Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2391115 A1 2002/12/21

(21) 2 391 115

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(22) Date de dépôt/Filing Date: 2002/06/21

(41) Mise à la disp. pub./Open to Public Insp.: 2002/12/21

(30) Priorité/Priority: 2001/06/21 (101 29 490.5) DE

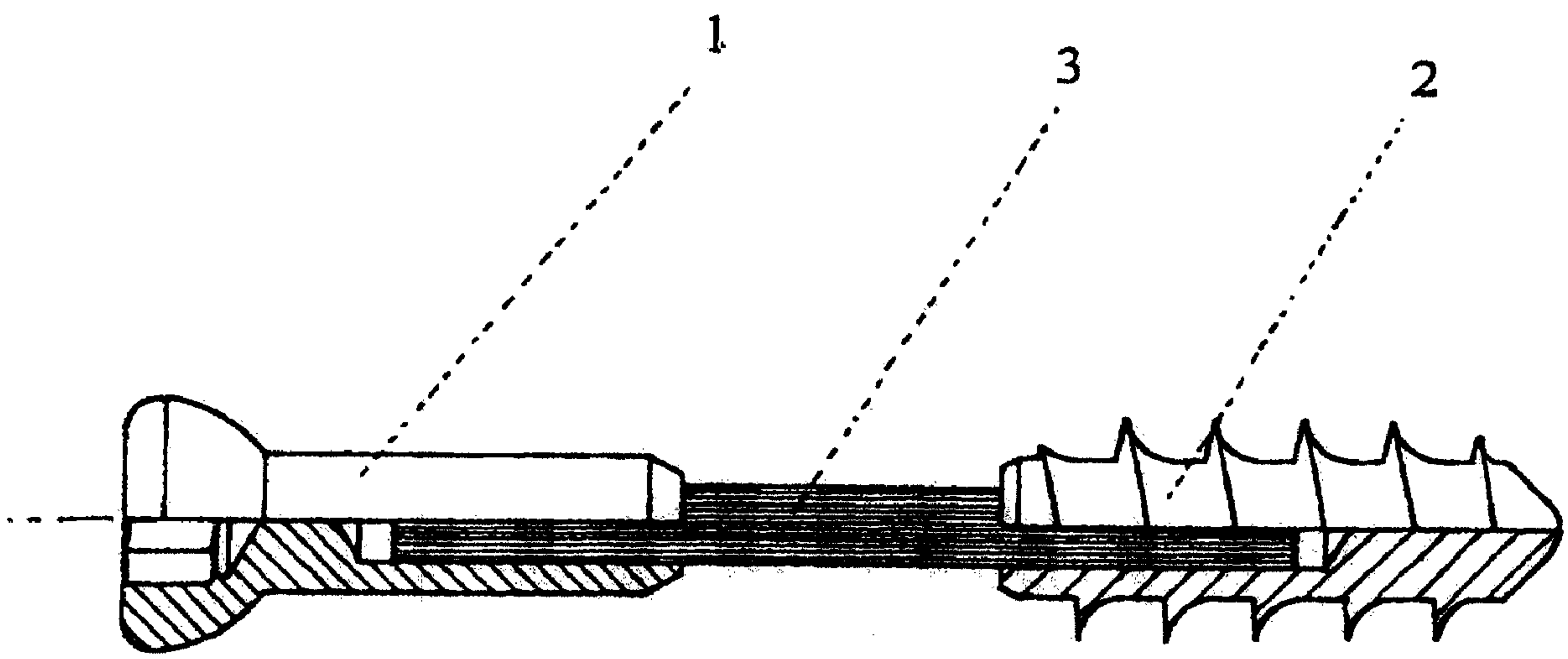
(51) Cl.Int.[7]/Int.Cl.[7] A61B 17/58, A61L 27/04

(71) Demandeurs/Applicants:
MUCKTER, HELMUT, DE;
HILDINGER, KARL HEINZ, DE

(72) Inventeur/Inventor:
MUCKTER, HELMUT, DE

(74) Agent: FETHERSTONHAUGH & CO.

(54) Titre : VIS IMPLANTABLE POUR LA STABILISATION D'UNE ARTICULATION OU D'UN OS FRACTURE
(54) Title: IMPLANTABLE SCREW FOR STABILIZATION OF A JOINT OR A BONE FRACTURE



(57) Abrégé/Abstract:
A bone screw has a flexible shaft which prevents relative movements in the direction of tension, but allows movements of a smaller extent in all other directions. In addition, it is possible to insert the bone screw into medullary cavities having a curved surface, where the screw adapts to the given contour.

P01547US/CA

ABSTRACT

A bone screw has a flexible shaft which prevents relative movements in the direction of tension, but allows movements of a smaller extent in all other directions. In addition, it is possible to insert the bone screw into medullary cavities having a curved surface, where the screw adapts to the given contour.

P01547US/CA

IMPLANTABLE SCREW FOR STABILIZATION OF A JOINT OR A BONE FRACTURE

This invention relates to an implant for augmenting stabilization of bone joints with a low relative movement and for interfragmentary stabilization of bone fractures, when primarily tensile forces are to be applied.

The joints of the body have different ranges of movement. In addition to the joints in the main axes of movement of the extremities as well as the mandibular joint, some of which have relative movements of a considerable extent, there are many joints with a low relative range of movement. Typical examples of this include the acromioclavicular joint as the connection between the shoulder blade and the collar bone (acromioclavicular joint), the joint between the collar bone and the breastbone or sternum (sternoclavicular joint), the iliosacral joint, the pubic symphysis, the articulated connections between the tibia and fibula (proximal and distal tibiofibular joints), the joints between the wrist (carpal bones) and the foot (tarsal bones) as well as the joints between the bones der metacarpus (metacarpal joints) and those of the metatarsus (metatarsal joints). Likewise, injuries to these joints can in many cases lead to serious physical impairments, where a painful arthrosis develops as a result of a permanent joint incongruence. The therapeutic goal must therefore be to accurately reposition these joints and restore the capsule-ligament apparatus. In most cases, this cannot be accomplished by simply suturing the capsule-ligament apparatus. The sutures would not be able to withstand the stress and would rupture, and the joint would slip back into a false, incongruent position. Instead, the injured joint must be kept in a correct position through a suitable surgical implant in the sense of an augmentation until the capsule-ligament apparatus has healed to a sufficient level of strength and can again withstand the forces required to move the joint. The same thing is also true of unstable bone fractures, where an implant is supposed to keep the bones in the correct position, after repositioning the fracture, until the fracture has healed to an adequate level of strength.

Various techniques have been described for augmenting stabilization of a ruptured joint with small relative movements, and these techniques can be divided into roughly four groups: 1. temporary rigid bridging of the joint, 2. bridging with flexible implants, 3. retaining implants, which are bolted to one side of a joint and engage like a hook on the opposite side, 4. implants with an articular connection.

The best known representative of the first group (rigid implants) is the so-called locking screw. When using this principle, the two partners in the joint are secured rigidly relative to one another by a direct screw connection, which guarantees congruence of the joint, but blocks relative movement of the joint. Similar functions are achieved by bridging the joint with Kirschner's wires, optionally supplemented by wire cerclage or by using rigid osteosynthesis plates (especially in the area of the pelvis).

Known representatives of the second group (flexible implants) include plastic cords or bands made of absorbable or non-absorbable materials (literature: R. W. Fremerey et al. (1996) "Surgical treatment of acute, complete rupture of the AC joint," *Unfallchirurg* [Trauma Surgeon] 99:341-5), wire cables in the technique proposed by LABITZKE (literature: R. Labitzke (1982) "Wire cables and intraosseous pressure distribution systems in surgery," *Chirurg* [Surgeon] 53:741-3) or the use of wire cerclage.

Known representatives of the third group (screw-in implants with hooks) include hook plates proposed by BALSER, WOLTER or DREITHALER in a similar design for stabilization von ruptures of the acromioclavicular joint or the syndesmosis hooks developed by ENGELBRECHT (literature: E. Engelbrecht et al. (1971) "Syndesmosis hooks for treatment of tibio-fibular syndesmosis ruptures," *Chirurg* 42:92) for stabilization of ruptures of the ankle joint. These implants allow good augmentation of the joint and essentially preserve mobility, but it is difficult to adjust the proper congruence of the joint, which can often be achieved only by bending the implant subsequently, because these implants do not have any suitable possibilities for adjustment. In addition, a relatively large surgical access area is required, which necessitates a greater surgical trauma.

A typical representative of the fourth group (implants with an integrated joint) is the joint plate developed by RAMANZADEH for stabilization of ruptures of the acromioclavicular joint. However, this plate has the disadvantage that it is difficult to adjust the correct congruence of the joint, and the axes of rotation of the joint and the implant do not match, so the natural movement of the joint is at least partially blocked.

Therefore, the object of this invention is to develop an implant which augments the ligament connections reliably in joints with a small relative movement, while causing little or no impairment of the natural range of movement of the joint.

This object is achieved with an implantable screw which has a flexible shaft for stabilization of a joint or a bone.

This design of the implant guarantees a transfer of tensile forces almost exclusively, whereas there is little or no transfer of bending torque, compressive forces and transverse forces through the flexible shaft.

The use of one or more such screws with a flexible shaft makes it possible to connect the bones involved in an unstable joint in such a way that there is little or no impairment of the natural joint movement.

Likewise, it is possible through the use of one or more such screws having a flexible shaft to apply primarily interfragmentary tensile forces when creating screw connections in bone fractures.

Such a screw makes it possible for both bones involved in a joint injury or both fragments involved in a bone injury to be joined by one or more screws which have a flexible shaft. This design of the implant guarantees transfer of tensile forces almost exclusively, while bending moments, compressive forces and transverse forces are not transmitted at all by the flexible shaft or only to a slight extent. In the case of capsule-ligament injuries of a joint, the screw is preferably installed so that the axis of the screw corresponds to the direction of the resultant force of the ligament connection of the joint. Ideal augmentation of the joint can be achieved in this way. In bone fractures, the screw is introduced at a right angle to the plane of the fracture and causes interfragmentary compression due to the tensile force.

Widening of the surgical space can be achieved to advantage through this invention. In an advantageous embodiment, this invention is suitable for a so-called minimally invasive implantation.

In addition, the screw according to this invention may be designed for use in surgery so that primarily tensile forces are transmitted but no significant bending moment is transmitted. Likewise, the screw according to this invention may be designed so that it can be introduced into the medullary cavity of a fractured bone in the sense of a so-called creep screw, thereby adapting to the contour of the medullary cavity, which is usually curved.

It is advantageous if the planar axial moment of inertia of the screw is 30 % less, preferably more than 50 % less than that of a screw having the same outside diameter.

The flexibility in the shaft area can be achieved by a wire cable, a wire bundle, a cord, a spiral or multiple webs and by fibers.

When using a wire cable or a wire bundle, it is especially advantageous if the wire cable or wire bundle is reinforced on the outside by sleeves or a spiral. Twisting of the wire cable or wire bundle is thereby limited when a torsional moment is applied, and thus the wire cable or wire bundle is stabilized. In addition, the bending movement of the shaft can be limited by the size of the sleeve or the spiral windings and their spacing relative to one another.

It is especially advantageous if the threaded part has a bone thread.

According to a preferred embodiment, the head part has a wrench socket and has a smooth surface or a bone thread matching the threaded part, depending on the intended application of the implant, said thread having a larger diameter and a smaller thread pitch than the bone thread in the threaded part.

With a high flexibility of the shaft and therefore inadequate transferability of the torsion moments required for the thread to penetrate, it is advantageous if the implantable screw has wrench sockets in the head part as well as in the threaded part. This allows a stepped wrench to act on these wrench sockets in synchronization.

Additional advantageous embodiments are described in the subclaims.

Various embodiments of this invention are illustrated in the drawings and explained in greater detail below.

They show:

Fig. 1 a bone screw, whose shaft is designed as a wire cable or as a wire bundle to make it flexible,

Fig. 2 a bone adjusting screw, whose shaft is designed as a wire cable or as a wire bundle to make it flexible,

Fig. 3 a bone screw, which has on the distal side from the head a bone thread whose shaft is designed as a wire cable or as a wire bundle to make it flexible, and which has on the proximal head side a bone thread which has a larger diameter and a smaller thread pitch than the bone thread distal from the head,

Fig. 4 a screw, which has a bone thread on one side, its shaft being designed as a wire cable, a cord or a wire bundle to make it flexible, and on the other side having a bolt with a metal thread and a hexagon socket head nut screwed onto it,

Fig. 5 a bone screw, whose shaft is designed to be flexible in the sense of a spiral spring,

Fig. 6 a bone screw, which is preferably made of a biocompatible plastic and has a flexible shaft composed of multiple webs,

Fig. 7 a bone screw, in which the shaft consists of multiple fibers which are anchored alternately in the head part and in the threaded part of the bone screw,

Fig. 8 an embodiment for stabilization of the ankle joint (distal tibiofibular joint, syndesmosis),

Fig. 9 an embodiment for stabilization of the acromioclavicular joint,

Fig. 10 an embodiment for stabilization of the iliosacral joint,

Fig. 11 an embodiment for stabilization in the area of the wrist with scapholunate dissociation,

Fig. 12 an embodiment for interfragmentary traction screws in the area of the patella with a fracture of the patella,

Fig. 13 a bone screw according to Fig. 4, where the wire cable or the wire bundle is reinforced by individual sleeves.

Fig. 1 shows a bone screw, whose head part 1 and whose threaded part 2 are flexibly interconnected by a wire cable or a wire bundle 3. The wire cable or the wire bundle is fixedly connected in the head part as well as in the threaded part through suitable connection methods (e.g., pressed, glued, soldered or welded connections). The use of a wire cable or a wire bundle allows the application of tensile forces and the transfer of torsion moments in the sense of a flexible shaft. Compressive forces, transverse forces or bending moments, however, are transmitted only to a slight extent.

Fig. 2 shows a bone locking screw which has a head part 4, which is provided with a bone thread, and a threaded part 5, which are flexibly interconnected by a wire cable or wire bundle 6 by analogy with Fig. 1. The thread on the head part and the threaded part are of the same size and the thread flanks are the same. In this way, a previously defined distance between two bones to be joined is established, regardless of the tightening torque of the screw.

Fig. 3 shows a bone screw with a thread-bearing head part 7, which is flexibly connected to threaded part 9 by a wire cable or a wire bundle 8 by analogy with Fig. 1. According to the known function principle of the HERBERT screw, the thread on the head part has a larger diameter in comparison with the threaded part and it has a smaller thread pitch. When this screw is screwed into a fractured bone perpendicular to the plane of the fracture, the two fragments are moved toward one another and are braced against one another, where the extent of the movement toward one another per revolution of the screw is obtained from the difference between the two thread pitches.

Fig. 4 shows a screw which has a threaded part 10 on one side with a bone thread which is connected flexibly by a wire cable, a wire bundle or a cord 11 to a bolt 12, which has a metal or plastic thread. A hexagon socket head nut 13 is screwed onto this bolt. In implantation of such a screw, first the threaded part with the bone thread is screwed into the bone in the sense of a stud bolt. This is done by means of a cannulated wrench which is pushed over the wire cable or the wire bundle or the cord and the bolt and meshes with the hexagon insert bit 14 of the threaded part. Then the hexagon socket head nut is screwed onto the bolt with a metal thread by means of a cannulated hexagon socket wrench. Next, the wire cable or wire bundle that projects on the hexagon socket or the projecting cord is shortened with a knife forceps.

Fig. 5 shows the design variant of a bone screw 15, whose shaft 16 is designed in the form of a spiral. In addition to the flexibility of the shaft, an elastic component is added with this design variant. The amount of flexibility and elasticity of the shaft depend to a great extent on the design of the spiral. Large spirals have only a low flexibility and elasticity, whereas small spirals are highly elastic and flexible. Such a design variant is especially suitable for intramedullary screwing of bones with curved surfaces, e.g., as so-called creep screws in the area of the pelvis. The shaft length is limited by a wire cable, a wire bundle, a chain, a fiber or a flexible pin (not shown), preferably arranged in the spiral.

Fig. 6a shows a bone screw 17, which is preferably suitable for being fabricated from absorbable or non-absorbable plastics and is designed so that it can be manufactured by the casting technology. The flexibility of the shaft here is achieved due to the fact that it consists of multiple webs 18. The extent of the flexibility of this variant is defined by the number and dimensions of the webs and by the material properties of the material used. Since the webs are capable of transmitting the torsion moments which occur in tightening the screw only to a very limited extent, it is especially advantageous if a hexagon head 21, 22 (or a different type of wrench socket) is provided in both the threaded part 19 and the head part 20, so that a torsion load on the webs is prevented when using a corresponding stepped hexagon head wrench according to Fig. 6b. Likewise, it is advantageous for many applications if the threaded part is cannulated 23, so that application of the screw can take place through a corresponding guide wire.

Fig. 7 shows a bone screw 24, which is equally suitable for fabrication from an implant metal as well as from absorbable or non-absorbable plastics and which is designed so that the individual components can be manufactured by the casting technology. The flexibility of the shaft is achieved by the fact that it consists of multiple fibers 25 which are either held in eyelets 26, 27, anchored alternately in the head part 28 and in the threaded part 29 of the screw according to the figure or are each securely anchored in the head part and in the threaded part. Since this variant can transmit only tensile forces, a hexagon head socket 30, 31 (or a different type of wrench socket) is to be provided in both the head part and in the threaded part, by analogy with Fig. 6a, permitting the use of a stepped wrench according to Fig. 6b, with which the head part and threaded part can be screwed equally into the bone.

Fig. 8 shows an embodiment of a bone screw with a flexible shaft 32 according to Fig. 4, which is introduced into the area of the ankle for augmentation of a ruptured syndesmosis 33 (syndesmosis = ligament connection between the fibula 34 and the tibia 35 in the area of the ankle joint). In contrast with a conventional rigid screw connection, the natural relative movement between the fibula and tibia is preserved due to the flexible shaft. However, it is impossible for the ankle to yield, which would lead to instability of the ankle bone 36. The dimensions of the bone screw are selected so that it can be introduced into the bone through the boreholes in a conventional osteosynthesis plate when there is a concomitant fracture of the lateral malleolus.

Fig. 9 shows another embodiment of a bone screw with a flexible shaft 37 according to Fig. 1 in the area of the ligament connection between the shoulder blade 38 and the collar bone 39, on the acromioclavicular joint 40. The rupture of all three ligaments involved in this connection is diagramed schematically (acromioclavicular ligament 41, trapezoid ligament 42, conoid 43). According to the principle described in 1941 by BOSWORTH for the use of rigid screws, the screw is screwed into the coracoid process 44 through the collar bone. In contrast with a conventional rigid screw connection, the natural relative movement between the collar bone and the shoulder blade is maintained due to the flexible shaft. However, a high position of the collar bone, which would lead to incongruence of the acromioclavicular joint, is impossible.

Fig. 10 shows another embodiment of a bone screw having a flexible shaft 45 according to Fig. 4 in the area of the ligament connection between the sacrum 46 and the iliac bone 47 (iliosacral joint 48). In the case of an instability of the posterior pelvic ring due to injury, stabilization is accomplished by screwing one or more screws with a flexible shaft into the bone. In contrast with a conventional rigid screw connection, the natural relative movement between the sacrum and the ileum is preserved due to the flexible shaft. However, gaping of the joint gap is reliably prevented due to the screw having a flexible shaft.

Fig. 11 shows another embodiment of a bone screw having a flexible shaft 49 according to Fig. 4 in the area of the wrist in the case of a ruptured ligament between the scaphoid bone 50 and the lunate bone 51 (scapholunate dissociation). Repositioning and stabilization are accomplished by screwing a screw having a flexible shaft into the bone. In contrast with a conventional rigid screw connection or stabilization with Kirschner's wires, the natural relative movement between the scaphoid bone and the lunate bone is preserved due to the flexible shaft. However, the wrist bones that have been screwed together cannot yield laterally.

Fig. 12 shows another embodiment of bone screws with a flexible shaft 52, 53 according to Fig. 1 with a transverse fracture of the patella 54. According to the known tension belt principle, the tensile forces conducted from the quadriceps tendon over the patella and into the patellar tendon are transferred through the two bone screws with a flexible shaft and the two fragments of the patella are compressed together.

Fig. 13 shows a bone screw according to Fig. 4, where wire cable or wire bundle is reinforced by individual sleeves 55. In accordance with their winding, wire cables tend to twist and coil up when a torsion moment is introduced in the opposite direction to their winding. Due to the fact that sleeves or a spiral are pushed onto the wire cable or the wire bundle, this twisting can be limited, and at the same time, a stabilization of the wire cable can be achieved due to the resulting clamping of the wire cable in the sleeve or the spiral. This allows higher torsion moments to be transmitted than is possible with an unreinforced wire cable or wire bundle. In addition, depending on the design of the sleeve and the spacing of the individual sleeves or spiral windings relative to one another, the extent of the bending of the flexible screw shaft can be limited.

CLAIMS

1. An implantable screw for stabilization of a joint or a bone fracture,

   characterized in that

   the screw has a flexible shaft.

2. The implantable screw according to Claim 1,

   characterized in that

   the planar axial moment of inertia of the screw is 30 % less, preferably 50 % less than that with a screw having the same outside diameter.

3. The implantable screw according to Claim 1 or 2,

   characterized in that

   the flexibility in the shaft area is achieved by a wire cable or a wire bundle.

4. The implantable screw according to Claim 3,

   characterized in that

   the wire cable or the wire bundle is reinforced in the shaft area by a spiral or by sleeves pushed onto the wire from the outside.

5. The implantable screw according to one of the preceding claims,

   characterized in that

the flexibility in the shaft area is achieved by a cord or a spiral.

6. The implantable screw according to one of the preceding claims,

characterized in that

the flexibility in the shaft area is achieved through multiple webs or fibers.

7. The implantable screw according to one of the preceding claims,

characterized in that

the threaded part has a bone thread.

8. The implantable screw according to one of the preceding claims,

characterized in that

the head part has a wrench socket and a smooth surface or a bone thread corresponding to that on the threaded part or it has a bone thread which has a larger diameter and a smaller thread pitch than the bone thread in the threaded part.

9. The implantable screw according to one of the preceding claims,

characterized in that

the threaded part is designed as a stud bolt with a wrench socket and has a threaded bolt with a head nut in the area of the head part.

10. The implantable screw according to one of the preceding claims,

characterized in that

it has wrench sockets in the head part as well as in the threaded part.

11. The implantable screw according to one of the preceding claims,

characterized in that

a biocompatible metall as well as a biocompatible, absorbable or non-absorbable plastic or a combination of such materials is used as the material of the screw.

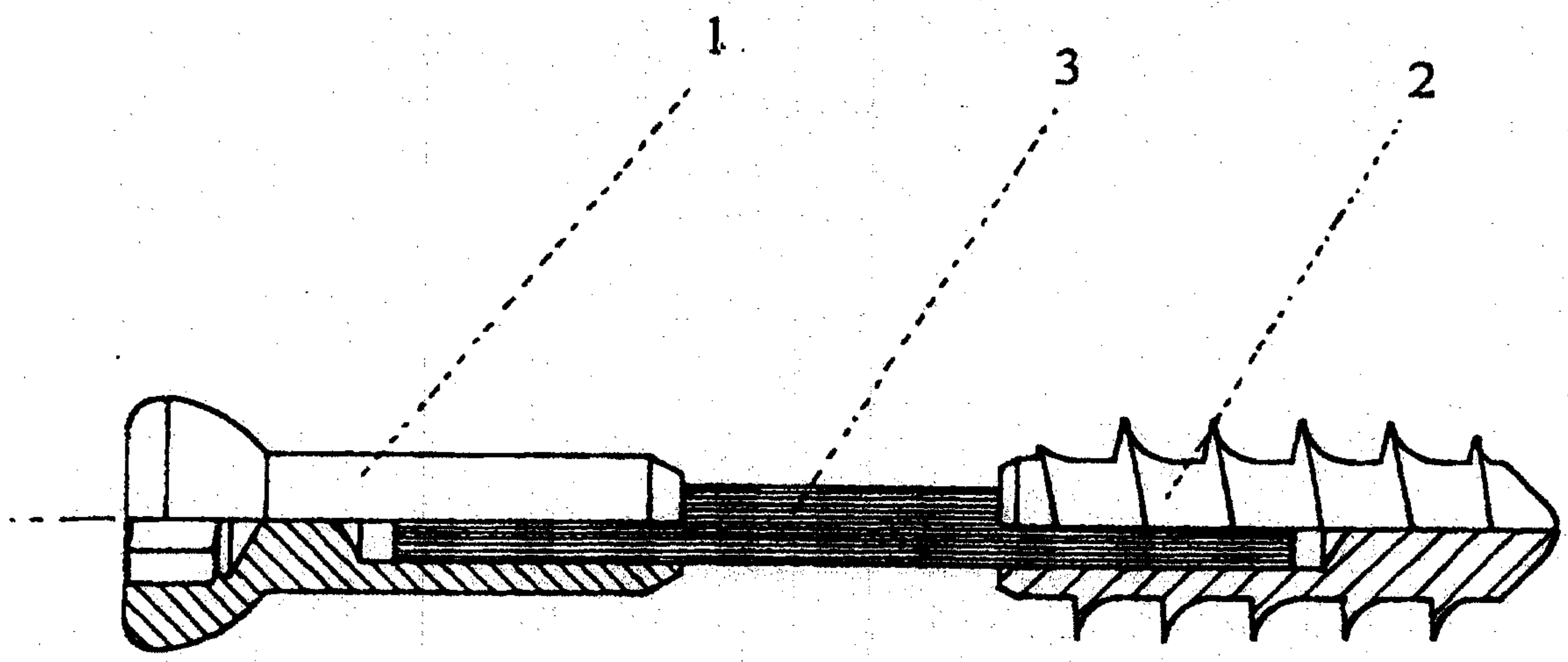


Fig. 1

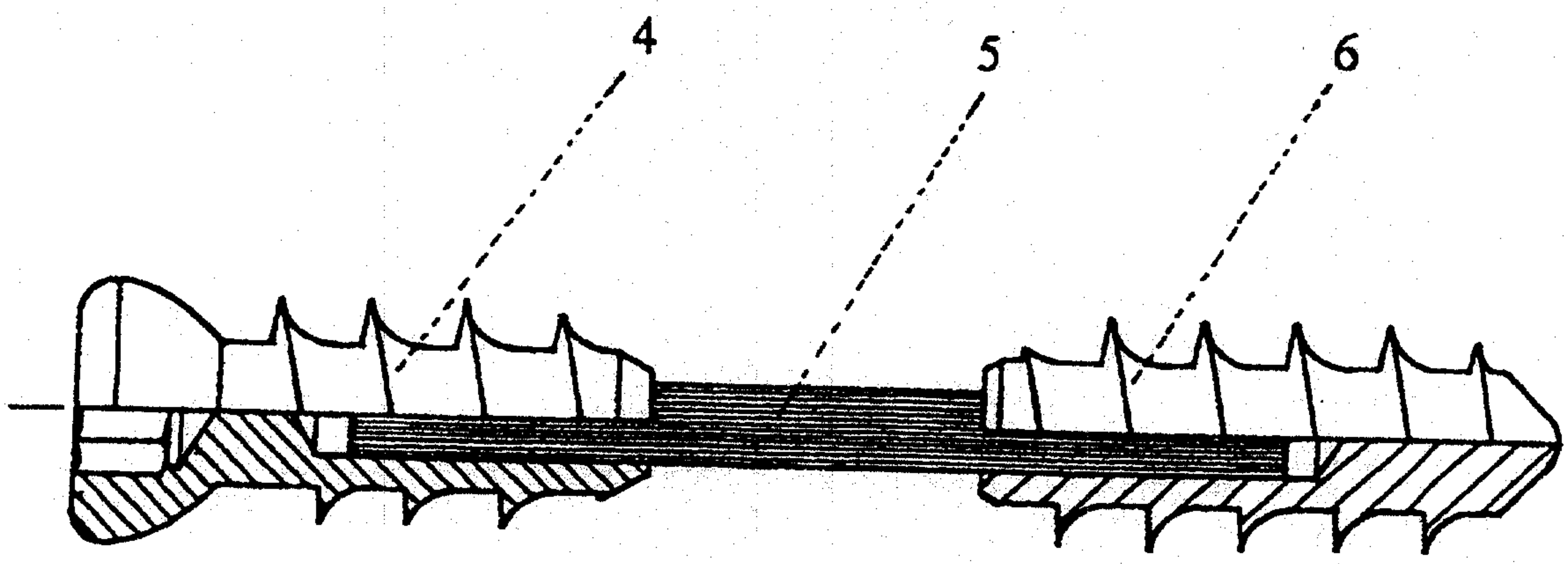


Fig. 2

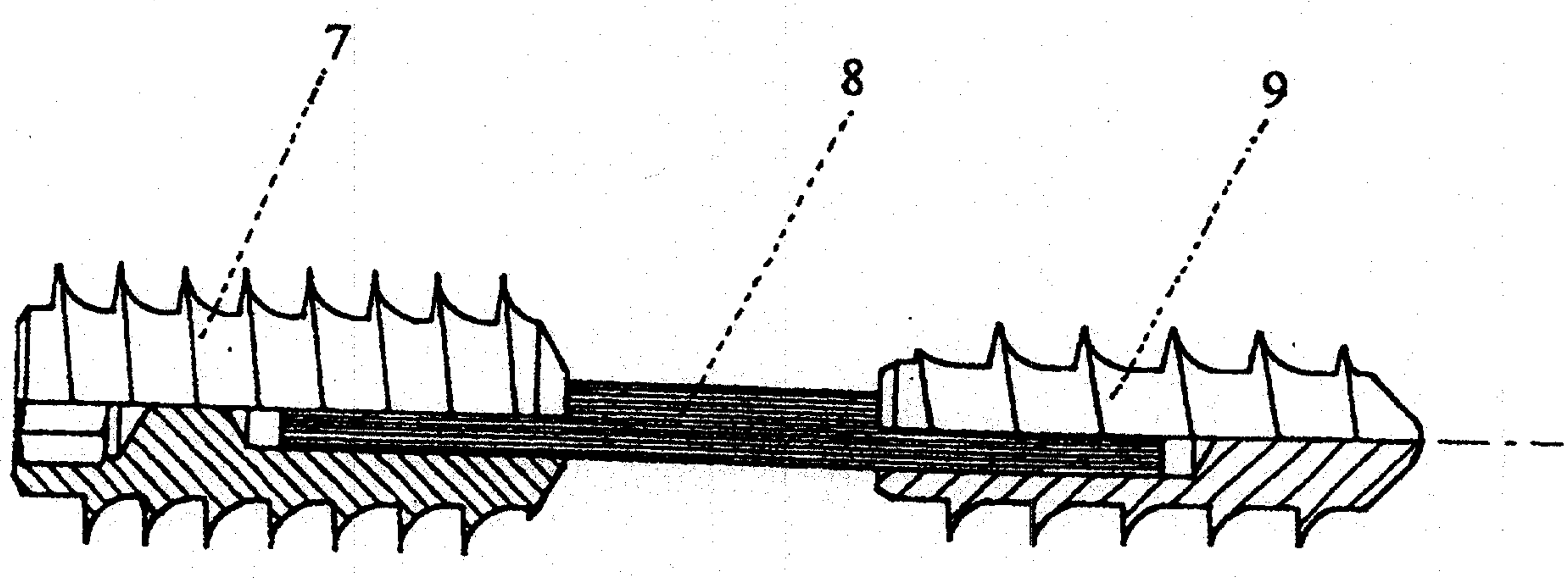


Fig. 3

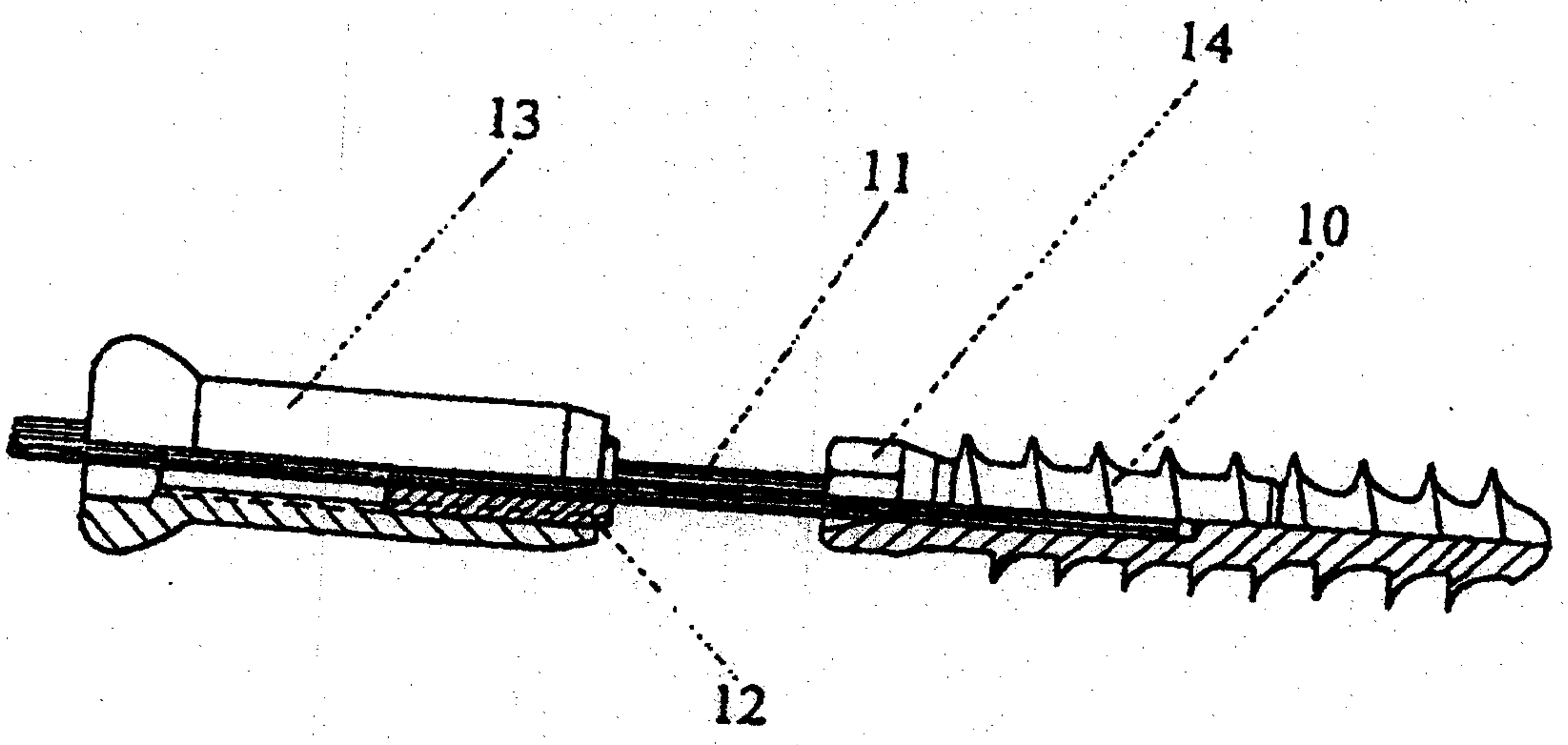


Fig. 4

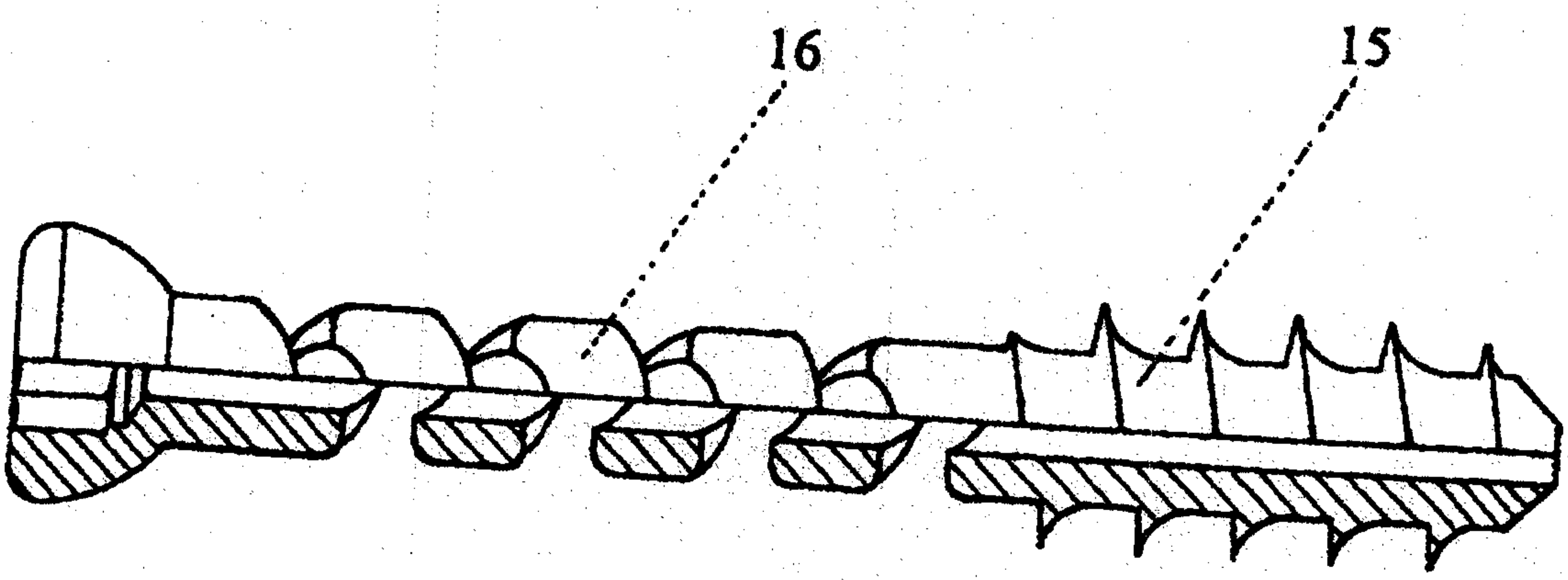


Fig. 5

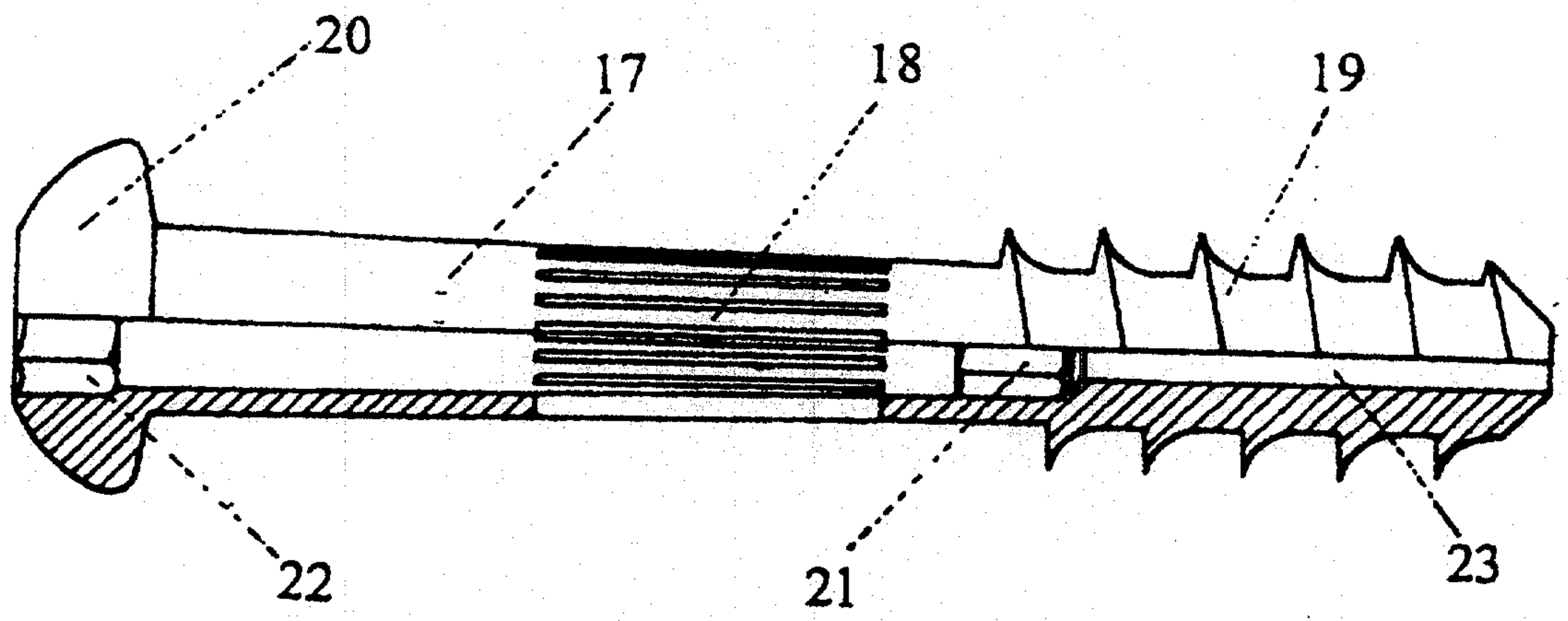


Fig. 6a

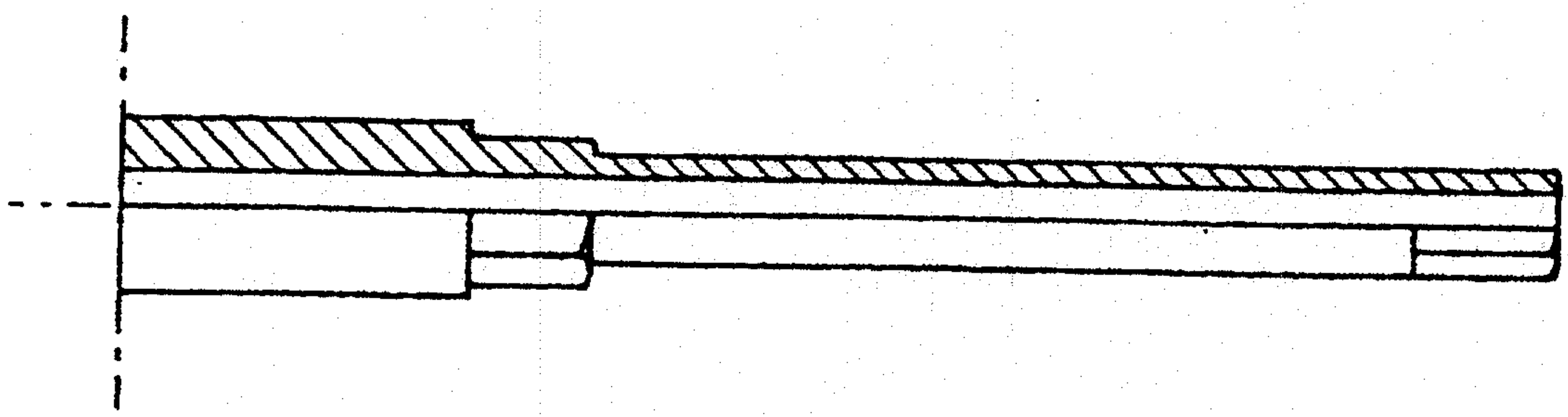


Fig. 6b

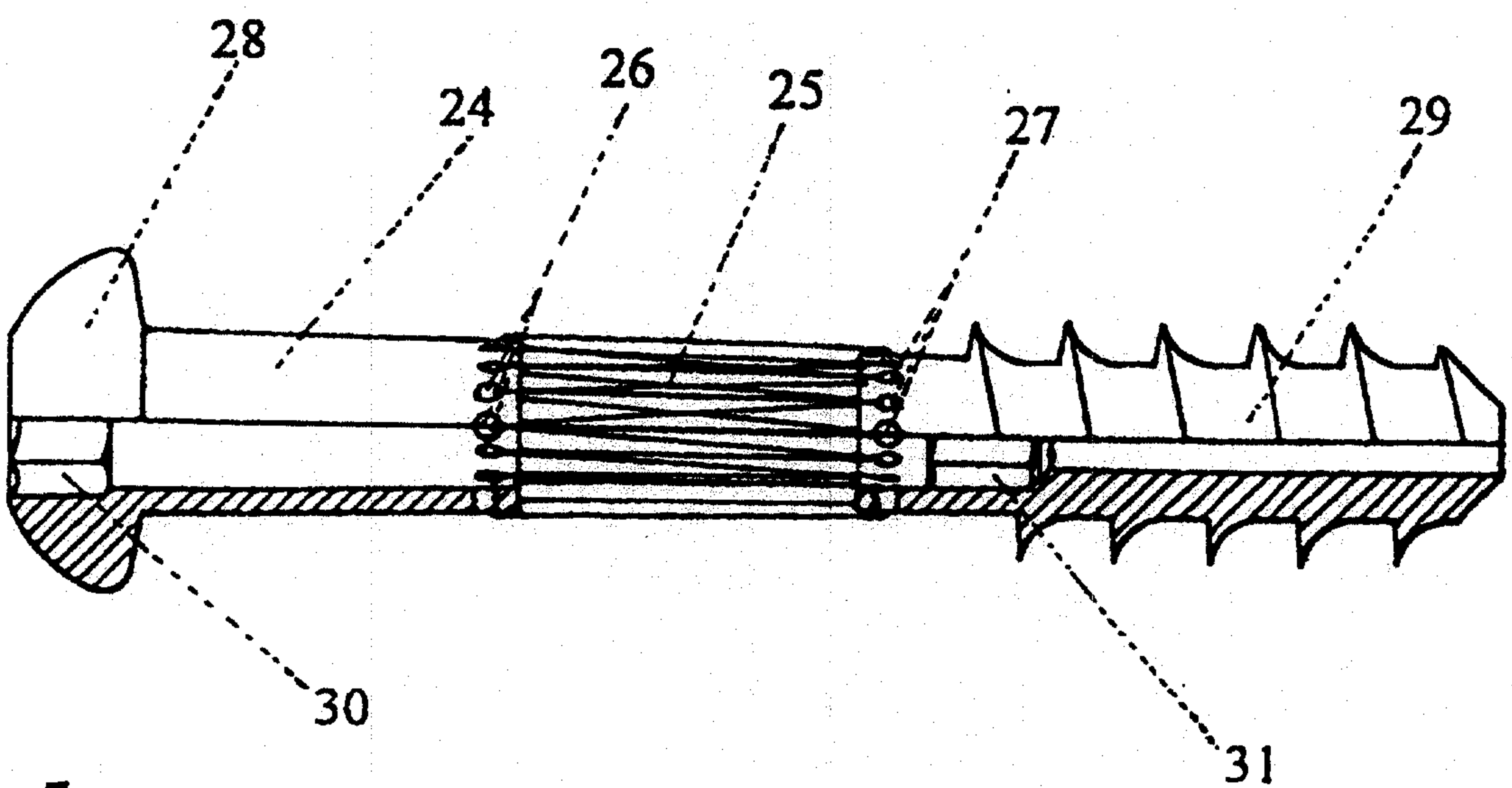


Fig. 7

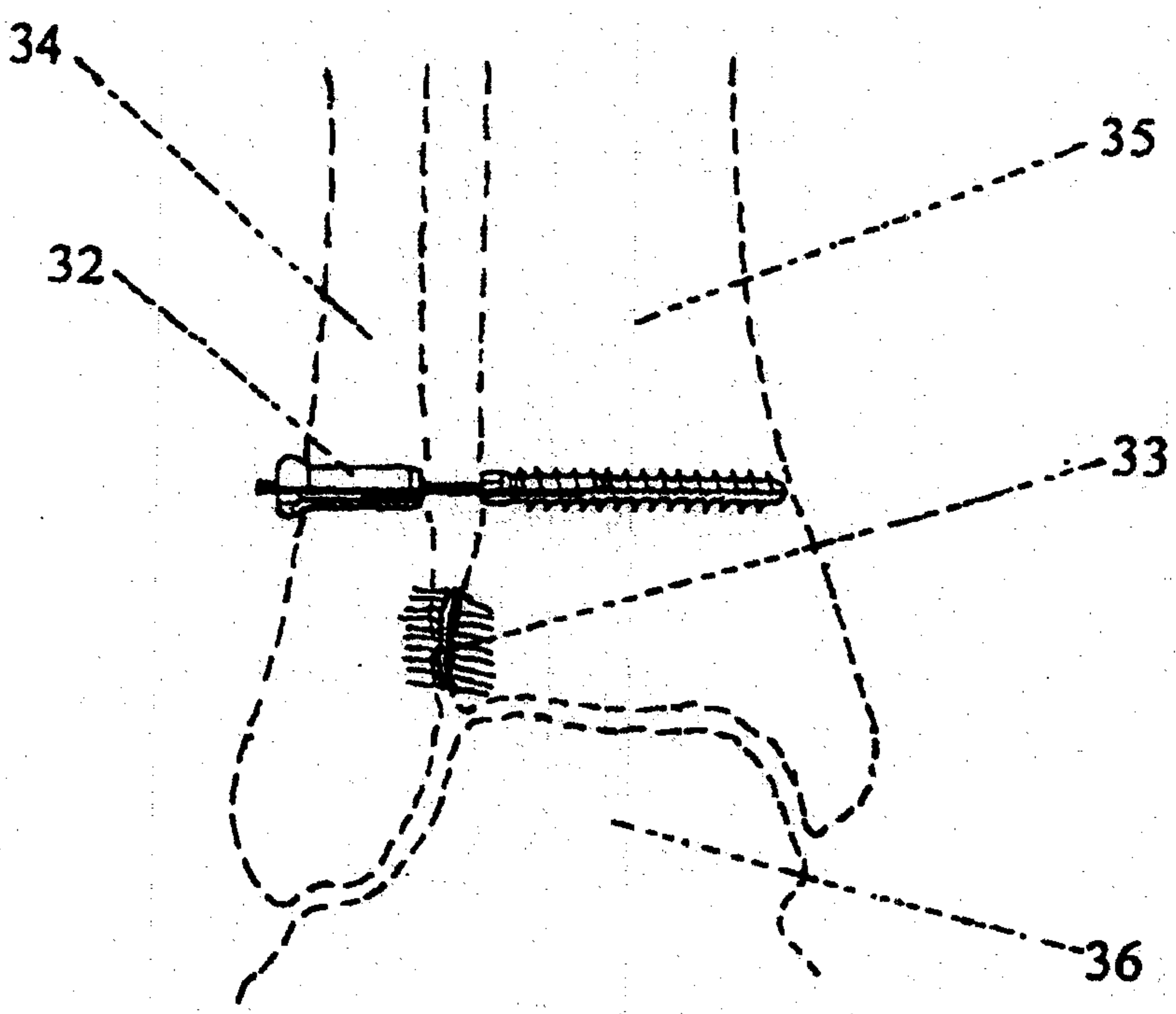


Fig. 8

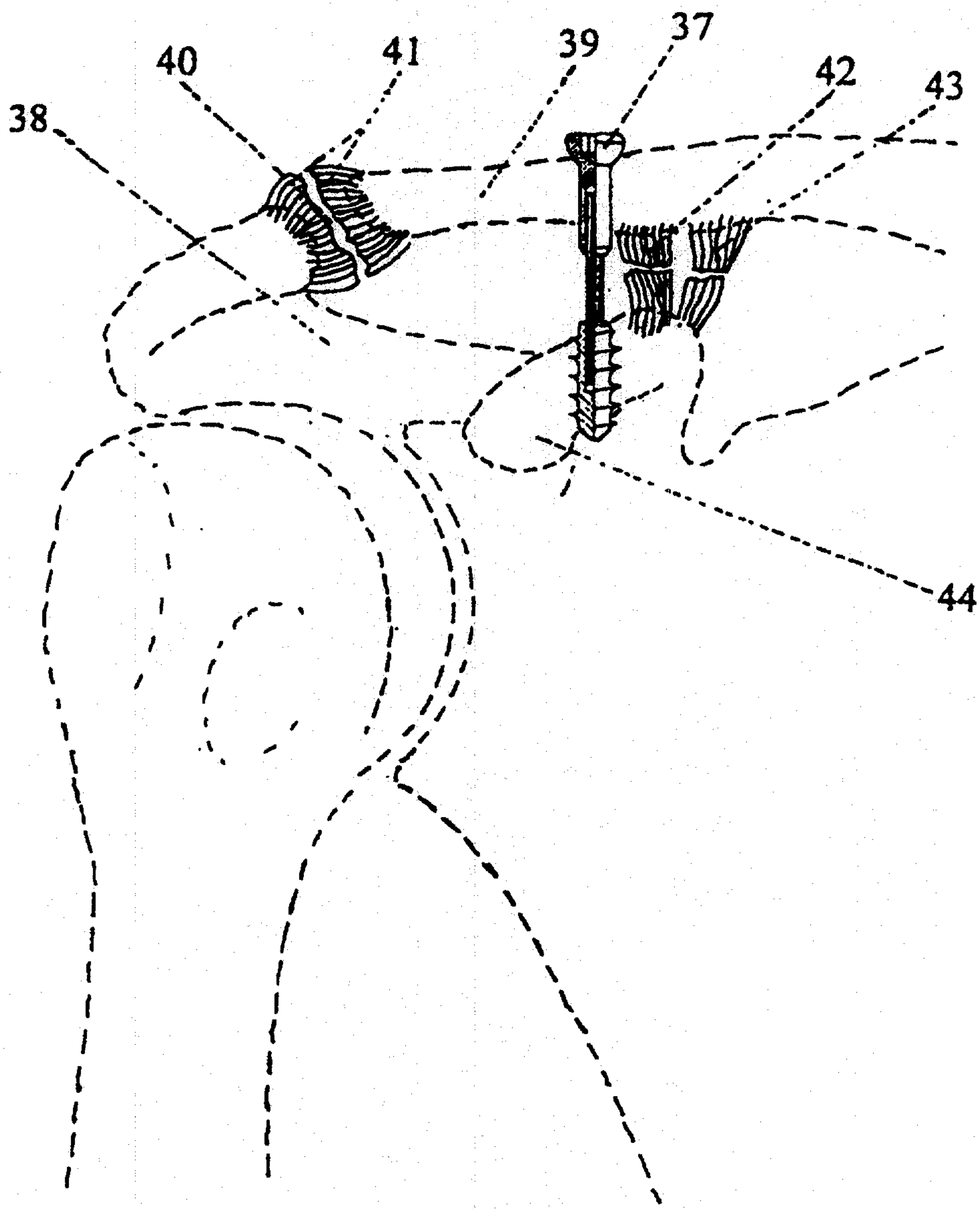


Fig. 9

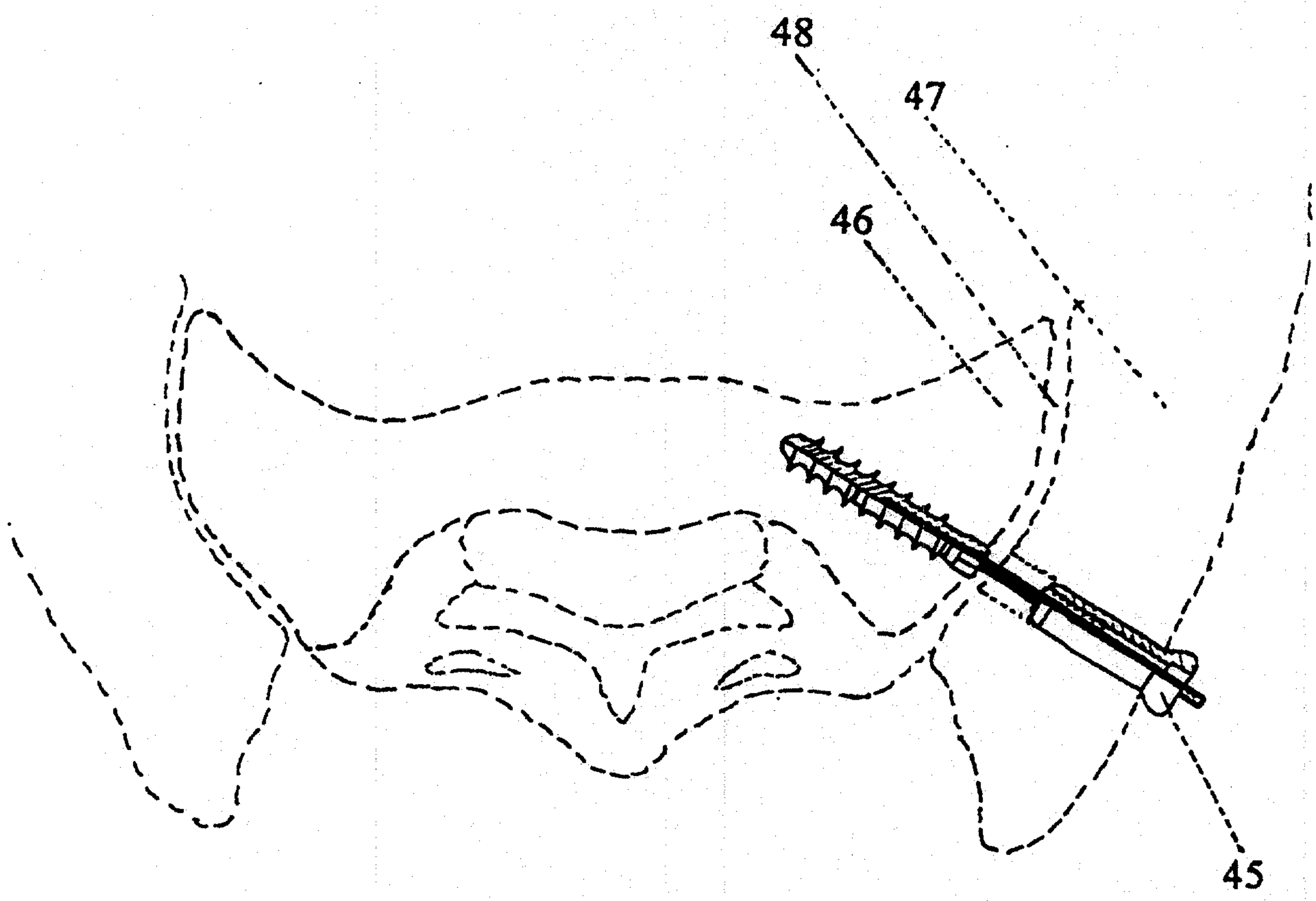


Fig. 10

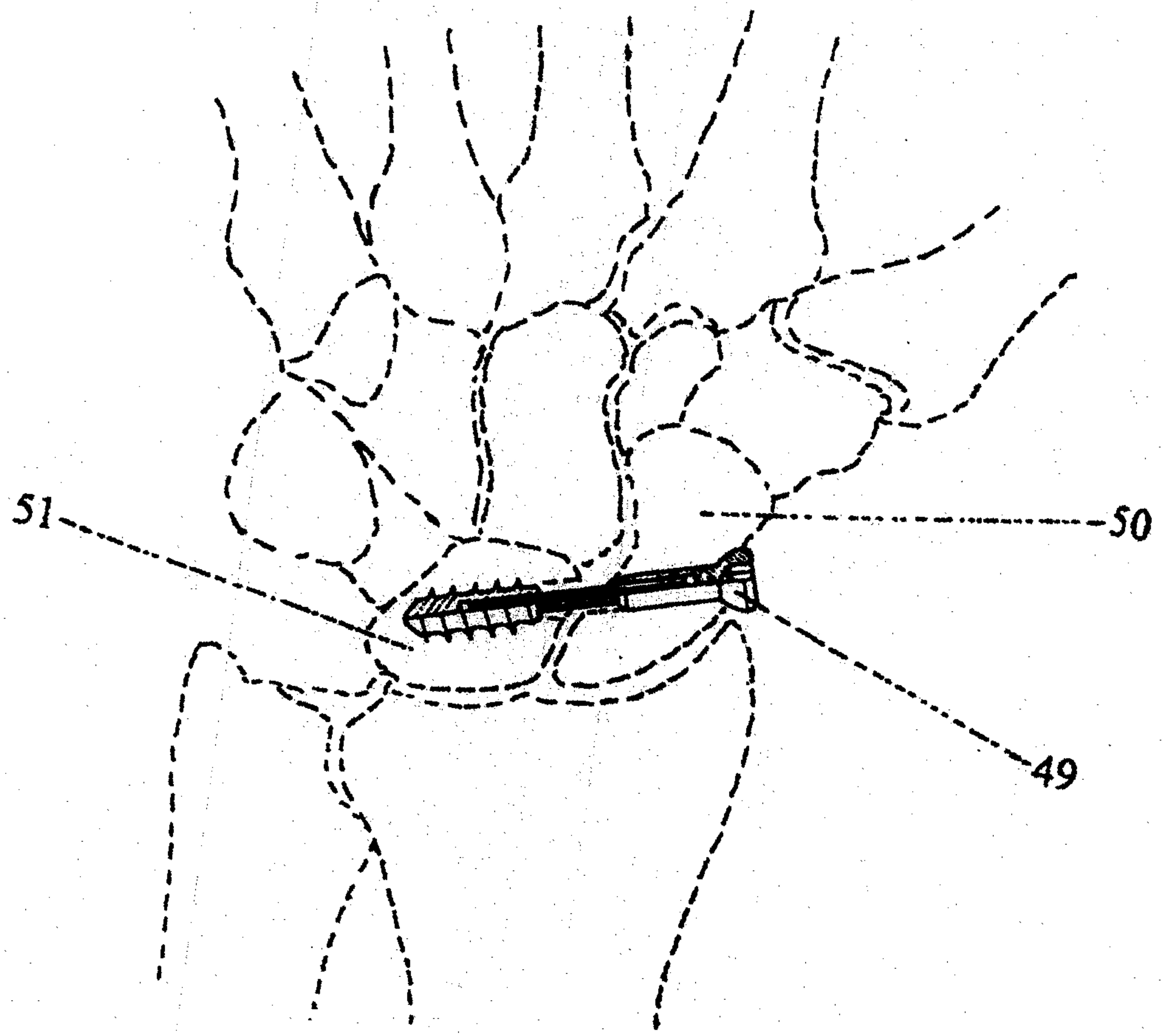


Fig. 11

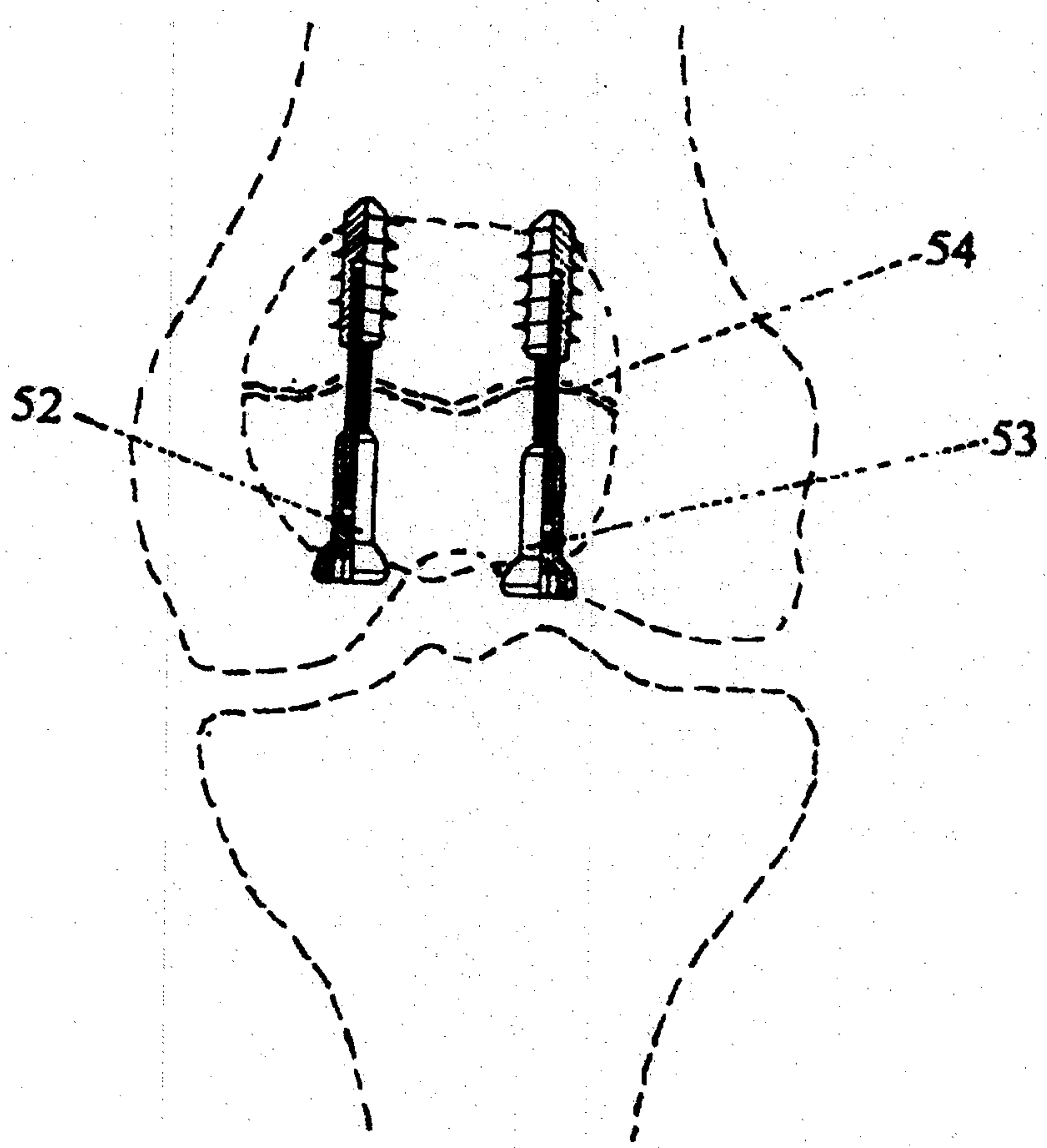


Fig. 12

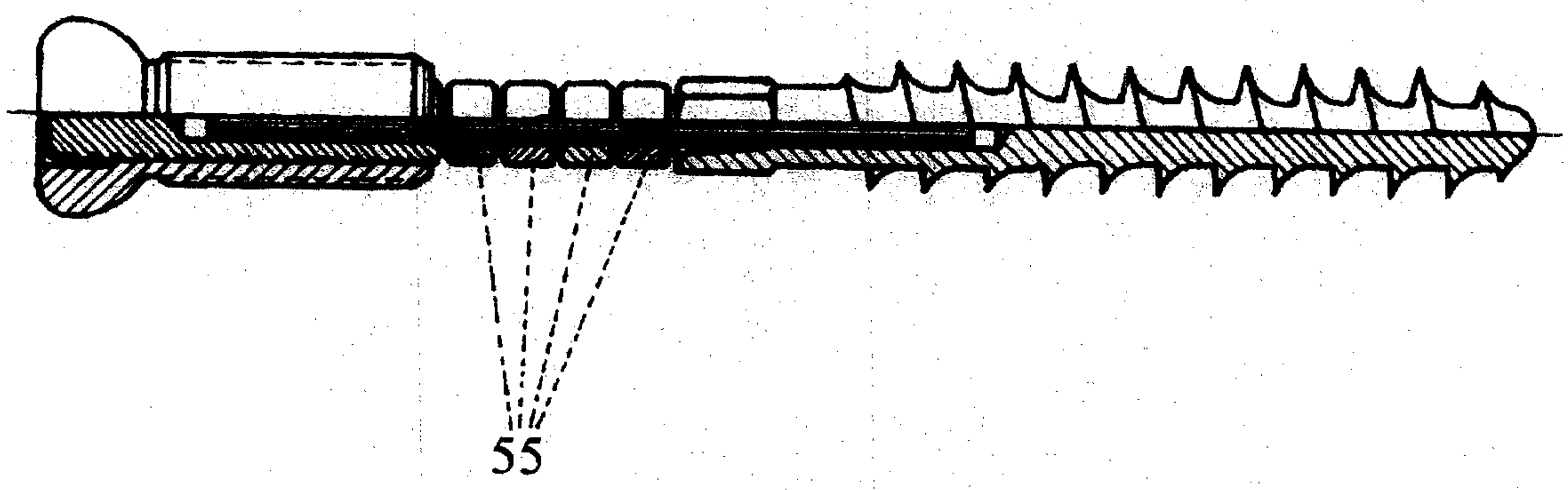
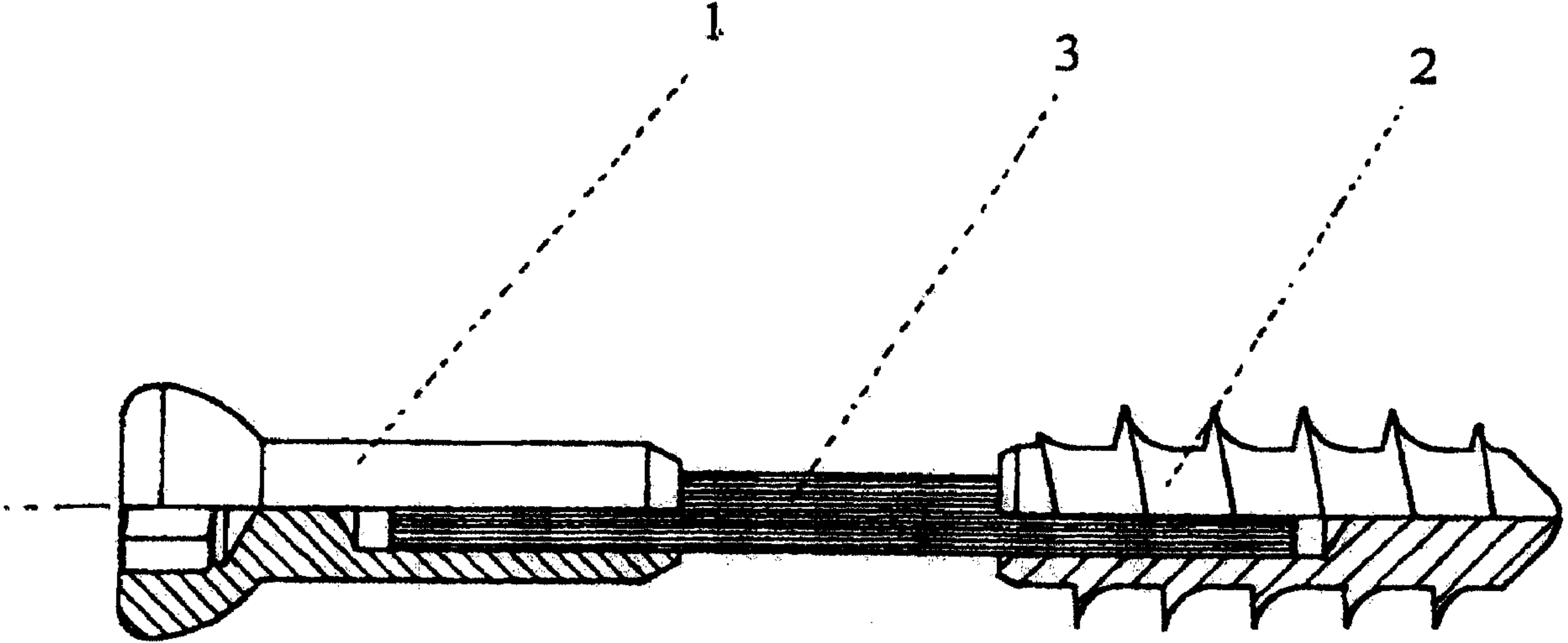


Fig. 13


1
3
2