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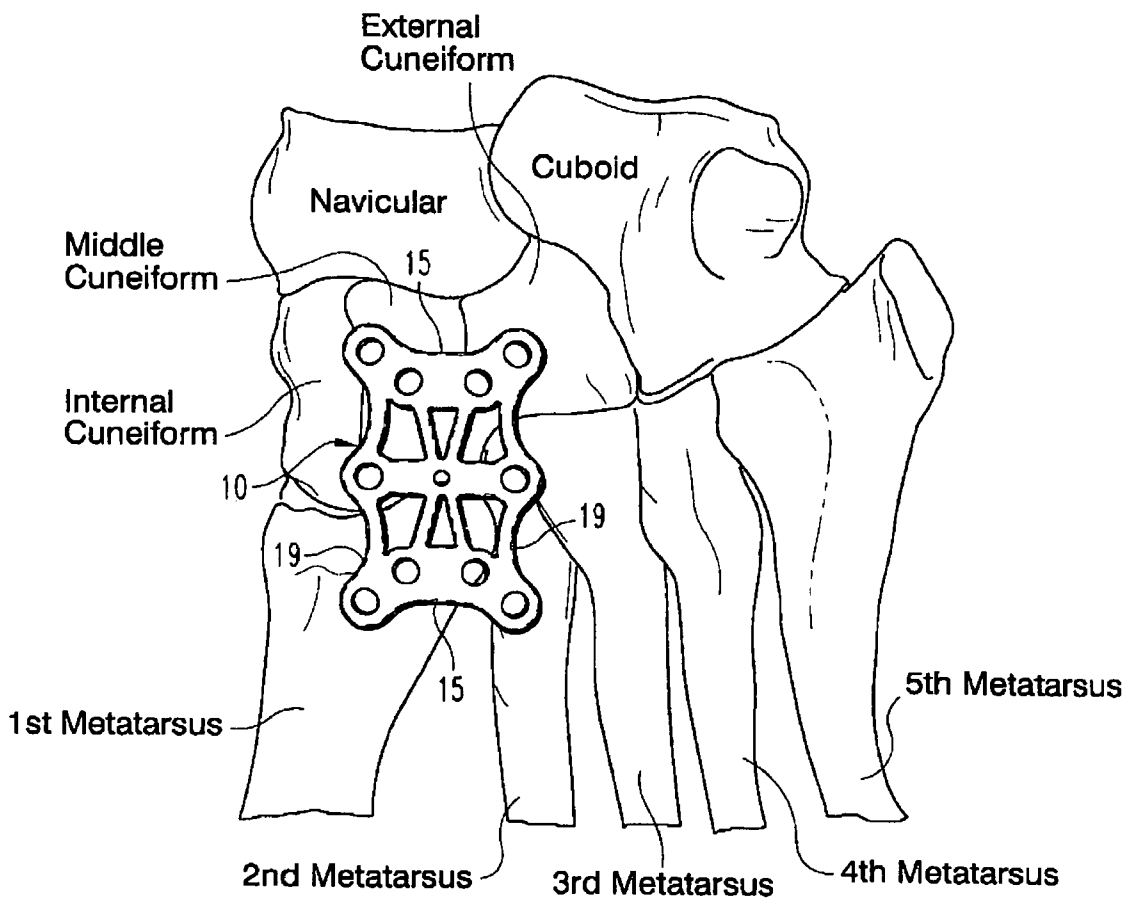
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(56) Related Art  
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**ABSTRACT OF THE DISCLOSURE**

A fixation device for fixation and/or fusion of the bones and joints of the mid-foot includes a plate having a plurality of screw holes for attachment of the plate around the perimeter of the fusion site. In one embodiment, four screw holes are  
5 positioned at the corners of the plate and two screw holes are located at the opposite sides and mid-length of the plate. Preferably, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case of a difficult mid-foot fracture. The plate includes a plurality of  
10 cut-outs defined between or interior of the screw holes. The cut-outs are sized to accept additional bone fasteners to either enhance the attachment of the plate to the mid-foot bones or to provide access for a fastener to reduce a bone fragment beneath the plate. The plate is configured so that the screw holes and cut-outs are not positioned over a fusion location when the plate is attached to the mid-foot.



**Fig. 1**

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**COMPLETE SPECIFICATION**

**FOR A STANDARD PATENT**

**ORIGINAL**

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**TO BE COMPLETED BY APPLICANT**

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**Invention Title:** MID-FOOT FIXATION PLATE

The following statement is a full description of this invention, including the best method of performing it known to us:-

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**MID-FOOT FIXATION PLATE****Background of the Invention**

The present invention relates to plates for fixation of bones and joints. More specifically, the invention pertains to a fixation plate configured for fixation of the  
5 mid-foot.

Trauma to the mid-foot often results in severe fractures and/or dislocations. One such trauma is the well-known Lisfranc injury, which was named after the French doctor who first described the injury during the Napoleonic Wars. The injury identified by Dr. Lisfranc occurred when a horseman fell from the horse with his/her  
10 foot caught in the stirrup. The resulting trauma was a fracture of multiple bones of the mid-foot with dislocation of the fragments. In modern times, a Lisfranc injury indicates an injury to the normal alignment of the cuneiforms and metatarsal joints with the loss of their normal spatial relationships. Injuries of this type may occur when a heavy item falls on the mid-foot or from stepping into a small hole and then  
15 falling with a twisting imparted to the foot. Athletic injuries are common with sports involving foot bindings, such as windsurfing or snow boarding, or sports where the foot is rotated during impact, such as dancing and soccer.

The most common Lisfranc injury occurs at the joint involving the 1st and 2nd metatarsals and the medial cuneiform, primarily because there is no connective  
20 tissue holding the first and second metatarsals to each other. If the ligaments between the medial and mid-cuneiforms are disrupted, or between the 1st, 2nd metatarsal and the medial cuneiform, then the bones separate and the normal alignment of the joints is lost. Failure to treat a significant Lisfranc injury may result in joint degeneration and even damage to the adjacent nerves and blood vessels.

Treatment of injuries of this type is usually surgical, especially if a significant  
25 separation of the bones exists. One surgical treatment, known as open reduction and internal fixation, usually requires that pins, wires and/or screws be inserted to stabilize the bones and joints and hold them in place until healing is complete. This treatment protocol re-establishes the normal anatomy of the mid-foot while the  
30 fractured bones mend. In one typical procedure, a pin or screw is introduced medially into the internal cuneiform and through the base of the second metatarsal bone.

In some cases, fusion of the joint between the first and second metatarsals and the middle and/or internal cuneiforms may be necessary. Arthrodesis may be indicated where arthritis arises in patients with a prior Lisfranc or similar injury, or where an acute fracture/dislocation has occurred anywhere at the mid-foot.

5           The use of pins, staples or screws is often acceptable for younger patients, especially where the injury is not too severe. However, this form of fixation frequently results in non-union in mid-foot arthrodesis attempts, possibly because the bone fragments and/or joints cannot be sufficiently immobilized by pins, screws, or staples alone. Consequently, there is a significant need for a fixation device that  
10 provides solid fixation and stabilization of a mid-foot injury. Broad treatment possibilities also requires that the fixation device be capable of multiple points of attachment to the mid-foot bones and bone-fragments.

#### Summary of the Invention

15           In view of these needs, the present invention provides a fixation device for fusion of bones or bone segments in the human mid-foot, including a plate sized for implantation within the mid-foot of a patient, said plate defining a plurality of holes, each having a diameter sized for receiving a bone engaging fastener for attachment  
20 of said plate to bone or bone segments of the mid-foot, wherein four holes are positioned in protrusions at the corners of the plate, two holes are positioned in protrusions at the opposite sides and mid-length of the plate and four additional interior holes are orientated within the perimeter defined by the holes formed in the protrusions and wherein two generally triangular cut-outs are positioned along the  
25 longitudinal axis of the plate inboard of the interior holes and four larger cut-outs surround the triangular cut-outs, but still fall within the perimeter defined by the holes formed in the protrusions and wherein each of the cut-outs is dimensioned greater than the diameter of said plurality of holes.

#### Summary of Embodiments

30           In a further preferred feature, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case

of a difficult mid-foot fracture. The four additional screws are oriented within the perimeter defined by the six screws formed in the protrusions.

In yet another feature of a preferred embodiment of the invention, a plurality of cut-outs are defined in the plate between or interior of the screw holes. In the most preferred embodiment, two generally triangular cut-outs are positioned along the longitudinal axis of the plate inboard of the interior screw holes, and four larger cut-outs are surround the triangular cut-outs, but still fall within the perimeter defined by the screw holes. At least the larger cut-outs are sized for passage of additional bone

fasteners, such as screws or pins. The cut-outs may be used to provide additional points of attachment or fixation. In addition, the cut-outs may provide access for a fixation pin or screw to reduce a bone fragment underneath the plate.

5 The cut-outs are bounded by struts that may be positioned over mid-foot fusion sites or bones to help stabilize the bones or bone segments. The plate is configured so that the screw holes and cut-outs are not oriented over the fusion site(s).

10 The protrusions and cut-outs help reduce not only the prominence of the plate, but also the material requirements. The plate is also formed at a minimal thickness that still retains the ability to stabilize the fusion site. In a preferred embodiment, the plate has a thickness of less than 1.0mm. In order to more accurately conform to the local anatomy, the plate is defined at a spherical curvature, which is preferably at a fixed radius.

15 One benefit of the fixation plate of the present invention is that it is much more versatile than prior devices for achieving fusion of the mid-foot. A further benefit is that the plate offers a plurality of options for bone screw placement to stabilize the mid-foot bones and joints, accomplish firm reduction of bone fractures and ultimately ensure union and/or fusion.

20 Other benefits and specific objects of the invention will become apparent upon consideration of the following written description taken together with the accompanying figures.

#### Description of the Figures

25 **FIG. 1** is an enlarged view of the dorsal aspect of the mid-foot with a fixation plate positioned thereon in accordance with one embodiment of the invention.

**FIG. 2** is a top plan view of the fixation plate shown in **FIG. 1**.

**FIG. 3** is a side cross-sectional view of the plate shown in **FIG. 2**, taken along line 3-3 as viewed in the direction of the arrows.

30 **FIG. 4** is an end cross-sectional view of the plate shown in **FIG. 2**, taken along line 4-4 as viewed in the direction of the arrows.

**FIG. 5** is an enlarged view of the dorsal aspect of the mid-foot with a fixation plate positioned thereon in accordance with a further embodiment of the invention.

### Description of the Preferred Embodiments

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no  
5 limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

10 The bones of the mid-foot are illustrated from the dorsal aspect in **FIG. 1**, along with a fixation plate **10** in accordance with a preferred embodiment of the invention. As can be seen in the figure, the plate **10** spans between the base of the first and second metatarsal bones across to the internal (or medial) and middle  
15 cuneiforms. In the embodiment illustrated in **FIG. 1**, a large plate **10** is provided that permits attachment to each of the bones of this portion of the mid-foot.

Details of the plate **10** may be gleaned from **FIGS. 2-4**. The plate **10** is generally configured from a body **11** of generally uniform thickness and material composition. In the preferred embodiment, the body **11** is formed of a biocompatible material, most preferably a metal. In a specific embodiment, the body material is  
20 titanium or a titanium alloy, such as Ti-6Al-4V. In order to reduce the prominence of the plate **10** above the bones of the mid-foot, the plate has a nominal thickness between upper surface **12** and bone engaging surface **13** that is minimized while still retaining sufficient strength to ensure solid fixation of the bones and joints of the  
25 mid-foot. In a preferred embodiment, the plate has a thickness of less than 1.0mm, and most preferably about 0.9mm. This thickness provides sufficient strength while retaining the ability to bend the plate as required to conform to the geometry of the implantation site. In particular, the plate **10** is configured to be positioned anywhere  
30 along the mid-foot, not just at the location shown in **FIG. 1**. Thus, geometry of the middle cuneiform may require a differently contoured plate than a plate positioned across the cuboid bone.

Preferably, however, the plate does not require any on-site contouring since the bone engaging surface **13** is curved in two dimensions to follow the anatomy of

the mid-foot, especially across the metatarsal joints. Thus, as shown in the side cross-sectional view of **FIG. 3**, the surface **13**, and hence the plate **10**, is curved along the length of the plate. The plate is preferably curved at a uniform radius, such as about 75mm in a specific embodiment. Similarly, the plate is curved across its width, as reflected in the end cross-sectional view of **FIG. 4**. This curvature is also at about 75mm in a specific embodiment. Most preferably, the entire plate is formed at a spherical radius, which may be about 75mm in the specific embodiment.

The body **11** further includes end edges **15** and side edges **19**. In order to reduce material requirements and minimize prominence of the plate **10**, the edges define indentations **16** and **19**, respectively. As shown in **FIG. 1**, the end edges **15** define a single indentation **16** that is flanked on opposite sides of the plate by corner protrusions **17**. These protrusions **17** merge into the indentations **19** at the side edges **18**. A center protrusion **20** is defined on each side edge **18** that is preferably equidistant from each of the corner protrusions **17**. In the preferred embodiment, all of the edges **15**, **18** are rounded to reduce trauma to the soft tissue surrounding the implant plate.

As shown in **FIG. 2**, each of the protrusions **17**, **20** provides a location for a screw hole **25**. Each screw hole is configured to receive a bone engaging fastener configured to attach the plate **10** to the bones of the mid-foot. In the preferred embodiment, the fastener is a bone screw that is appropriately sized for implantation within the base of the metatarsus, any of the cuneiforms or the cuboid bone. The length and diameter of the screw is generally dictated by the location and the size of the bone or bone fragment being fixed. As shown in **FIG. 2**, the plate **10** includes additional screw holes **26** within the interior of the plate. These screw holes **26** increase the versatility of the plate **10** to provide additional attachment points to a given bone, or to provide a path for fixation of a bone segment, such as in the case of a severe fracture.

The plate **10** of the present invention is specifically configured for implantation and fixation of the mid-foot. Thus, the plate is sized so that the screw holes **25**, **26** are optimally positioned for correction and arthrodesis of numerous mid-foot injuries. In a specific embodiment, the plate has a width dimension of about 21.5mm between the screw holes in the corner protrusions **17** and intermediate

protrusions **20**. The interior screw holes **26** are preferably at a width dimension of about 10.0mm. The plate **10** has a length between screw holes **25** at the corner protrusions of about 36.8mm.

5 The screw holes **25, 26** are formed at a diameter commensurate with the size of the bone screw used to attach the plate to bone. In the preferred embodiment, the screw holes are configured for 2.7mm or 3.5mm screws that are commonly used for fixation of the bones of the foot. In one feature of the invention, the screw holes may include a circumferential chamfer, such as the chamfer **53** for the screw holes **52** of the plate **50** shown in **FIG. 5**. This configuration of the screw holes allows the plate  
10 to accept either size screw at any screw hole location. The present invention further contemplates that the screws may be non-locking or self-locking screws, with the screw holes configured accordingly. In a specific embodiment, locking screws are used and the screw holes **25, 26** define tapered threads (not shown) of conventional design.

15 A further feature of the invention is best seen in **FIG. 2**. In particular, the body **11** of the plate defines a plurality of cut-outs, including two cut-outs **32** on each side and two central cut-outs **30**, for a total of six cut-outs. The cut-outs **30, 32** reduce the amount of material used to form the plate **10**. In addition, the cut-outs create opposite end portions **34** and a center portion **36** spanned by struts **38, 40**. The  
20 end and center portions **34, 36** carry the screw holes **25, 26**. The struts **38, 40** help stabilize the bones or bone segments underneath the struts. The portions **34, 36** and the struts **38, 40** are configured so that screw holes are not located where fusion must occur to stabilize the mid-foot, as reflected in **FIG. 1**. In the preferred embodiment, the cut-outs **30** are triangular in shape, while the side cut-outs **32** are generally  
25 trapezoidal or rectangular in shape. The cut-outs **30, 32** are dimensioned greater than the diameter of the screw holes **25, 26**.

In addition to reducing the plate material, the cut-outs **30, 32** provide additional locations for placement of bone screws to augment the fixation or to connect bone segments. In the former case, the bone screws may be positioned at a  
30 corner of any of the cut-outs **30, 32**. In the latter case, the bone screw is passed through the cut-out and across adjacent bone segments, such as to bridge a fracture.

The cut-outs **30** are especially sized to accept a standard bone screw for fixation of mid-foot bone fragments.

In order to facilitate proper placement of the plate **10**, a small diameter hole **28** is defined at the center of the plate **10** in the center portion **36**. The hole **28** is preferably sized to receive a K-wire or other similar guide wire. In an exemplary procedure for correction of a Lisfranc fracture/dislocation, a K-wire may be inserted into the middle cuneiform to guide the plate **10** across the metatarsus-cuneiform spaces. In one aspect of the invention, the plate **10** provides for screw placement around the perimeter of the mid-foot segments to be fused, in particular with screws placed in the screw holes **25** at the protrusions **17**, **20**. In some cases, attachment at these locations is sufficient to adequately stabilize the injury for eventual fusion. In other cases, additional screws may be implanted through the screw holes **26** and even through the cut-outs **30**, **32**. Where bone fragments are present, reduction may be accomplished by passing reduction screws through one or more of the cut-outs **30**, **32**.

For a smaller mid-foot anatomy or a smaller fusion region, the plate **10** may be modified to form a smaller plate **50**, as shown in **FIG. 5**. This smaller plate retains the spherical curvature and minimal plate thickness described above in connection with the larger plate **10**. In addition, the plate **50** includes the corner protrusions **51** which carry the screw holes **52**. Screw holes **54** may be provided at the interior of the plate **50** to increase the versatility of the plate. A K-wire hole **56** may also be provided at the center of the plate. The smaller plate **50** is preferably adapted for patients with smaller mid-foot bone and joint structure.

In the preferred embodiment of the invention, a fixation device is in the form of the plate **10** having a plurality of screw holes for attachment of the plate around the perimeter of the fusion site. In the most preferred embodiment, four screw holes are positioned at the corners of the plate with two screw holes at the opposite sides and mid-length of the plate. Preferably, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case of a difficult mid-foot fracture. In yet another feature of the preferred embodiment, a plurality of cut-outs are defined in the plate between or

interior of the screw holes. In the most preferred embodiment, two generally triangular cut-outs are positioned along the longitudinal axis of the plate inboard of the interior screw holes, and four larger cut-outs surround the triangular cut-outs, but  
5 still fall within the perimeter defined by the screw holes.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applicants that  
10 come within the spirit of the invention are desired to be protected.

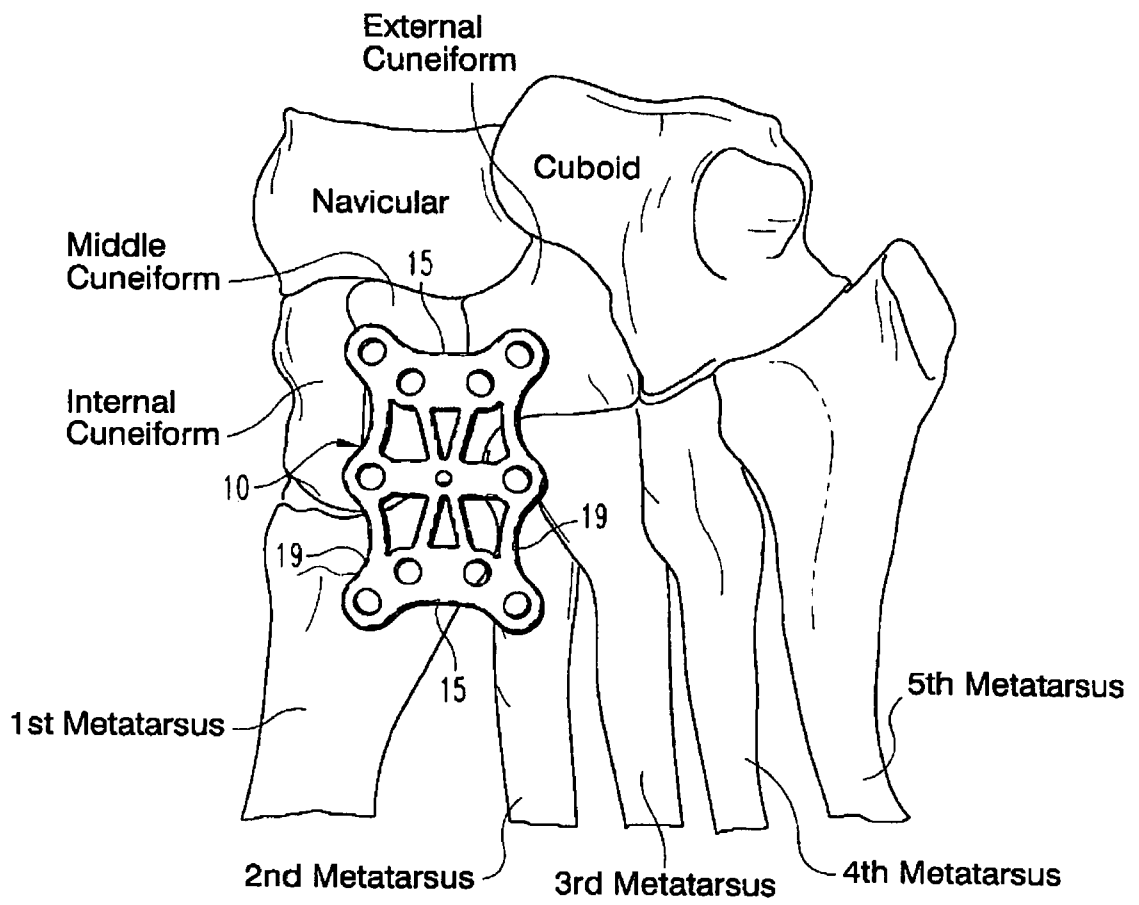
Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group  
15 of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form or suggestion that the prior art forms part of the common general knowledge in Australia.

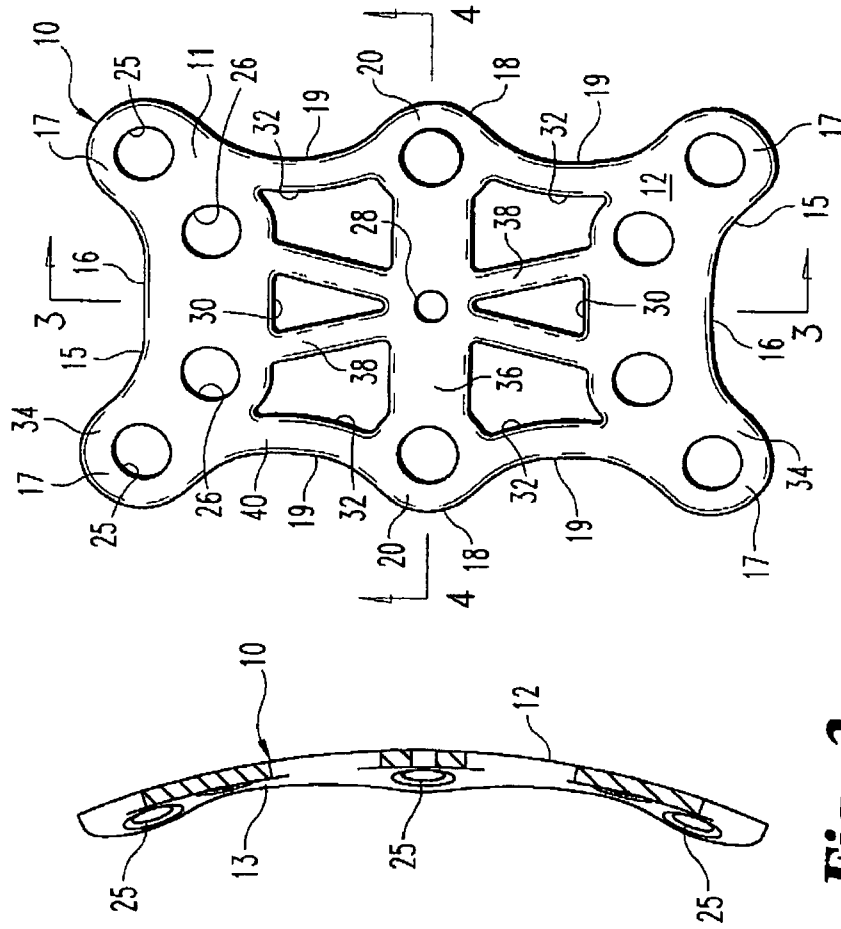
The claims defining the invention are as follows:

1. A fixation device for fusion of bones or bone segments in the human mid-foot, including:
  - 5 a plate sized for implantation within the mid-foot of a patient, said plate defining a plurality of holes, each having a diameter sized for receiving a bone engaging fastener for attachment of said plate to bone or bone segments of the mid-foot;  
wherein four holes are positioned in protrusions at the corners of the plate,  
10 two holes are positioned in protrusions at the opposite sides and mid-length of the plate and four additional interior holes are orientated within the perimeter defined by the holes formed in the protrusions;  
and wherein two generally triangular cut-outs are positioned along the longitudinal axis of the plate inboard of the interior holes and four larger cut-outs  
15 surround the triangular cut-outs, but still fall within the perimeter defined by the holes formed in the protrusions; and  
wherein each of the cut-outs is dimensioned greater than the diameter of said plurality of holes.
- 20 2. A fixation device according to claim 1, wherein said plate has substantially uniform thickness less than about 1.0mm.
3. A fixation device according to either claim 1 or claim 2, wherein said  
25 plurality of screw holes include circumferential chamfer so the screw holes can receive different sizes of fasteners.
4. A fixation device according to any one of claims 1 to 3, wherein said plurality of holes are arranged around the perimeter of said plate.
- 30 5. A fixation device according to claim 4, wherein said plurality of cut-outs are arranged inboard of each of said plurality of holes.

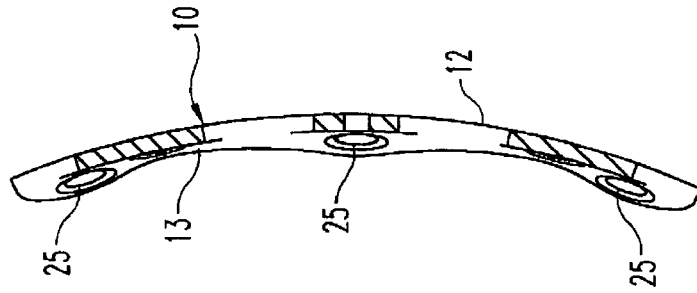
6. A fixation device according to any one of claims 1 to 5, wherein said plurality of cut-outs includes a pair of triangular shaped cut-outs arranged along a longitudinal axis of said plate.
- 5 7. A fixation device according to any one of claims 1 to 6, wherein said plurality of cut-outs includes two cut-outs adjacent each side of said plate.
8. A fixation device according to claim 7, wherein said two cut-outs adjacent each side are trapezoidal or substantially rectangular in shape.
- 10 9. A fixation device according to any one of claims 1 to 8, wherein said plate further defines a guide wire hole sized to receive a guide wire or K-wire.
10. A fixation device according to claim 9, wherein said guide wire hole is
- 15 disposed substantially in the centre of said plate.
11. A fixation device according to any one of claims 1 to 10, wherein the edges of said plate define a plurality of indentations and protrusions in which at least some of the plurality of holes is defined in a corresponding one of said protrusions.
- 20 12. A fixation device according to any one of claims 1 to 11, wherein said plate includes a bone engaging surface that is curved at a substantially uniform spherical radius.
- 25 13. A fixation device substantially as hereinbefore described with reference to the accompanying figures.



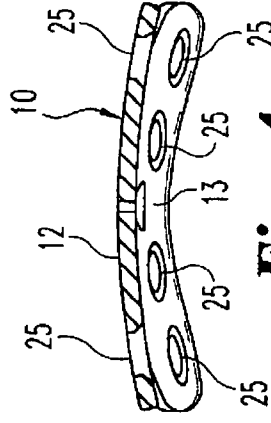
**Fig. 1**



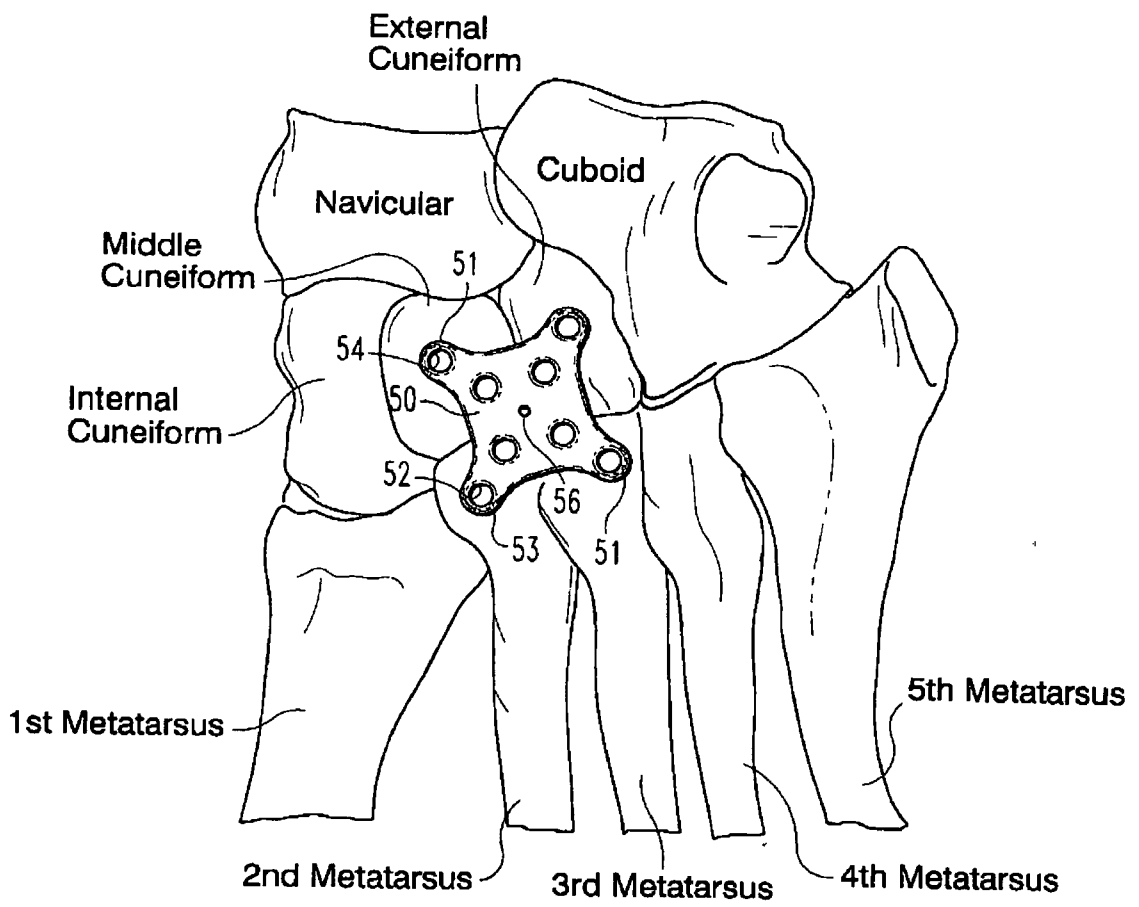
**Fig. 2**



**Fig. 3**



**Fig. 4**



**Fig. 5**