotational alignment of the first locking screw 2.

30 In order to allow for placement of the second locking screw 3, the first locking screw 2 may have to be inserted at a correct depth in the first aperture 8. The correct depth of the first locking screw 2 may have a range or acceptable placement window 31, that will enable the nail system 100 to function correctly. The acceptable placement window 31 may be located along the length of the first locking screw 2. In some examples, this window 31 is between 5mm and 20mm in length, and in some examples may be approximately 10mm in length. To assist in positioning the first locking screw 2, the first locking screw 2 may comprise further radiographic markings in the form of at least two

radial notches 30, as shown in **Figures 19 to 21**. In the example shown, when the first locking screw 2 is at an acceptable depth in the aperture 8, only one of the radial notches 30 is visible on the portion 32 of the first locking screw 2 yet to be inserted through the aperture 8. Portion 32 of the first locking screw 2 is shown in **Figures 1 to 12**. When the first locking screw 2 is placed too deep within the aperture 8, none of the radial notches 30 will be visible on the portion 32 of the first locking screw 2 yet to be inserted through the aperture 8. When the first locking screw 2 is placed too shallow within the aperture 8, both of the radial notches 30 will be visible on the portion 32 of the first locking screw 2 yet to be inserted through the aperture 8. In other examples, different variations of the radial notches 30 may be used to indicate correct depth placement. In all cases, exactly one radial notch 30 should be visible for correct placement.

Additionally, a targeting arm (300, see **Figures 48 to 51**) is used for nail placement in the femur 200 and pilot drilling and placement of the first locking screw 2 and the second locking screw 3 in the nail system 100,101. The targeting arm 300 is configured to cooperate with the nail system 100,101 in order to implant the nail 1 and place the first locking screw 2 and the second locking screw 3 in the desired trajectories. For background, before implantation, the nail 1 is assembled to the targeting arm 300 using a connecting bolt (a threaded screw that connects the two together). The nail 1 is implanted with the arm 300 attached and placed in the correct position. The arm 300 contains holes (see below) through which the surgeon drills (using a drill sleeve 304 through the targeting arm 300) and places the first and second locking screws 2,3, respectively. The surgeon first drills for and places the first locking screw 2 followed by drilling for and placement of the second locking screw 3. Once the locking screws 2,3 are placed, the targeting arm 300 is removed from the nail 1.

The targeting arm 300 comprises an aiming arm 302, a connecting bolt (not shown), and a positioning element 306. The positioning element 306 of the aiming arm 302 comprises a hole 303 to accommodate placement of the first locking screw 2, as well as two additional holes 301a,301b to accommodate placement of the second locking screw 3 at an angle matching the angle between the first locking screw 2 and the second locking screw 3. The first locking screw 2 moves relative to the two additional holes 301a,301b of the aiming arm 302, such that any placement depth within the acceptable depth window 31 will allow for successful targeting of the angled offset trajectory. The positioning element 306 can be rotatable to allow placement of both locking screws, 2,3 at different neck angles. Furthermore, the targeting arm 300 may be adjustable between

different angles to assist the user. The aiming arm 302 is attached to the first end 6 of the nail stem 11, rotation is controlled by a raised tooth on the end of the aiming arm 302 that mates with a groove in the first end 6 of the nail stem 11 (not shown).

5 As described above, the first locking screw 2 must be placed in the acceptable placement window 31 defined by the interaction between the radial notches 30 and the nail stem 11. When one notch 30 is hidden from view, the first locking screw 2 is perfectly positioned. If no overlapping radiographic marking 29 is visible, the first locking screw 2 is in the perfect rotational position. If two radial notches 30 or no radial notches 30 are
10 visible, then the first locking screw 2 is at an incorrect depth and must be readjusted until only one radiographic marking 29 is visible to signal the correct depth and to be in the acceptable placement window 31. The targeting arm 300 contains two holes 301a, 301b that allow placement of the second locking screw 3, wherein the hole 301a is used for inferior placement and the hole 301b is used for superior placement. The holes
15 301a, 301b are configured to align perfectly with the aperture 7 of the first locking screw 2 when it is in the exact middle of the acceptable placement window 31. However, depending on the position of the first locking screw 2 in this acceptable placement window 31, holes 301a, 301b will likely be somewhat misaligned with the aperture 7 of the first locking screw 2.

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In summary, the radial notches 30 on the first locking screw 2 describe an acceptable placement window 31 which when used can result in the first locking screw 2 being at a minimum depth, a maximum depth, or anywhere in between. Any of these locations of the first locking screw 2, position the aperture 7 of the first locking screw 2 such that,
25 even though it may not be perfectly aligned, will allow the placement of the second locking screw 3 through the holes 301a, 301b in the targeting arm 300.

This is outlined in **Figure 49**, **Figure 50**, and **Figure 51A**, where the targeting arm 300 is connected to the proximal end 4 of the nail 1. The nail stem 11 has accommodated
30 the first locking screw 2 in the centre of the placement window 31 and the second locking screw 3 is being placed into the aperture 7 of the first locking screw 2. Similarly **Figure 51A** shows the nail stem 11 having accommodated the first locking screw 2 at the minimum depth within the placement window 31 (one radial notch 30 is visible and the second radial notch 30 is only just hidden inside the body of the nail stem 11) and the
35 second locking screw 3 advancing to be placed into the aperture 7 of the first locking screw 2. This configuration allows placement of the second locking screw 3. Similarly

Figure 51B shows the nail stem 11 having accommodated the first locking screw 2 at the maximum depth within the placement window 31 (one radial notch 30 is only just visible outside of the body of the nail stem 11) and the second locking screw 3 advancing to be placed into the aperture 7 of the first locking screw 2. This configuration allows placement of the second locking screw 3. Also, **Figure 51C** shows the nail stem 11 having accommodated the first locking screw 2 at the depth that is central (or optimal) within the placement window 31 (one radial notch 30 is clearly visible) and the second locking screw 3 advancing to be placed into the aperture 7 of the first locking screw 2. This configuration allows placement of the second locking screw 3. When placed at this depth, the aperture 7 in the first locking screw 2 is aligned perfectly with targeting hole 301b in the targeting arm 300.

The cephalomedullary nail system 100,101 with the first locking screw 2, the second locking screw 3 and the targeting arm 300 described above advantageously may provide a rotationally stable neck 203 and head 204 of the femur 200, as well as increased fixation, improved overall stability (rotational and/or translational), and improved migration resistance. As mentioned above, improved stability reduces post operative complications such as non-union, malunion, cutout, cut-through and limb shortening.

Figures 25 to 29 show another example of a first locking screw 2 which does not comprise the aperture 7, and which is given reference numeral 2a. The first locking screw 2a may be used in situations where the second locking screw 3 is not required. This third configuration requires the nail 1, the first locking screw 2a, and the set screw 24. As with the first and second configurations, the use of the third configuration may depend on a number of different factors, for example, the patient's specific fracture pattern or anatomy. One of the advantages of the cephalomedullary nail system 100 of the present invention is the ability to choose between the three different configurations depending on the patient's need. If the fracture is considered to be stable, then the first locking screw 2a can be used, while if the fracture is considered to be unstable, the locking screw 2 with the locking screw 3 can be used.

Figures 7 to 12 show another example of a cephalomedullary nail system 101. The various features of the cephalomedullary nail system 101 may be similar to those described above for the cephalomedullary nail system 100 and the nail 1, and have been given the same reference labels. **Figures 16 to 18** show the nail 1 of the cephalomedullary nail system 101. The nail 1 of the cephalomedullary nail system 101

in this example has a shorter body member 45a at the distal end 40 when compared to the body member 45 of the nail 1 shown in **Figures 1 to 6 and 13 to 15**. In use, the shorter nail 1 may not be inserted as far down the femur as that shown in **Figure 52**. The nail 1 of cephalomedullary nail system 101 may comprise only one aperture 9 and one slot 9a in which one or more screws 10 can be placed to secure the bottom end of the nail 1 to the femur 200. The body member 45a is substantially straight, unlike the body member 45 which can be slightly curved.

The use of the cephalomedullary nail system 100,101, which includes the nail 1 having a fluted nail stem 11, the first locking screw 2, the second locking screw 3, the targeting arm 300, and the set screw 24, target a non-fixed trajectory in an implant using a fixed trajectory in the targeting arm 300. The system 100,101 allows placement of a first locking screw 2 with a second locking screw 3 placed at an offset to the first locking screw 2, with both correctly interacting with a primary implant. The at least two radial notches 30 of the system 100,101 provide feedback to the user on an acceptable "window" to place the first locking screw 2 to allow drilling and placing of the second locking screw 3 into this non-fixed offset trajectory. The second locking screw 3 prevents rotation of the first locking screw 2, spreads the load out so there is less risk of cut out (a clinical complication driven at least partially by a lack of fixation in the fastening screw(s)); the system 100,101 limits the slide of the locking screws 1,2 *in situ* so there is limited to no risk of cut through (another clinical complication driven at least partially by a lack of fixation in the fastening screw(s)) and there is no chance of back out of the first locking screw 2. The radiographic markings 29 on the first locking screw 2 aid positioning of the locking screw 2 and allow for placement of the second locking screw 3.

Various components of the cephalomedullary nail system 100,101 have been described above as substantially cylindrical in shape. In other examples, the components may have an alternative shape for instance an elongate shape with one of an oval, square, rectangular, or triangular cross-section.

In the specification the terms "comprise, comprises, comprised and comprising" or any variation thereof and the terms "include, includes, included and including" or any variation thereof are considered to be totally interchangeable and they should all be afforded the widest possible interpretation and vice versa.

35

The invention is not limited to the embodiments hereinbefore described but may be varied in both construction and detail.

All publications, patents, patent applications and other references mentioned herein are
5 hereby incorporated by reference in their entireties for all purposes as if each individual publication, patent or patent application were specifically and individually indicated to be incorporated by reference and the content thereof recited in full.

Reference List

10	1	nail
	2,2a	first locking screw
	3	second locking screw
	4	proximal end of the nail
	5	outer surface of the nail stem
15	6	first end of the nail stem
	7	aperture
	8	aperture
	9	apertures
	10	fixing screw
20	11	fluted nail stem
	12	protrusions
	13	grooves
	15	entry point
	16	exit point
25	17	threaded portion of the first locking screw
	18	threaded portion of the second locking screw
	19	non-threaded portion of the first locking screw
	20	non-threaded portion of the second locking screw
	21	internal thread of the first aperture
30	22	first indentation
	23	second indentation
	24	set screw
	24a	threaded member
	25	complementary threaded portion
35	26	engaging member
	27	wings

	28	flat sides
	29	radiographic markings
	30	notches
	31	window
5	32	portion of the locking screw
	40	distal end of the nail
	42	bore
	45	body member
	45a	shorter body member
10	50	proximal side of the first aperture
	52	distal side of the first aperture
	60	second end of the nail stem
	100	cephalomedullary nail system
	101	cephalomedullary nail system
15	200	femur
	201	shaft
	202	greater trochanter of the femur
	203	neck of the femur
	204	head of the femur
20	300	targeting arm
	301a,301b	hole
	302	aiming arm
	303	hole
	304	– drill sleeve
25	306	- positioning element

Claims

1. A cephalomedullary nail system (100,101) comprising:
 - a nail (1) comprising a proximal end (4) and a distal end (40), and having a substantially elongate cylindrical body member (45,45a), wherein the proximal end (4) further comprises a non-circular nail stem (11);
 - a first locking screw (2) comprising a threaded portion (17) configured to engage with bone; and
 - a second locking screw (3) comprising a threaded portion (18) configured to engage with bone;
 - wherein the first locking screw (2) has a greater diameter than the second locking screw (3);
 - wherein the first locking screw (2) comprises an aperture (7) configured to accommodate the second locking screw (3) within and through the structure of the first locking screw (2);
 - wherein the nail (1) comprises an aperture (8) having an entry point (15) and an exit point (16) configured to accommodate the first locking screw (2) and the second locking screw (3) when the second locking screw (3) is fitted within and through the structure of the first locking screw (2); and
 - wherein the first locking screw (2) further comprises one or more radiographic markings (29) configured to indicate rotational alignment of the first locking screw (2) and at least two radial notches (30) configured to indicate the correct depth of the first locking screw (2) in the nail stem (11).
2. The cephalomedullary nail system (100,101) of claim 1, wherein the non-circular nail stem (11) comprises a first end (6) located further from the distal end (40), and a second end (60) located closer to the distal end (40).
3. The cephalomedullary nail system (100,101) of claim 2, wherein the non-circular nail stem (11) is a fluted nail stem comprising a plurality of protrusions (12) extending radially outwards from an outer surface (5) thereof; and a plurality of grooves (13) formed between the protrusions (12).
4. The cephalomedullary nail system (100,101) of claim 3, wherein the protrusions (12) are equally sized and spaced around the circumference of the nail stem (11).

5. The cephalomedullary nail system (100,101) of claim 3 or claim 4, wherein the grooves (13) have a substantially square or substantially semi-circular cross-sectional shape.
6. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the cross-sectional shape of the nail stem (11) is constant along at least a length of the nail stem (11).
7. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein at least a portion of the nail stem (11) is tapered in the direction of the first end (6) to the second end (60).
8. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the first locking screw (2) further comprises a partial internal thread (21) which corresponds to the threaded portion (18) of the second locking screw (3).
9. The cephalomedullary nail system (100,101) of Claim 8, wherein the length of the threaded portion (18) of the second locking screw (3) limits the depth that the second locking screw (3) can be placed within the first locking screw (2).
10. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the threaded portions (17,18) are the leading ends of the first locking screw (2) and the second locking screw (3), respectively, that are inserted into bone.
11. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the threaded portion (17) of the first locking screw (2) is shorter in length than the threaded portion (18) of the second locking screw (3).
12. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein in a first configuration the second locking screw (3) is superior to the first locking screw (2) when in use.
13. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein in a second configuration the second locking screw (3) is inferior to the first locking screw (2) when in use.

14. The cephalomedullary nail system (100,101) of Claim 12 or Claim 13, wherein the first locking screw (2) further comprises at least one radiographic marking (29), wherein when viewed on the inferior side of the first locking screw (2) indicates that the second locking screw (3) can be placed in the superior configuration; and wherein when viewed on the superior side of the first locking screw (2) indicates that the second locking screw (3) can be placed in the inferior configuration.
15. The cephalomedullary nail system (100,101) of Claim 14, wherein when the at least one radiographic marking (29) is visible the first locking screw (2) is in an incorrect rotation; and wherein if no radiographic markings (29) are visible, the first locking screw (2) is in a correct rotation.
16. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the first locking screw (2) further comprises at least one radial notch (30), wherein the interaction between the at least one radial notch (30) and the entry point (15) in the non-circular nail stem (11) indicates the correct depth placement window (31) for the first locking screw (2).
17. The cephalomedullary nail system (100,101) of Claim 16, wherein if one radial notch (30) is visible the depth of the first locking screw (2) is acceptable; and wherein if two radial notches (30) are visible the depth of the first locking screw (2) is too lateral; and wherein if no radial notches (30) are visible the depth of the first locking screw (2) is too medial.
18. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the aperture (7) has an axis offset from the axis of the first locking screw (2) by between 0° and 90°.
19. The cephalomedullary nail system (100,101) of Claim 18, wherein the aperture (7) has an axis offset from the axis of the first locking screw (2) by between 5° and 15°.
20. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the aperture (8) has a longitudinal axis offset from the longitudinal axis of the nail (1) by between about 115° and about 140°.

21. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the aperture (8) has a longitudinal axis offset from the longitudinal axis of the nail (1) by between about 120° and about 130°.
22. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the aperture (8) comprises a first indentation (22) on the exit point (16), wherein the first indentation (22) is located on a proximal side (50) of the aperture (8).
23. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the aperture (8) comprises a second indentation (23) on the entry point (15), wherein the second indentation (23) is located on a distal side (52) of the aperture (8).
24. The cephalomedullary nail system (100,101) of Claim 22 and Claim 23, wherein the first indentation (22) and the second indentation (23) limit the axial movement of the first locking screw (2) and the second locking screw (3) when both are conjoined in the nail stem (11).
25. The cephalomedullary nail system (100,101) of any one of the preceding claims, further comprising a targeting arm (300) configured to engage with the first locking screw (2) and the second locking screw (3), the targeting arm (300) comprising an aiming arm (302) and a positioning element (306) having at least one hole (301a,303) adapted to accommodate placement of the second locking screw (3) within an aperture (7) in the first locking screw (2) and a hole (301b) adapted to accommodate and position the first locking screw (2).
26. The cephalomedullary nail system (100,101) of any one of the preceding claims, wherein the nail (1) further comprises a set screw (24) to hold the first locking screw (2) and the second locking screw (3) in place when inserted inside the aperture (8).
27. The cephalomedullary nail system (100,101) of Claim 26, wherein the set screw (24) comprises: a threaded member (24a) configured to engage with a complementary threaded portion (25) located within the bore (42); and an engaging member (26) connected to the threaded member (24a);
wherein the engaging member (26) comprises up to two wings (27) configured to engage the first locking screw (2) when inserted inside the aperture (8);

wherein when the threaded member (24a) is tightened the engaging member (26) moves in a direction towards the first locking screw (2) such that the up to two wings (27) engage the first locking screw (2); and

wherein when the threaded member (24a) is loosened the engaging member (26) moves in a direction away from the first locking screw (2) such that the up to two wings (27) disengage the first locking screw (2).

28. The cephalomedullary nail system (100,101) of Claim 27, wherein the first locking screw (2) has at least one flat side (28) configured to engage the up to two wings (27).

29. A kit of parts for use in repairing a bone fracture, the kit comprising the cephalomedullary nail system (100,101) according to any one of the preceding claims.