Final Diploma

Patent Examination Board

FD4 Infringement and Validity

Tuesday 17 October 2023

10:00 to 15:30 UK British Summer Time (GMT + 1 hour)

Examination time: 5 hours 30 minutes plus 10 minutes upload time

The 5 hours 30 minutes is allocated as follows:

10 minutes – Downloading and printing the question paper;
5 hours – Answering the questions;
20 minutes – Four screen breaks of 5 minutes each.

At 15.30 you MUST immediately stop answering the questions. You then have **10 minutes** in which to upload your Answer document to the PEBX system.

You MUST upload your Answer document to the PEBX system by 15.40. After 15.40 you will not be able to upload it and your examination will be void.

INSTRUCTIONS TO CANDIDATES

1. The whole assessment task is to be attempted.
2. The total number of marks available for this paper is 100.
3. You must use the Answer document for your answers.
4. Do not attempt to change the font style, font size, font colour, line spacing or any other pre-set formatting.
5. Start each part of your answer on a new page. Press the control key and the enter key simultaneously to begin a new page.
6. Do not state your name anywhere in the answers.
7. This question paper consists of **19 sheets**, including this sheet, and comprises:
   Assessment task (1 sheet)
   Client letter (1 sheet)
   Document A GB2333000 (10 sheets including four pages of drawings)
   Document B Accu-Stitch™ suturing device (3 sheets)
   Document C JP 2012-918273 (2 sheets including one page of drawings)
   A spare set of Claims (Document A) to use in your answer if you wish (1 sheet).

AT THE END OF THE EXAMINATION

8. Save your Answer document to your hard drive and follow the instructions for uploading your document onto the PEBX system.

Assessment task

Your client sends you the letter and documents listed on Instructions to Candidates.

Your task is to prepare advice to your client on whether the attached granted patent may be enforced and defended.

You should prepare notes on which you would base your advice in which you:

a) Provide an opinion on infringement and validity, in the UK only.

b) Identify other patent-related legal issues pertinent to the facts presented.

c) Outline possible actions that may be taken to strengthen your client's legal position.

d) Summarise the opinions formed in a) to c) above.

Note the following:

a) You should accept the facts given to you and base your answer on those facts.

b) You should not make use of any other special knowledge that you may have of the subject matter concerned.

Allocation of marks

Construction: 24 marks
Infringement: 18 marks
Novelty: 24 marks
Inventive Step: 22 marks
Sufficiency: 1 mark
Amendment: 1 mark
Advice: 10 marks
Total: 100 marks

Client letter

Dear Attorney

My recently-formed business, Stitch-Up Limited, is a new spin-out from the University of Hard Knocks (UHK) and has been set up to exploit my expertise and know-how in surgical devices, especially in the field of stitching (suturing) wounds after injury or surgery.

I have designed a new device (described in Document B) that allows a surgeon to suture a wound or incision at whatever location within the wound the surgeon desires.

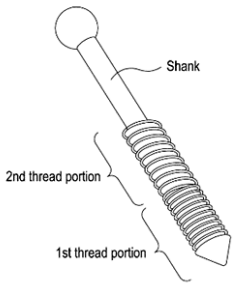
We have recently begun our first funding round to raise money from investors to allow us to bring this device to the market. To date we have only performed experiments to confirm that the proposed technique will work.

I mentioned my device last week at a medical conference to Professor Leggitt from the College of Life. He became angry and went to inform the conference organiser that I was infringing his patent and asked to have me removed. I was shocked because, as far as I knew, Leggitt had turned his attention from surgery to industrial devices a good few years ago.

This allegation could have a negative effect on potential investors. I have discussed this matter with UHK's technology transfer office, and they have uncovered Leggitt's patent (Document A). The patent seems to concentrate on ground pegs. I understand Leggitt is a major shareholder in a very successful business selling these devices.

Having read Leggitt's patent I can see some problems, especially with the last claim, which seems to be what I want to do. However, I do not see what is so special about asymmetric threads.

Femur or thigh bone screws used to lock plates to the bone after a break having different thread portions on the shank have been well known for many years (see drawing).



However, my device is better than his because of my needles' unique shape and the fact that the needles are only driven in one direction which leads to less trauma.

Please can you review this patent and send me a memorandum of your conclusions and any other points I should note. I need to have as robust a position as possible to take to my potential investors. I need to confirm:

- that we can make and sell my device for use in suturing;
- that we can make and sell my device for ground peg use;
- what we can do about Leggitt's allegations that we infringe his patent; and
- any actions we can take to improve our position.

The UHK technology transfer team also uncovered a published Japanese patent document JP 2012-918273 which they said you might be able to use (partial translation Document C).

Yours sincerely

Dr. Bryana Odgett

Granted British Patent GB2333000

(Filed 15 June 2021, Granted 08 March 2023)

Pegs

This invention relates to anchoring pegs, and in particular to anchors which are useful as ground pegs.

Typically ground pegs are used to support items like telegraph poles. Ground pegs are tubular with a ground-penetrating head end and an opposite end which is tethered to the item. Once the ground peg is in the ground, a side bar is driven along the tube by hammering until it encounters a deflecting surface which forces the side bar to bend and emerge from the tube sideways through a hole in the tube wall or in the ground-penetrating head.

Because the side bar resists bending, the bar tends to pass through the tube close to the wall adjacent to the hole and emerge from the hole at an angle which is close to tangential to the outer wall of the tube. The projecting side bar has a relatively large radius of curvature and the part of the side bar near the tube, being almost parallel to the tube, is relatively ineffective in resisting pulling forces tending to uproot the ground peg.

Tethers or cables are typically attached to a collar located at the opposite end of the ground peg which protrudes out of the ground in use. This enables the operator to install the ground peg and then attach the cable to the pole or other article to be anchored. Many ground pegs fail because over time the tension in the cable decreases. It has been proposed previously to secure the tether to the pole first and then using the side bar to drive the tether into the ground, so that tension is maintained, and anchoring is improved. Figure 1 shows a well-known earth anchor in which two linear side bars are bent as they exit the shaft on opposite sides.

This invention is intended to provide a peg in which the radius of curvature of the side bar as it is driven outwardly may be adjusted and the side bar may be caused to extend from the side of the tube at a relatively large angle from the outer tube wall, with a reduced radius of curvature.

The invention provides a peg in accordance with Claims 1 to 5.

Because the side bar is pre-bent it is possible to make the radius of curvature much smaller than in prior art devices. The ‘radius of curvature’ of the side bar may refer to a non-circular path.

An asymmetric thread encourages the side bar to adopt a reduced radius of curvature compared to a side bar with a symmetric thread (or indeed with no thread at all).

The bent end and asymmetric thread also act synergistically to make a peg suitable for use as a suturing device in the mammalian body, as is described below.

Examples of asymmetric threads include a thread where the thread pitch changes continuously along the length of the side bar, where there are distinct regions along the length in which the thread pitch is different, or where the thread is discontinuous over or along the length of the side bar.

The peg may have more than one side bar.

In an embodiment the side bar has a flexible line, wire, or cable. The side bar can be long enough that it is able to bend out of the substrate in which the peg is located so that the wire protrudes from the substrate. Where there are two side bars, each may have a line, cable, or wire, and these can be visually differentiated (e.g. different colours).

The invention also provides a method in accordance with Claim 6.

Whilst the method can be used to further secure a peg at a site (by tethering it from two ends), we have found that it is also useful in medical applications and can be used to stitch or suture deep wounds or surgical incisions with improved healing time and outcomes.

Drawings

Figure 1 is a known ground peg.

Figure 2 is a cross section of a ground peg according to the invention.

Figure 3 shows a side bar used in the ground peg of Figure 2.

Figures 4 is a cross section of a further peg according to the invention.

Figures 5a to 5d show a sequence of a peg being deployed as a medical suturing device.

The ground peg of Figure 2 comprises a cylindrical tube 1 with an earth-penetrating pointed head 2 of cruciform cross section at one end. The tube 1 has a hole 3 and an inwardly extending flap 4 above the head 2, formed by cutting the wall of the tube 1 and bending the flap 4 inwardly. The flap 4 forms a deflecting surface within the tube 1 leading to the hole 3.

The side bar 5 is made of deformable rigid metal such as mild steel and has circular cross section with a pointed and bent head 6 which extends at an angle to the axis of the elongate shank of the side bar.

The side bar 5 is placed within the tube 1 as shown in Figure 2 with the bent head 6 within the tube 1, resting on the deflecting surface (flap 4) and pointing towards the hole 3. In this embodiment, the side bar 5 is shorter than that of the tube 1.

The bent head 6 of the side bar 5 has a screw thread S (Figure 3) on its outer surface. The pitch P (the distance between adjacent turns of the thread) of the screw thread S increases away from the bent end so that the pitch P1 at the bent head 6 is smaller than the pitch P2 along the shaft of the side bar 5.

A cylindrical sleeve 7 is located in the tube 1 surrounding the side bar 5. The lower inner edge of the sleeve 7 contacts the surface of the bent head 6 facing the hole 3, and the inner surface of the sleeve 7 at its upper part 10 contacts the surface of the straight part of the side bar 5 facing away from the hole 3.

The inner wall of the tube 1 has a raised bump 8 that engages the upper end of the sleeve 7 to resist upward movement of the sleeve 7.

In use, the head 2 and tube 1 are driven into the ground by hammering the upper end of the tube 1 until the hole 3 is below the ground surface by a desired distance. A ramrod (not shown) is then inserted in the open upper end of the tube 1 and hammered to drive the side bar 5 down the tube 1 and out through hole 3. During this operation the side bar 5 becomes curved as it is deflected towards the hole 3 by the surface 4 and extends outwardly from the hole in a curve of constant radius R, as shown in broken lines in Figure 2. When the side bar 5 has been extended in this manner below the ground surface, the ground peg can only be uprooted by digging or applying a very large pulling force to the upper end of the tube 1.

In this anchor, the radius of curvature of the extended side bar 5 is determined by the relative positions of the elements of the device bearing on the side bar 5 as it is extended: the deflecting surface 4 and the lower edge 9 and inner surface of the sleeve 7.

The presence of the screw thread S decreases the bend radius R as the side bar 5 emerges from the hole 3. We believe this to be related to the asymmetric nature of the screw thread because identical side bars with symmetrical threads (or no threads at all) do not exhibit the decreased bend radius seen with the anchors of the invention.

As the side bar 5 is extended through the hole 3, the reaction between the side bar 5 and the lower edge 9 of the sleeve 7 forces the sleeve 7 up in the tube 1. This would increase the radius

of curvature of the extending side bar 5 and is avoided by bump 8, which prevents the sleeve 7 from rising in the tube 1.

In embodiments other than ground pegs, the side bar 5 can have an optional cable T which extends either along the length of the side bar 5 or, preferably, through a bore extending along the body of the side bar 5. In the latter case a tip 6A (Figure 3) of the side bar 5 is removable to expose the end of the cable T so that it can be pulled through the bore.

When the side bar 5 has been driven to its fullest extent, it may protrude from the substrate in which the peg is inserted. When the side bar 5 does so, the tip 6A can be removed and the cable T drawn through the side 5 and tethered to another article.

Figure 4 shows a second embodiment of a peg 50 of the invention. The peg 50 comprises an open-ended tube 51 with a penetrating head 52 secured at its lower end. The penetrating head 52 includes an integral plug 53 located within the tube 51 which defines a pair of deflecting surfaces 54 adjacent to opposed holes 55 in the wall of the tube 51. A pair of flexible side bars 56 are located in the tube 51. The side bars 56 are curved and have pointed penetrating ends 57 so that when they are driven downwardly, they are forced out through respective holes 55. A pin 58 extends across the tube 51 above the deflecting surfaces 54 so that it lies between the side bars 56 and bears on the surfaces of both side bars 56 so that the end of each side bar 56 is bent between the pin and a respective deflecting surface 54.

Each side bar 56 has an asymmetric thread S1, S2 at its pointed end and a thread of suture material T1, T2 respectively (as is seen in Figure 5) extending along a bore formed through the centre of each side bar 56.

Figures 5a to 5d show the device of Figure 4 in use in a wound W. Firstly, the device 50 is located within a wound W to the appropriate depth (Figure 5a). The head 52 is shaped to allow the device 50 to be inserted into the wound W. Typically, the head 52 will be pointed but other shapes are possible. The ends of the side bars 56 are engaged by a driving tool (not shown) and are driven downwardly and out of the holes 55 in the tube 51. As the side bars 56 (561 and 562 in Figures 5b and 5c) penetrate the facing walls of the wound W, the asymmetric threads S1, S2 cause the side bars 561, 562 to bend along a tight radius of curvature in the direction of the arrows A. Continued forcing of the side bars 561, 562 causes them to protrude from the skin adjacent to the wound W (Figure 5b). The threads of suture material T1, T2 are pulled through the side bars 561, 562 and the side bars 561, 562 are withdrawn into the tube 51 (Figure 4) in

the direction of the arrows B (Figure 5c) by pulling on the driving tool (not shown). Once the side bars 561, 562 are within the tube 51, the device 50 can be removed from the wound W leaving the threads T1, T2 in place (Figure 5d).

The process can be repeated at different locations within the wound W, for example at different depths.

The threads are different colours. For example, thread T1 may be blue and thread T2 may be yellow. The end of thread T1 extending from the wound W is secured to the end of thread T2 extending through the skin and vice versa. The different coloured threads T1, T2 help to identify which thread should be attached to which other thread. In this way the facing surfaces of the wound are brought into intimate contact. We have found that wounds which have been sutured in this fashion heal faster and with less scarring.

Claims

1. A peg, comprising:

   a body portion having a tubular shaft connected to a penetrating head; and

   a side bar having a driving end, a shank, and a head end, the head end extending at an angle to the shank;

   wherein the side bar is located within the tubular shaft;

   so that when the driving end is forced along the tubular shaft, the head end is forced from the shaft in a tightly curved path.

2. A peg according to Claim 1, wherein the side bar carries a flexible cable.

3. A peg according to Claim 1, comprising a pair of side bars.

4. A peg according to Claim 1 or 2, wherein the end of the side bar is provided with an asymmetric screw thread.

5. A peg according to Claim 4, wherein the asymmetric thread has a thread pitch which increases along each of the side bars.

6. A method of securing a flexible wire, comprising:

   locating a peg in a cavity formed in a substrate, the peg comprising a side bar having an asymmetric screw and carrying a flexible thread;

   forcing the side bar along a hollow shaft of the peg so that it extends from the tubular shaft of the peg along a curved path and out of the substrate to expose an end of the flexible thread.

1/4

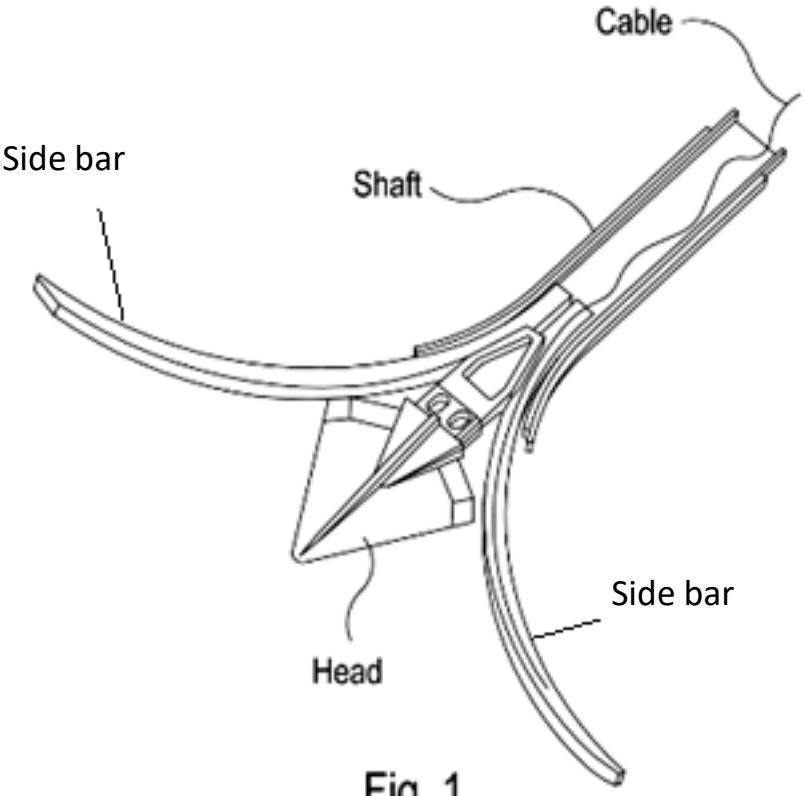


Fig. 1

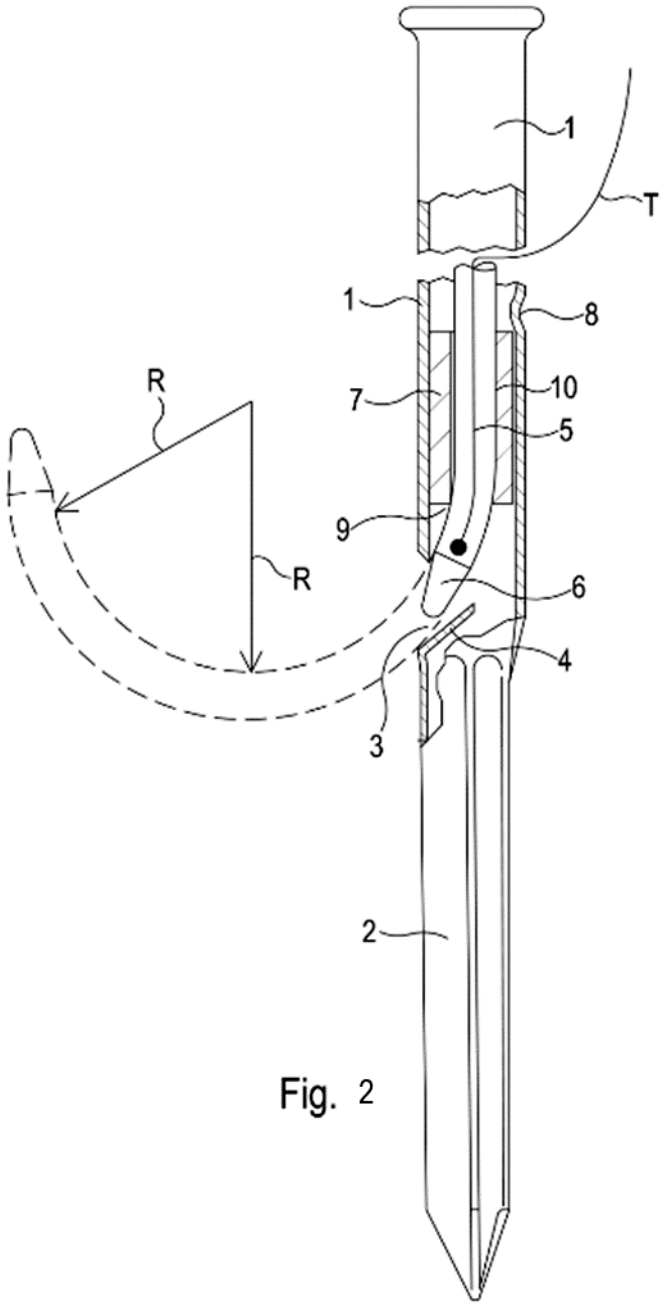


Fig. 2

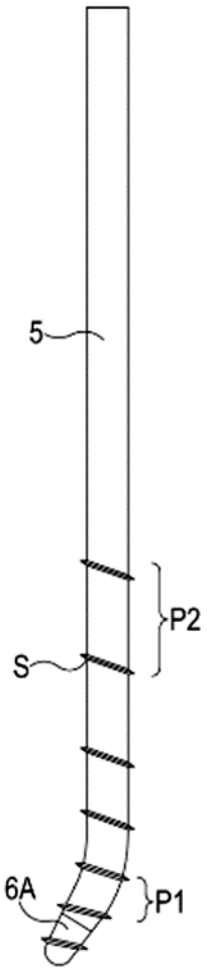


Fig. 3

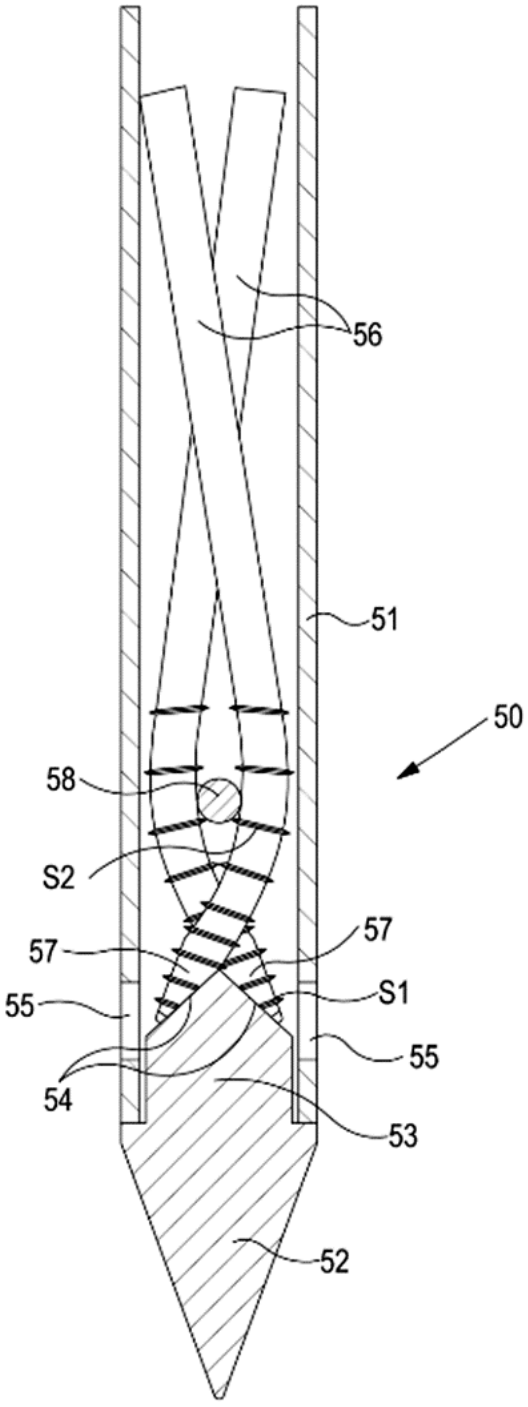


Fig. 4

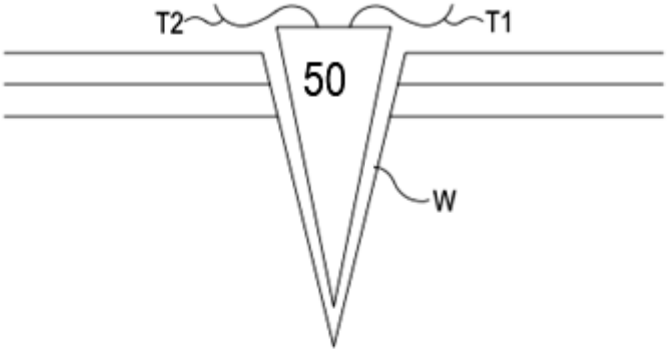


Fig. 5a

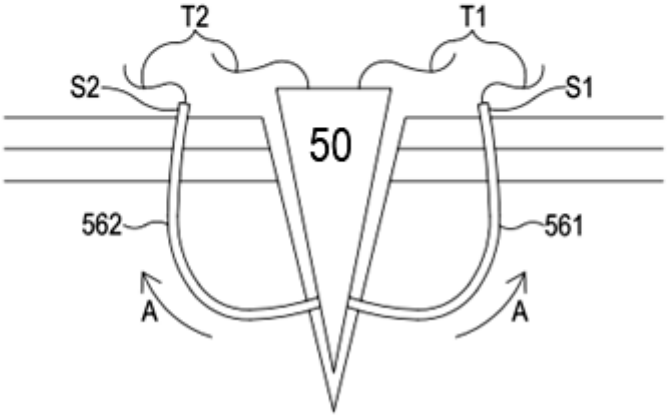


Fig. 5b

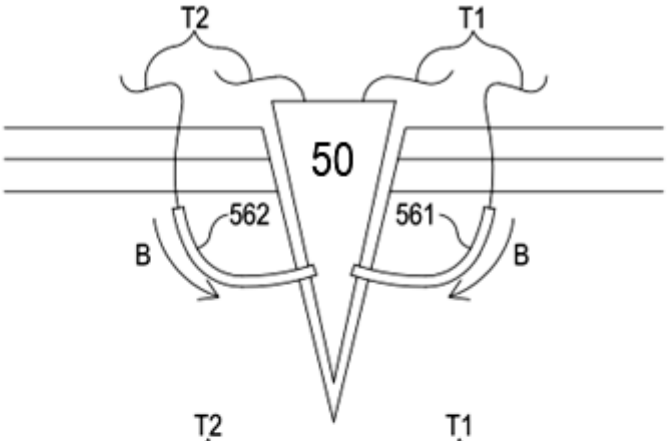


Fig. 5c

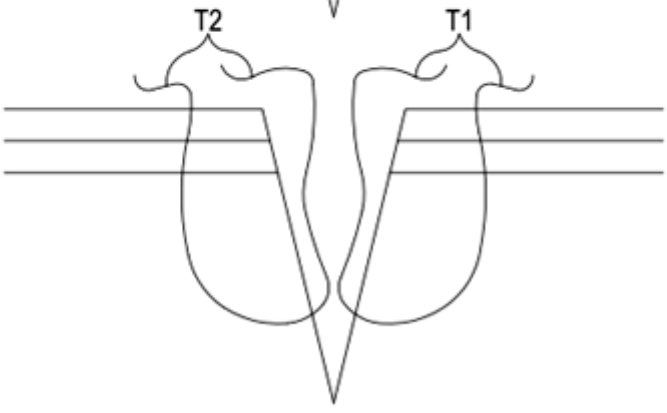


Fig. 5d

Document B: Accu-Stitch™ suturing device

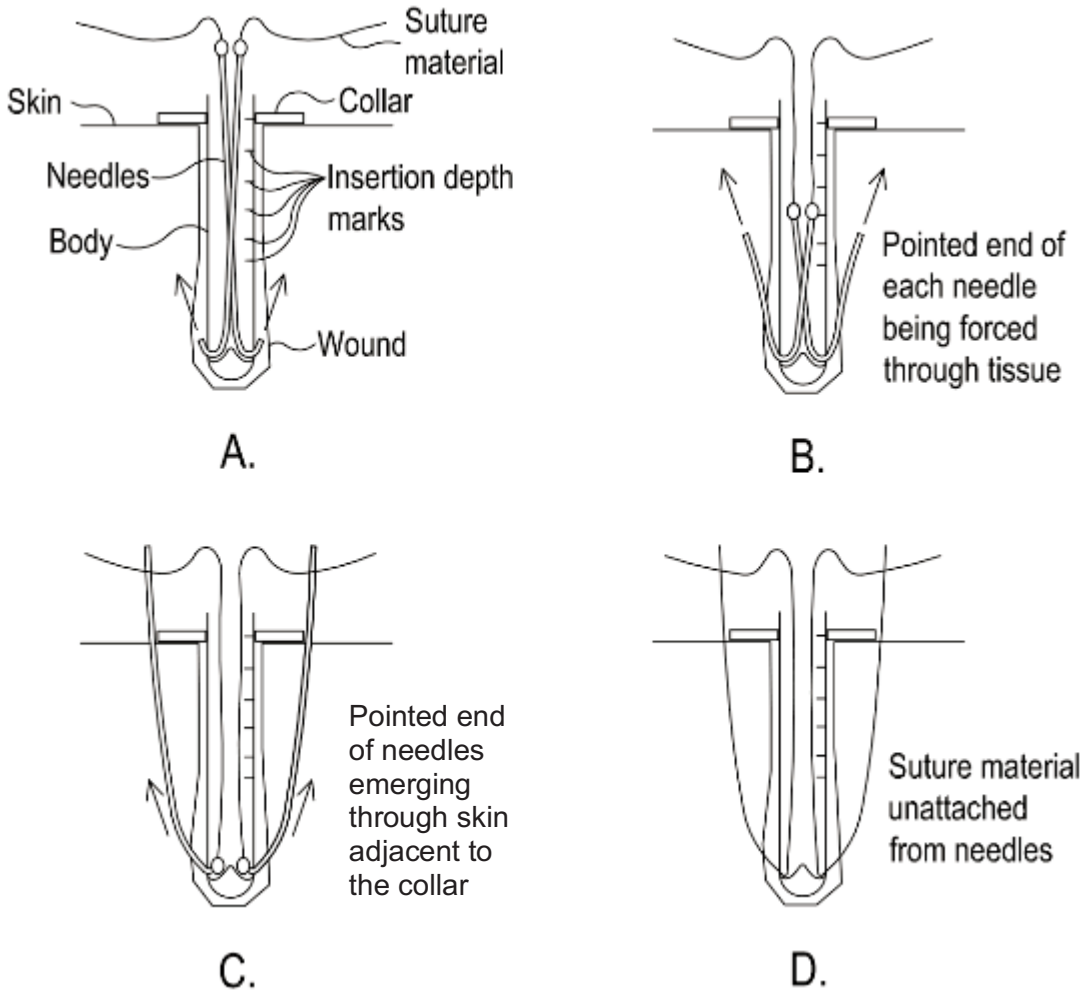
Excerpt from Stitch-Up Limited's Prospectus for Investors

Highly Confidential – Release August 16th 2023

Accu-Stitch™ suturing device

Deep cavity wounds require suturing or stitching at various positions within the wound to ensure that the facing parts of the wound are brought into accurate alignment. In this way the wound heals faster and more robustly. However, this can often be a challenge for surgeons, especially at the end of a long surgical process. The Accu-Stitch helps to solve this problem.

The following drawings illustrate the Accu-Stitch in use.



The Accu-Stitch has an elongate body with a rounded leading end and an open trailing end. The body includes insertion depth marks and a slidable collar to limit the depth of insertion.

A pair of flexible plastic needles are located within the body. The needles have a pointed first end and have medical suture material attached to the opposite end.

A diverting surface is mounted at the base of the body which encourages the needles to bend upwardly. In the 'as supplied' condition shown in Figure A, the pointed end of each needle protrudes slightly from the body through an aperture and is angled away from the base. The protrusion of the pointed end helps to secure the body in situ and ensures that each needle quickly and effectively penetrates the wound wall in use.

As each needle is forced along the body, the diverting surface encourages the needle to take the path through the wound shown in Figure B.

Continued driving of the needles along the length of the body causes the needles to protrude from the skin of the patient. The material of the needle, coupled with the shape of the diverting surface, ensures that the needle adopts a known path through the patient's tissue and appears adjacent to the collar. This will happen on both sides of the wound simultaneously by driving both needles at the same time.

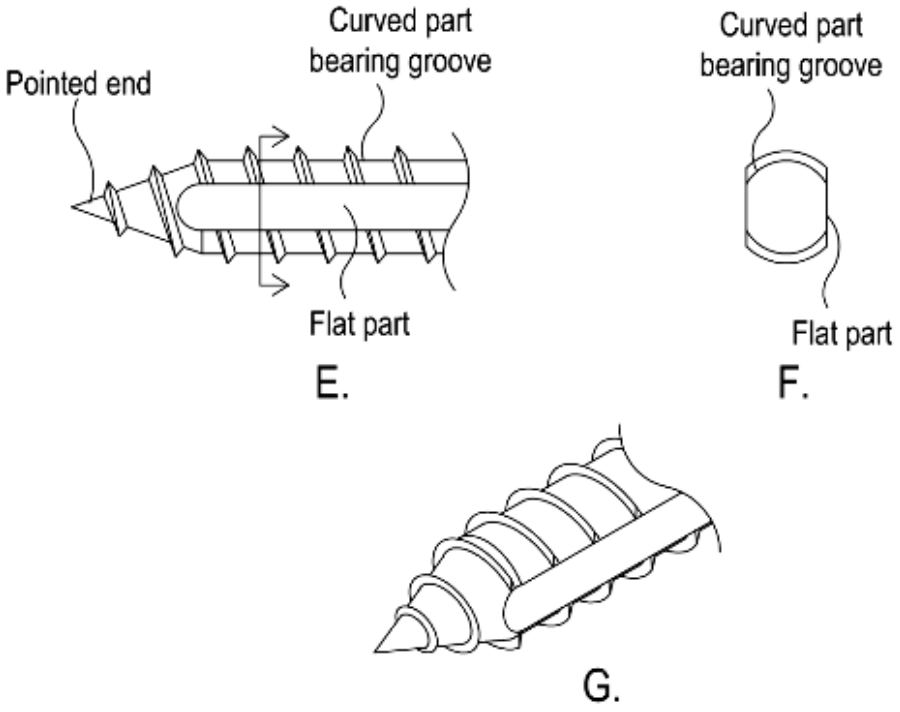
Once a needle has emerged it may be grasped by a grasping tool (not shown) and pulled to free it from the patient's tissue, thereby dragging the suture material through the wound and along the path traversed by the needle. The needles can then be detached from the suture material leaving the suture material extending through the wound and the tissue adjacent to the wound.

The collar can then be indexed to the next insertion depth mark and two new needles inserted into the device and the process repeated at a different depth within the wound.

Although it is possible to secure the sutures as soon as they have been inserted, it is preferred to wait to secure the sutures until all of the required sutures have been located within the wound. To ensure attachment of each thread to its correct suture pair, the threads can have different thicknesses or they can be colour coded. For example, the deepest threads are the thinnest and/or may be coloured black and white, the shallowest threads are thickest and/or may be coloured blue or green.

One of the most important features of the needles is that they are not circular in cross section, but have the form shown below:

Document B: Accu-Stitch™ suturing device



The needles are relatively thin (about 1mm gauge) and flexible, but strong. Because the needles are not circular in cross section, we have found that they travel through tissue with less resistance. Also, the presence of the grooves (which are in helical form around the curved parts) allows communication of fluids from one side of the needle to another, which further eases insertion.

Partial Translation of JP 2012-918273 published 24 April 2012

[Introduction section omitted]

Fig. 1 is a perspective view of a device according to the invention.

Fig. 2 is a cross-sectional view along the line *II–II* of Fig. 1.

Fig. 3 is an end view of the device of Fig. 1.

The Figures represent a stake 2 for anchoring an object to the ground.

The stake 2 comprises a metal tube 3. Rods 4 are engaged in this tube 3 which open out at the end 2a of the stake 2 and are intended to be engaged in the ground.

The tube 3 has a tubular portion 3a. A collar 5 is provided in the end 2b of the stake 2 that is not intended to be engaged in the ground for attachment of a cable (not shown).

The tube 3 also has a flattened end portion 3b comprising a central wall 6 bordered by two lateral ribs 7. The portion 3b terminates in a penetrating tip 8. As shown in the figures, the wall 6 is disposed substantially on the centre line of the tubular portion 3a.

Diametrically opposed holes 9 are provided in the walls 10 transitioning between the portions 3a and 3b for the sliding of the rods 4. An opening 11 is provided in the wall 6, distant from holes 9.

The wall 6 also comprises two grooves 12 extending on each of its faces from the edge of the opening 11 in the direction of the end 2a. The grooves 12 are disposed on either side of the central axis of the stake 2, as shown in Fig. 3.

The rods 4 are for the most part straight and have a curved end 4a. They are engaged in the stake 2 through the holes 9 and through the opening 11 in which they intersect, their curved ends 4a coming to bear against the surface of the wall 6 delimiting the opening 11 in the lower part.

In practice, the stake 2 is first pressed into the ground. The two ribs 7 support the wall 6 from buckling.

Once the adequate depth has been reached, the rods 4 are pushed axially into the ground by means of a forcing tool (not shown) located in the end 2b of the stake 2. As the forcing tool is driven along the stake 2, it forces the rods 4 along the stake. The rods 4 then come to bear against the surface of the wall 6 which delimits the opening 11 in the lower part and deform against it. The diametrically opposite position of the holes 9 causes each hole 9 to be offset laterally with respect to the part of the opening 11 in which the bent end 4a of the rod 4 which passes through it is engaged, as clearly shown in Fig. 2. The rods 4 are thus positioned slightly obliquely with respect to the axis of the tube 3 when their ends 4a are engaged in the opening 11 and deform in a more or less helical trajectory, shown in chain-dotted lines in Fig. 1. This allows the rods 4 to occupy, after deformation, a large area. The shape of the rods 4 ensures a secure anchorage.

[Claims omitted]

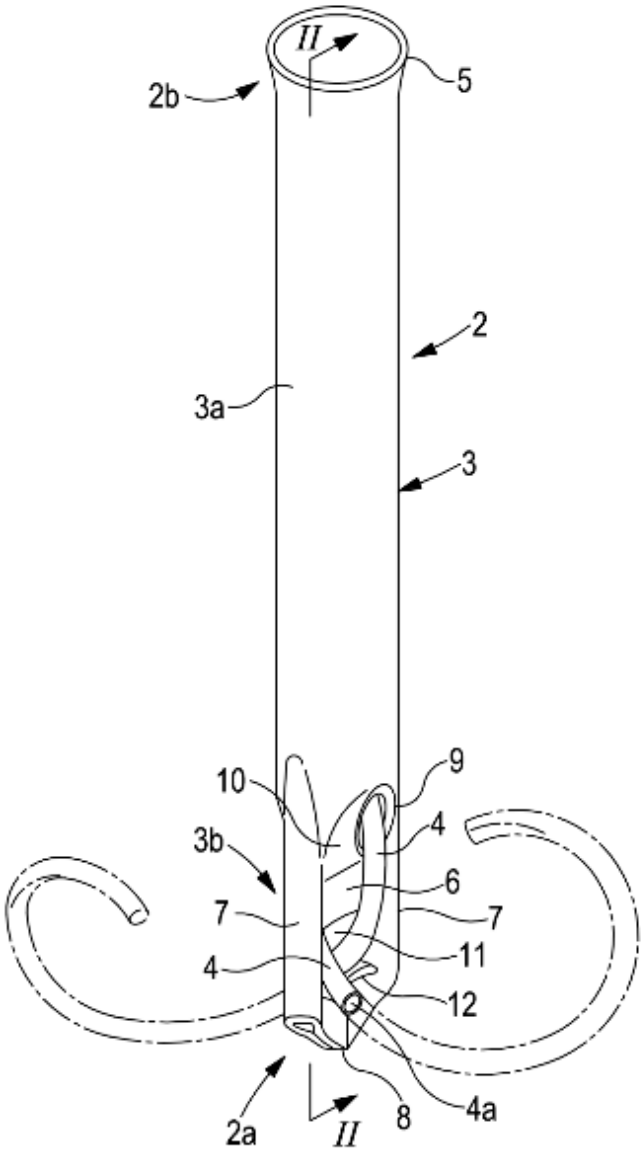


Fig. 1

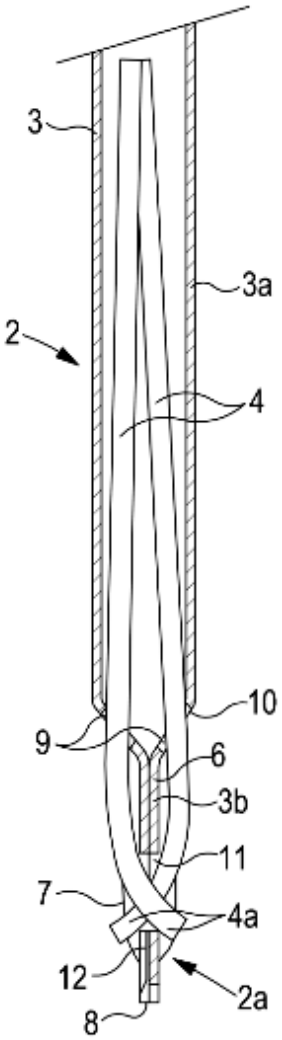


Fig. 2

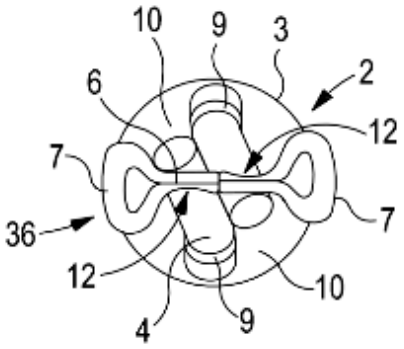


Fig. 3

Spare set of Claims

Claims

1. A peg, comprising:

   a body portion having a tubular shaft connected to a penetrating head; and

   a side bar having a driving end, a shank, and a head end, the head end extending at an angle to the shank;

   wherein the side bar is located within the tubular shaft;

   so that when the driving end is forced along the tubular shaft, the head end is forced from the shaft in a tightly curved path.

2. A peg according to Claim 1, wherein the side bar carries a flexible cable.

3. A peg according to Claim 1, comprising a pair of side bars.

4. A peg according to Claim 1 or 2, wherein the end of the side bar is provided with an asymmetric screw thread.

5. A peg according to Claim 4, wherein the asymmetric thread has a thread pitch which increases along each of the side bars.

6. A method of securing a flexible wire, comprising:

   locating a peg in a cavity formed in a substrate, the peg comprising a side bar having an asymmetric screw and carrying a flexible thread;

   forcing the side bar along a hollow shaft of the peg so that it extends from the tubular shaft of the peg along a curved path and out of the substrate to expose an end of the flexible thread.