

54 Title: **Locked nail system for arthrodesis
reconstruction of fractures of the calcaneus.**

57 Abstract:

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Locked nail system for arthrodesis reconstruction of fractures of the calcaneus.

10 This system consists of a wedge-shaped nail having two threaded holes into which two cannulated screws are inserted, stabilizing the entire assembly.

These elements are assembled by means of an insertion and destination-guide system.

15

The principal purpose thereof is the reconstruction of severe comminuted fractures of the calcaneus in a human being and the fixation of this bone once the principal form thereof has been reconstructed to the talus in order to achieve arthrodesis or fusion with it.

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The surgical procedure is performed by means of a small incision in the external pre-Achilles area, the technique being enclosed by virtue of the fracture not being exposed.

25

The nail is inserted into the greater tuberosity of the calcaneus and is then pierced by the screws that screw into the nail itself and into the body of the talus. The system takes advantage of the tension of the Achilles tendon and the plantar fascia for the stabilization thereof.

30

DESCRIPTION

A locked nail system for the arthrodesis reconstruction of fractures of the calcaneus.

5

Field of art

Orthopedic surgery

10 Present state of the art

Chronic residual pain is the most common after effect following comminuted talamic fracture of the calcaneus. This problem may have multiple origins: compartment
15 syndrome, reflex-sympathetic dystrophy, plantar fasciitis, tarsal and peroneal tunnel syndrome, and subtalar arthritis. This latter has been found to be responsible for the majority of the poor long-term outcomes of the treatment of these fractures.

20

In my experience, talamic fractures are the cause of 8 - 10% of tarsal tunnel syndrome, above all in the external plantar ramus, and of 78 % of peroneal entrapment (external submalleolar pain). In 70 % of these severe
25 fractures, chronic pain originating in the posterior subtalar joint arises, which normally becomes ankylosed following trauma.

Although the bibliography has recently supported the
30 results of open reduction and internal fixation of fractures of the calcaneus, orthopedic treatment still has many defenders. In my hospital we have always initially adopted a conservative approach and we prefer to treat after effects, should they appear. Agreeing with
35 Barnard and Odegard (1) we believe that perfect restoration of the subtalar joint is impossible. Numerous arthrodesis techniques, including prosthetic replacement, have been described for the treatment of

post-traumatic subtalar arthritis. In 1943 Gallie (2) introduced the technique which, with slight modifications, we have been utilizing for a long time. Some authors have advocated triple arthrodesis over
5 isolated subtalar fusion, having the objective of improving the biomechanics of the foot and avoiding the degeneration of the adjacent joints. My hospital's statistics cover in excess of 1300 cases having more than 5 years of evolution, one of the most numerous datasets
10 in existence.

In a review undertaken by myself, isolated arthrodesis of the subtalar joint does not cause degeneration of the adjoining joints, even with many years of evolution.

15 This experience has led me to consider that the old postulates of Stulz (4) and Noble (3) may provide the key to a fracture yet to be resolved, by virtue of the fact that in the most severe fractures the subtalar joint
20 cannot be surgically reconstructed, and always degenerates. The solution would be to arthrodesis it from the outset during the acute period, so as to avoid the disabling after effects that appear during the evolutionary course.

25 However, in addition to fusing the damaged joint, an attempt should be made as far as possible to reconstruct the form of the hindfoot, having the objective of avoiding other associated complications, such as
30 compartment syndrome, reflex-sympathetic dystrophy, plantar fasciitis, and tarsal and peroneal tunnel syndrome, which without doubt would benefit from the reduction of the fracture.

35 Having this objective I have conceived a system of reconstruction-arthrodesis comprising a nail locked by two cannulated screws, which I shall describe below.

Bibliography

- 1 **Barnard, L; Odegard, J K:** *Conservative approach*
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5 J Bone and Joint Surg 37-A: 1231-6. 1955.
- 2 **Gallie, W E:** *Subastragalar arthrodesis in*
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- 3 **Noble J; McQuillan W M;** *Early posterior subtalar*
10 *fusion in the treatment of fractures of the os*
 calcis. Bone Joint Surg 61-B. 90-3. 1970.
- 4 **Stulz E; Folscheveiller J; Naett R; Kempf I:**
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Description of the invention

20 The locked nail system for the arthrodesis reconstruction
 of fractures of the calcaneus comprises the following
 components:

Nail:

25 This is a part (1) having the form of a sharp wedge on
 the blunt edge of which it has a threaded hole and
 recesses for coupling the guide. It is perforated by two
 threaded holes (2 and 3) through which the screws pass.
 These holes have an inclination of 10 degrees to the
30 horizontal.

Screws:

35 These are cannulated screws having a thread for spongy
 bone (4). This thread must be self-tapping at the two
 ends thereof. The shank is hollow for the guide pin. At
 the base of the screw is located the second thread for
 metal, which has the same pitch as that for spongy

material. The total length of the screws will range between 40 and 70 mm in 5 mm increments.

Guide:

5

The guide consists of an applicator tube (5) into which the base of the nail is screwed by means of a long screw (6). This tube has, at the end thereof, the projections corresponding to the recesses of the nail, which serve to prevent movements of the latter once secured.

The guide has a handle which, in addition to serving as a grip, has holes in order to pass through the cannulas which orient the screws in relation to the nail.

15

This guide must be made of a strong material due to the fact that it serves for hammering of the nail and also for levering and reducing the fracture by means thereof. The screw securing the nail to the guide must have an end stop resistant to impacts due to the fact that the hammer blows to introduce the nail into the calcaneus will be applied thereto.

Cannulas:

25

These must be made in duplicate and permit the correct orientation of the different tools for placing the screws. These are: the guide pin, the 4 mm drill bit, and the screw itself. Consequently we require three cannulas (7, 8 and 9) having different diameters.

30

Drill bit:

4 mm in diameter by virtue of the fact that it corresponds to the shank of the screw. It must be cannulated for a 2 mm guide pin. The recommended length is at least 25 cm.

35

Other elements:

- Depth gauge to determine the length of the screws.
- Cannulated screwdriver.
- 5 - 6 mm cannulated drill bit for the rear part of the screws.
- Hammer.
- 10 - 4 mm diameter milling cutter for cruentation of the joint having a stem of 10 cm.

The dimensions of the components have been defined
15 following the analysis and measurement of 12 different parameters in the radiographs of 30 patients without a fracture. The corresponding corrections have been applied arising from the magnification of the radiographic image.

20 **Description of the drawings**

- Figure 1: Side cross section of the nail (1).
- Figure 2: Elevation of the nail (1).
- Figure 3: Cross section of the screw (4).
- 25 Figure 4: Upper view of the nail (1).
- Figure 5: Guide screw (6).
- Figure 6: Detail of the guide (5).
- Figure 7: Cannulas (7, 8 and 9).
- Figure 8: Diagram of the nail with the guide in
30 position.
- Figure 9: Diagram of the screw and the threads (4).
- Figure 10: Zone of insertion of the nail.
- Figure 11: Diagram of the bases of the art in a fracture.
- 35 Figure 12: Situation following the implantation of the system.

Description of a preferred embodiment

On the operating table, the patient being in a prone position with preventative ischemia, in an optional manner one may, as a function of the severity of the
5 displacements of the fracture, apply transcalcaneal traction to reduce the greater tuberosity of the calcaneus.

By means of an external para-achilleal incision of about
10 5 cm, the pre-achilleal portion of the calcaneus is approached, taking care to preserve the sural nerve. Employing a 15 mm chisel, a canal is created immediately in front of the tendon to facilitate the entry of the nail.

15 The nail being attached to the guide, it is applied at the previously cut canal and it is introduced by means of hammer blows and under radioscopic guidance such that it is directed to the inferior area of the greater
20 tuberosity where the plantar fascia inserts.

The nail must be fully introduced without any protrusion such that under radioscopy we may observe the correct direction of the holes for the screws towards the body
25 of the talus.

With the cannulas in position upon the guide we make a small incision of 1 cm where each one is pointing, reaching the bone. The guide pin is passed in, it being
30 possible to correct the position of the nail should it not be satisfactory, driving it further into the calcaneus. Following the pin, the 4 mm drill bit is passed in as far as the talus and the 6 mm drill bit as far as the nail. The screws are then positioned, subsequent to
35 measuring the length thereof with the depth gauge. On introducing the reverse thread into the nail a distraction of this latter is produced in the direction of the screws. By virtue of this the screws must be

tightened in an alternate manner to prevent twisting of the nail.

5 Once the system is in position, milling cruentation is performed upon the joint surface of the talus and calcaneus, with bone graft harvested from the iliac crest or allograft being supplied.

CLAIMS

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1 A system for the arthrodesis reconstruction of fractures of the calcaneus **which comprises** a wedge-shaped nail (1) having two threaded holes (2 and 3), the nail being locked by two screws (4).

15

2 The system as claimed in claim 1, **wherein** the screws (4) are threaded at the two ends thereof, one for spongy bone and another special thread securing them to the nail.

20

3 The system as claimed in claims 1 and 2, **which has** a specific insertion and destination-guide device for the nail and screws; this device consists of an applicator tube (5), into which the base of the nail is screwed by means of a long screw (6), and a welded handle having two
25 holes in order to pass through the cannulas (7, 8 and 9).

[Coat of arms] SPANISH PATENT AND TRADEMARK OFFICE 11 ES 2 164 543
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REPORT ON THE STATE OF THE ART

51 **Int. Cl.⁷**: A61B 17/58

RELEVANT DOCUMENTS

Category	Documents cited	Claims affected
A	SANDERS, R & GREGORY, P. Operative treatment of intra-articular fractures of the calcaneus. Orthopedic Clinics of North America, 1995, Volume 26, number 2, pages 203 - 214, ISSN 0030-5898, the entire document.	1
A	GALLIE, W.E. Subastragalar arthrodesis in fractures of the os calcis. The Journal of Bone and Joint Surgery, 1943, Volume 25, number 4, pages 731 - 736, the entire document.	1
Category of the documents cited X: of particular relevance O: referring to non-written disclosure Y: of particular relevance when combined with others of the same category P: published between the priority date and the filing date of the application A: reflecting the state of the art E: earlier document but published after the filing date of the application		

**The present report has been
compiled**

☒ in respect of all the ☐ in respect of claims nos.:
claims

Date of completion of report 01.22.2002	Examiner Fco. J. Haering Pérez	Page 1/1
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FIGURE 1

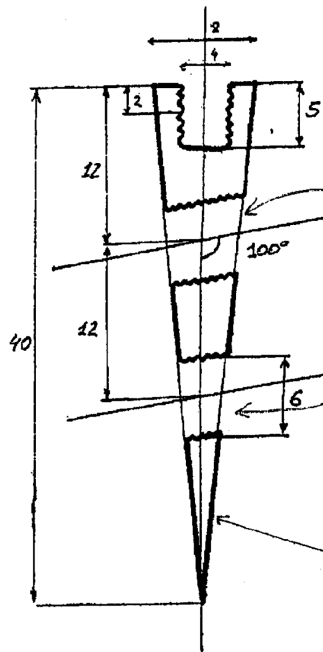


FIGURE 2

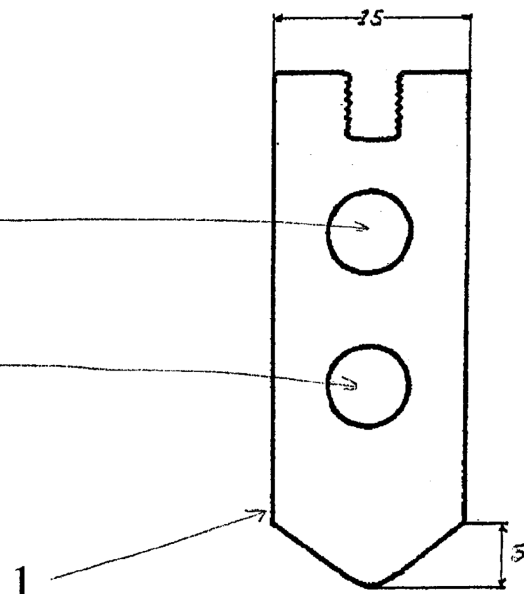


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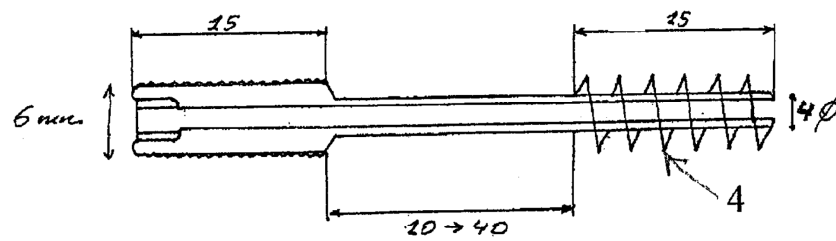


FIGURE 4

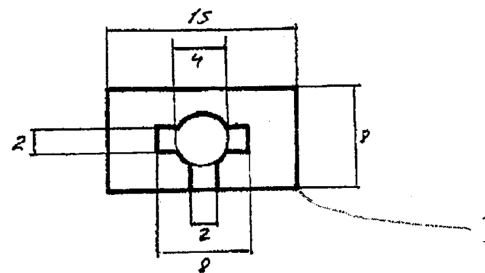


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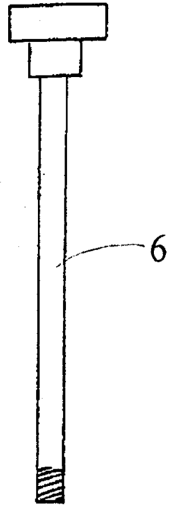


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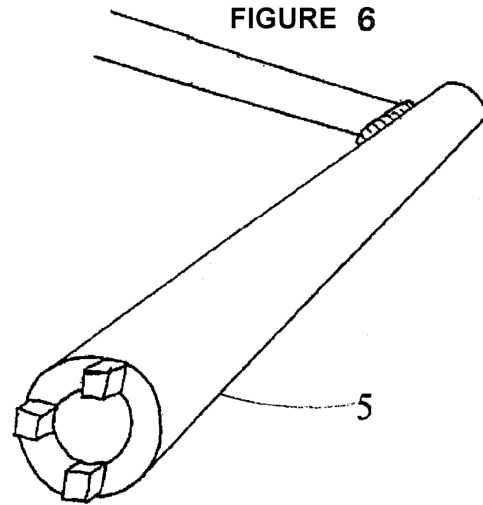


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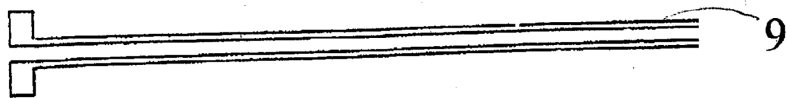
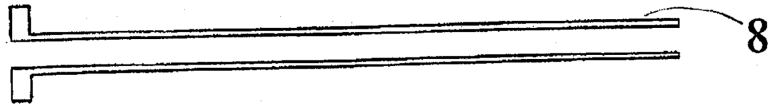
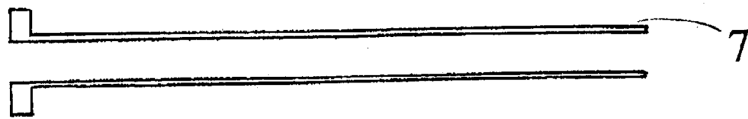


FIGURE 8

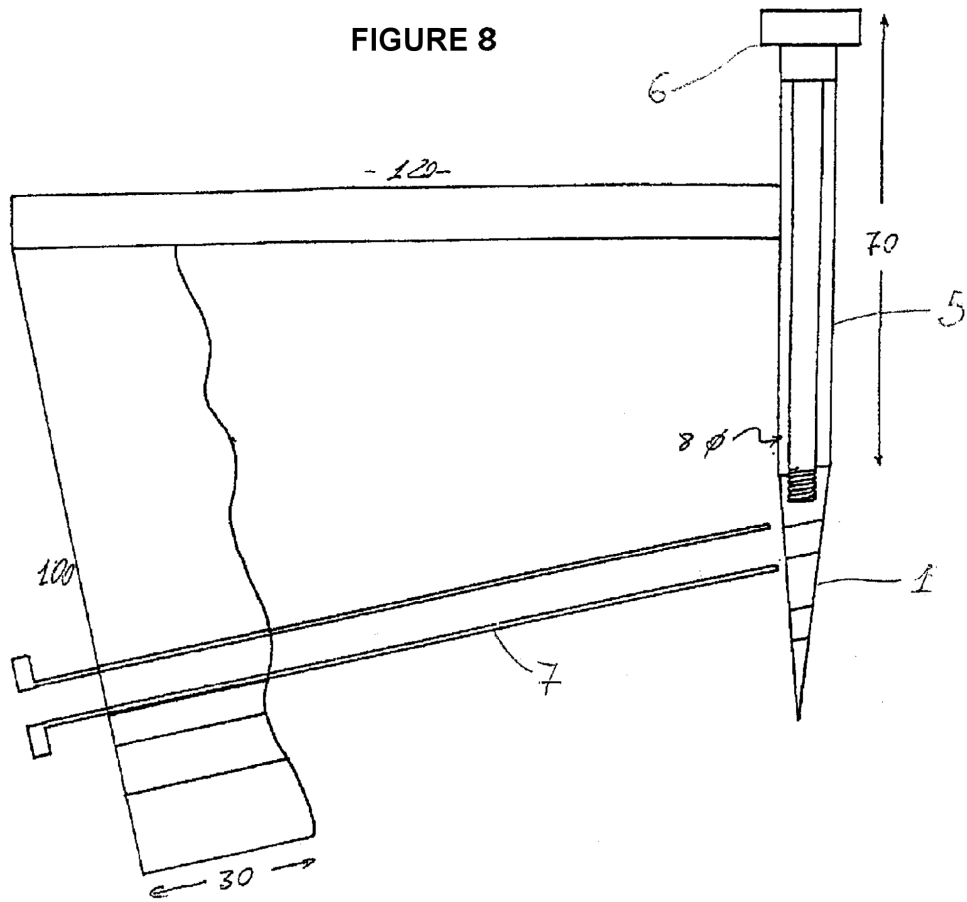


FIGURE 9

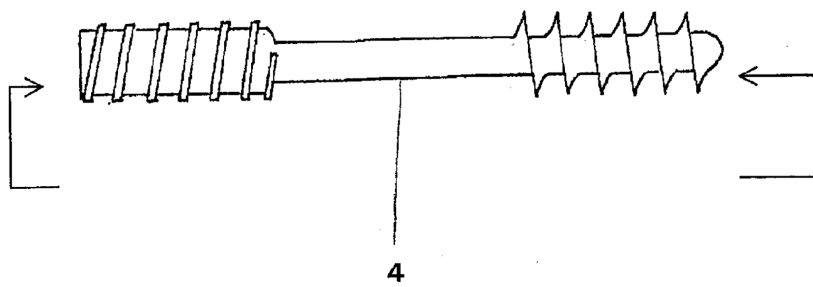


FIGURE 10

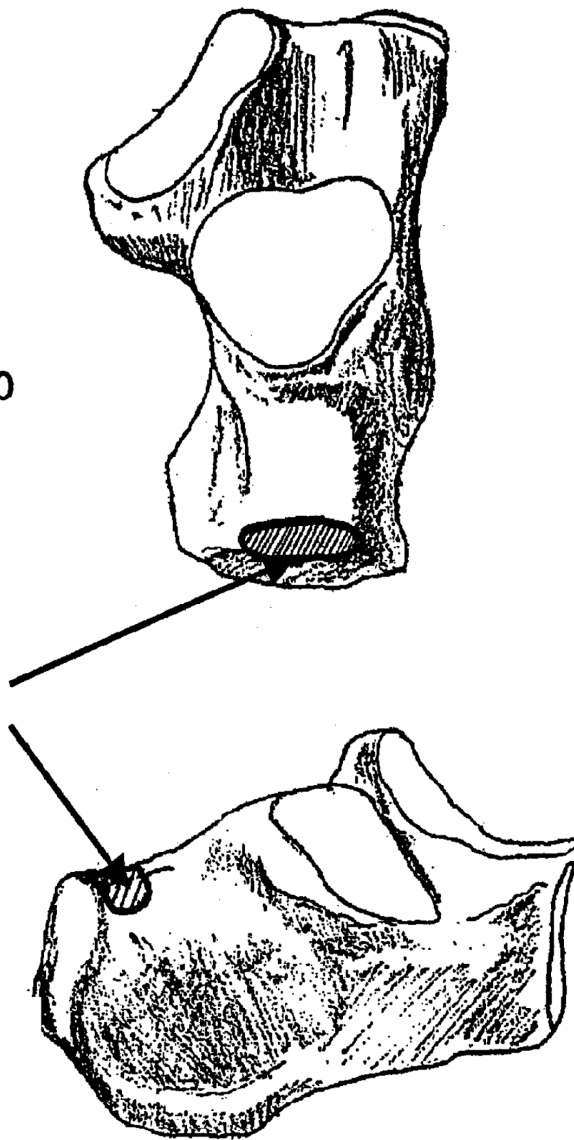


FIGURE 11

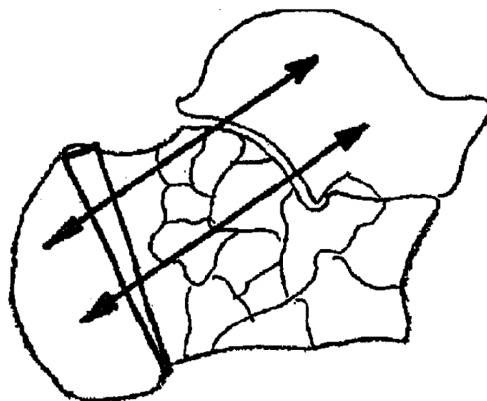
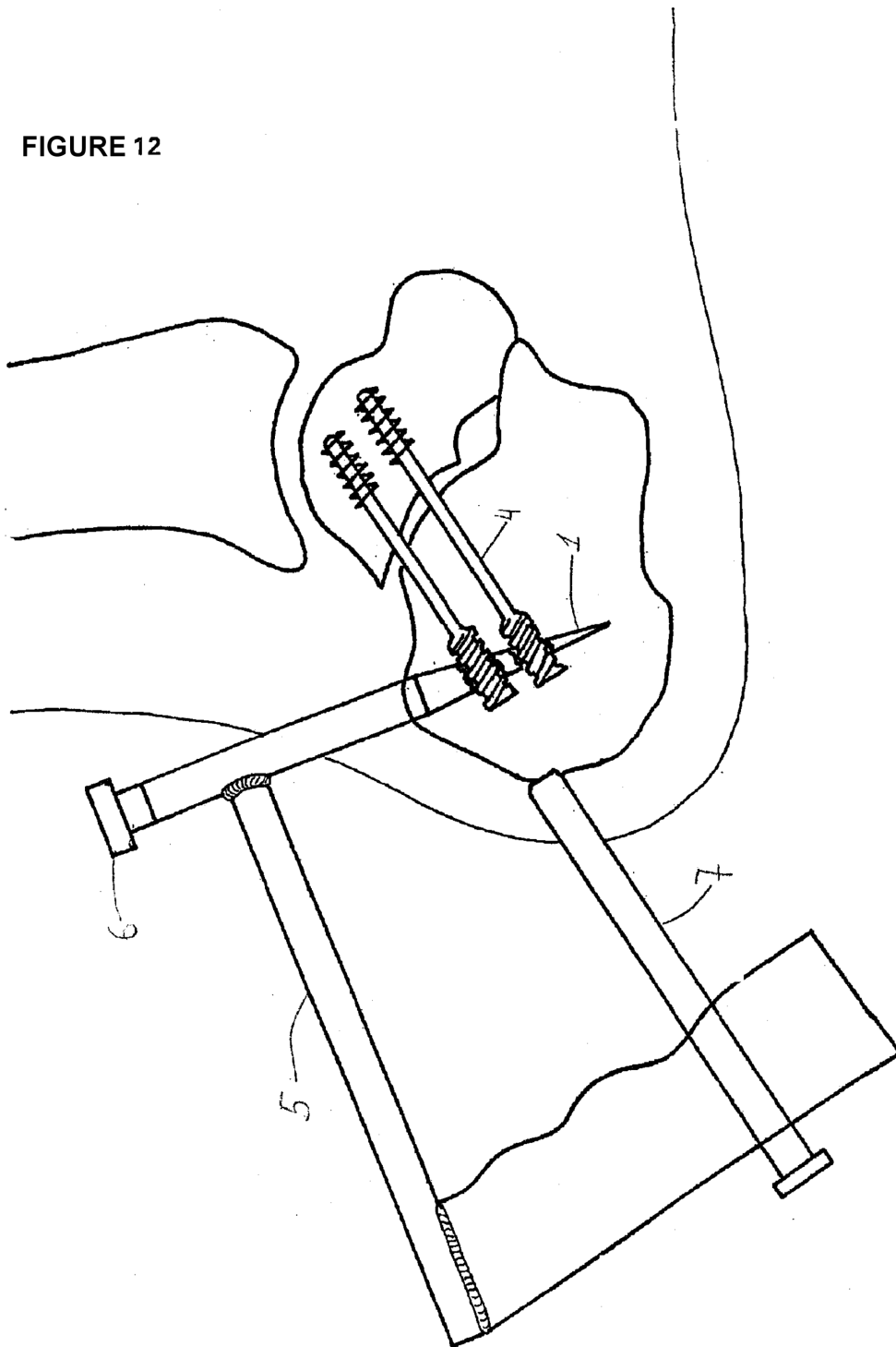


FIGURE 12



UNITED STATES PATENT AND TRADEMARK OFFICE

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2. That I am well acquainted with the Spanish and English languages.
3. That the attached is, to the best of my knowledge and belief, a true translation into the English language of the accompanying copy of the specification filed with the application for a patent in Spain on February 16, 2002 under the number 009901624 and the official certificate attached thereto.
4. That I believe that all statements made herein of my own knowledge are true and that all statements made on information and belief are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application in the United States of America or any patent issuing thereon.

Date: April 15, 2024



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For and on behalf of RWS Translations Ltd