(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 August 2007 (02.08.2007)

PCT

(10) International Publication Number
WO 2007/085819 A1

(51) International Patent Classification:
A61B 17/04 (2006.01) *A61M 25/04* (2006.01)
A61B 17/06 (2006.01) *A61M 25/02* (2006.01)
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/GB2007/000233

(22) International Filing Date: 24 January 2007 (24.01.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0601504.4 25 January 2006 (25.01.2006) GB

(71) Applicant *(for all designated States except US)*: **VINCTUM LIMITED** [GB/GB]; 24 Beaulands Close, Cambridge CB4 1JA (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **FERGUSON, Jonathan, Irvine** [GB/GB]; 24 Beaulands Close, Cambridge CB4 1JA (GB). **BLACK, John, Joseph, Merrington** [GB/GB]; Greenville, Middle Road, Stanton St John, Oxford OX33 1EX (GB).

(74) Agent: **BUTLER, Michael, John**; Frank B. Dehn & Co., St Bride's House, 10 Salisbury Square, London EC4Y 8JD (GB).

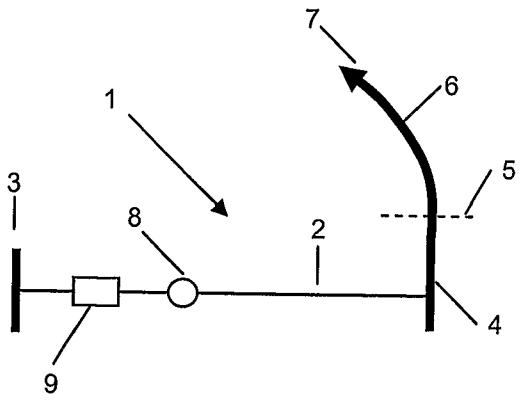
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SUTURE DEVICE



(57) Abstract: A device (1) for attachment to the tissue (11) of a patient and to a surgical implement (12) passing through the tissue, so as to secure the implement with respect to the tissue. The device comprises a longitudinally extending portion (2) of flexible suture material attached to a substantially rigid elongate terminating element (3, 4), the point of attachment of the suture material to the terminating element being in a region which is located generally centrally between the ends of the terminating element, so that in use the terminating element and the suture material can have a generally "T" shaped configuration. A tissue piercing component (6, 18) is removably attached to the terminating element (4), and may be an extension of the element (4) or may be attached to a primary loop (15) of the suture material by a secondary loop (17).

WO 2007/085819 A1

SUTURE DEVICE

This invention relates to a suture system for use in closing wounds or, for example, for securing surgical drains to human or animal patients.

Surgical drains are used in medicine for the drainage of fluid from a patient. For example, to treat potentially dangerous conditions of the lung, a prime consideration is the removal of excess fluids (liquids such as water and blood, and gases such as air) from the pleural cavity between a lung and the surrounding rib cage. Circumstances which create these dangerous conditions include any introduction of fluid into the pleural cavity. Such drains need to be secured to the tissue of the patient, and traditionally this has been done by means of sutures, with or without the use of surgical tape. The drains may be placed through surgical incisions or percutaneously with a needle.

A problem is that drains fastened in a conventional manner may easily fall out, meaning that considerable care has to be taken. Replacing a drain can be both uncomfortable and dangerous. When using sutures, drains should only be secured by people sufficiently well trained and experienced in knot tying, and in general these skills are limited to surgeons and anaesthetists. The process of securing a drain can be time consuming and can inhibit the doctor from performing other tasks. In practice, many drains are inserted by junior medical staff, paramedics and so forth and there is therefore a need for a system for securing a drain which will make it easier and quicker to provide effective securing of the drain, particularly by those without the knot tying skills of an experienced surgeon.

Similar problems arise in relation to wound closing in general, where people who are inexperienced may have difficulties with knot tying using conventional suture systems.

Viewed from one aspect of the present invention, there is provided a suture device comprising a longitudinally extending portion of flexible suture material attached to a

central region of a laterally extending, substantially rigid terminating element, the device also comprising a tissue piercing component which is removably attached to the terminating element.

The tissue piercing component, which in isolation may be similar in general terms to a conventional needle used in applying stitches to a patient, may be attached directly to the terminating element and separable therefrom. In a preferred embodiment of the invention, the tissue piercing component is attached indirectly to the terminating element by virtue of being removably attached to the suture material.

Depending on the manner of use, the terminating element will either assist in securing the suture material to the tissue of the patient when a wound is being closed or a surgical implement such as a drain attached to the patient, or will assist in securing the suture to such a surgical implement. In any event, in some modes of use the provision of the terminating element facilitates manipulation of the suture.

In a preferred embodiment, the terminating element is in the form of an elongate element so that so that in use the terminating element and the suture material can have a generally "T" shaped configuration with the terminating element forming the arms of the "T". The point of attachment of the suture material to the terminating element need not be exactly centrally. Whilst in general in an arrangement using an elongate element will have the arms of the "T" of substantially equal lengths, it is possible to have an asymmetrical arrangement. How short one of the arms may be will depend on the application. In general, each arm should be long enough so that if it engages the tissue of a patient through which the attached suture passes, the terminating element will reliably prevent passage of the end of the suture through the tissue and will lie flat on the surface of the tissue rather than tend to cut into it. For example, a terminating element of between about 10 mm and 25 mm in length, with arms of between 5 mm and 12.5 mm and preferably of equal length, would be appropriate in some applications.

It should be noted that in some preferred embodiments of the invention embodiments of the invention the terminating element does not engage the tissue of the patient

In general, an elongate terminating element will be straight, although a curved configuration or even a zigzag configuration, may be possible.

There are a number of preferred configurations of apparatus, depending on the preferred mod of application. In some embodiments, the tissue piercing component is attached directly to the terminating element, as an extension of one of its ends. Where the terminating element is attached directly to the tissue piercing element, it will be necessary for it to pass through the tissue of the patient, and in such case an elongate terminating element will generally be used. If the terminating element is straight, the tissue piercing component does not have to be also and may be curved as well as straight, a curved configuration being preferred for many applications. In such arrangements where the tissue piercing component is attached directly to the terminating element, it can be used to pull the terminating element through the tissue of a patient, to provide suture extending from one point on the surface of the tissue, through the tissue, and then to the terminating element on the surface at another point.

Where the terminating element is attached indirectly to the tissue piercing element, in general it will not be passed through the tissue of the patient and thus other configurations are possible, such as a flat terminating disc, rectangle or other shape, a terminating bead , a ring to put a finger through to assist manipulation, and so forth.

In a number of uses of a device in accordance with the invention, the terminating element will not contact the tissue of the patent but is used principally for manipulation purposes. In other uses, the terminating element will prevent the suture being pulled all of the way through or will help to retain other components on the suture.

The suture material may be in the form of a loop, so that once the suture material has been passed through the tissue of the patient, part of the loop can be passed over the terminating element (or the terminating element can be passed through part of the loop) and the suture tightened, so as the attach the suture firmly to the tissue. In another arrangement, the suture is a single strand and its free end terminates in a suitable element to prevent it passing through the tissue. This could be a second terminating element of any of the types referred to above, or could be a sliding bead and a sliding

fastener such as a clip or a crimpable collar to hold it in place when secured with respect to the suture material, with an end piece of a suitable type. In some embodiments there is a bead and fastener arrangement and an elongate terminating element of the type described above. In such embodiments, the bead can be slid so as to engage the tissue, the terminating element used to pull the suture tight, and the fastener, such as a collar, moved to engage the bead and then fastened in position with respect to the suture to hold the bead in place. In, general, in place of a bead and collar there can be another tissue engaging component mounted slidably on the suture and fastening means to retain the tissue engaging component in position. In some embodiments the features of tissue engaging and fastening could be combined in a single component, for example having a tissue engaging portion and a fastening portion. It is desirable that an action such as crimping fastening means does not damage the tissue of the patient accidentally.

Where the tissue piercing component is connected directly to the terminating element, as an elongate extension from one end, this may be achieved by the use of a readily frangible portion so that the tissue piercing component can be snapped off of the terminating element once it has been pulled through the tissue. The frangible portion may be defined by a region of reduced diameter such as a notch or groove.

Where the terminating element is to pass through the tissue of a patient, with the suture material attached to a mid point of the terminating element, preferably the arrangement is such that the suture material is contained within a groove in the terminating element extending from the point of connection to the free end (i.e. that remote from the tissue piercing component). This reduces the drag caused by the suture as the tissue piercing component, and terminating element, pass through the tissue.

In a preferred arrangement, the tissue piercing component is attached indirectly to the terminating element by virtue of being attached to end of the suture material remote from its attachment to the terminating element. In a preferred embodiment of this arrangement, the suture material attached directly to the terminating element is in the form of a first loop, and a second loop, preferably also of suture material, is attached to an end of the tissue piercing component and interlocks with the first loop. When the tissue piercing component passes through the tissue of a patient, it pulls both loops

through. The second loop passes completely through, with part of the first loop. At this point, the second loop is cut, so that the needle and the remnant of the second loop can be discarded. There is then a loop of suture material passing through the tissue, with a terminating element at one end. A sliding tissue engaging component may be provided on the loop of suture material, the arrangement being such that this may be slid into contact with the tissue, with the appropriate tension in the suture material, and then held in place. This may be achieved by having a bead as the tissue engaging component and for example a crimpable collar to hold it in place.

In use to secure a drain, means are provided to attach the suture material to a drain. This could be in the form of an adjustable diameter clamping element , such as a "cable tie", which can be used to clamp the suture to the drain, passing round the suture material and the drain. If the suture material is in the form of a loop, the clamping element may pass through the loop. In some embodiments, additional security is provided by providing an eyelet attached to the drain, through which the suture material passes.

More than one device in accordance with the invention may be used, to provide additional security when securing a drain or other surgical implement.

It will be appreciated that in preferred embodiments of the invention incorporating the above features, an advantage is that once the tissue piercing component has been removed there is not simply left a free end of a strand of suture material for the user to manipulate. Either there is left an elongate terminating element, from which the tissue piercing component has been detached, or there is left a loop of suture material. In either case, it is easier to manipulate the suture material.

Viewed from a further aspect the invention provides a device for attachment to the tissue of a patient and to a surgical implement passing through the tissue, so as to secure the implement with respect to the tissue, the device comprising a longitudinally extending strand of flexible suture material attached at one end to first terminating means in the form of a substantially rigid elongate terminating element, the point of attachment of the suture material to the terminating element being in a region which is located generally centrally between the ends of the terminating element, so that in use

the terminating element and the suture material can have a generally "T" shaped configuration; the device also comprising a tissue piercing component which is attached directly to the terminating element, as an extension of one of its ends, by a frangible portion so that in use the tissue piercing component can be detached from the terminating element after the tissue piercing component and the terminating element have passed through the tissue; and there further being second terminating means for the other end of the strand of suture material, of substantially greater cross section that the strand.

Viewed from a further aspect, the invention provides a device for attachment to the tissue of a patient and to a surgical implement passing through the tissue, so as to secure the implement with respect to the tissue, the device comprising a loop of flexible suture material attached to a substantially rigid elongate terminating element, the point of attachment of the suture material to the terminating element being in a region which is located generally centrally between the ends of the terminating element, so that in use the terminating element and the suture material can have a generally "T" shaped configuration; the device also comprising a tissue piercing component which is attached directly to the terminating element, as an extension of one of its ends, by a frangible portion so that in use the tissue piercing component can be detached from the terminating element after the tissue piercing component and the terminating element have passed through the tissue.

Viewed from a further aspect, the invention provides a device for attachment to the tissue of a patient and to a surgical implement passing through the tissue, so as to secure the implement with respect to the tissue, the device comprising a first loop of flexible suture material attached to a substantially rigid terminating element, the point of attachment of the first loop of suture material to the terminating element being in a region which is located generally centrally of the terminating element; the device also comprising a tissue piercing component which is attached to a second loop of material which is interlocked with the first loop and can be cut to separate the tissue piercing component from the first loop.

In an arrangement, such as the foregoing, in which removal of the tissue piercing component leaves a loop of suture passing through the tissue , with a free loop portion at one end and a terminating element at the other end, the free loop portion may be attached to the drains by suitable means. In such an arrangement, it is possible for the terminating element to bear against the tissue of the patient when the arrangement is tightened. However, as noted above, it is possible for there to be additional means on the suture loop, such as a fastener and a bead to engage the tissue, the terminating element serving to assist manipulation whilst using the bead and fastener.

As noted earlier, in such an arrangement using primary and secondary loops it is not necessary for the terminating element to be an elongate bar or the like, and it could be in the form of, for example, a flat disc or a bead since it does not have to pass through the tissue. The desirable features of the terminating element in such circumstances are that it will assist in manipulation and that when used ij the context of securing a drain or other implement, it may assist in preventing the suture material slipping through means, such as a cable tie, securing it to the implement.

Thus, viewed from a further aspect, the invention provides a suture device comprising a first loop of flexible suture material attached to a terminating element; the device also comprising a tissue piercing component which is attached to a second loop of material which is interlocked with the first loop and can be cut to separate the tissue piercing component from the first loop.

Such a device, and devices in accordance with other aspects of the invention, may also be used in other contexts, rather than just closing wounds or attaching a surgical drain to a patient, and the invention extends to a device suitable for those purposes additionally or alternatively.

There will also be other embodiments of the invention disclosed in which at least some of the advantages can be obtained with an alternative terminating element that is not necessarily a rigid elongate element and may not form a T shape with the suture material. The invention extends to these constructions also.

According to another aspect of the invention there is provided apparatus comprising a device in accordance with any of the above aspects, together with means for attaching the device to a surgical implement. The invention also extends to a surgical implement, such as a drain, supplied together with such apparatus.

The invention further extends to a procedure for attaching a surgical implement, and in particular a surgical drain, to a patient comprising inserting the implement into the patient, passing the tissue piercing component of a device in accordance with any of the above aspects of the invention through the tissue of the patient, securing the suture material to the tissue of the patient, separating the tissue piercing component from the remainder of the device, and attaching the remainder of the device to the surgical implement.

Another aspect of the present disclosure concerns a novel use of a thoracostomy port. A known port, typically used for the introduction of endoscopic instruments, is the Thoracoport (TM) manufactured by United States Surgical. It is a single use trocar which consists of a blunt-tipped obturator and a threaded port with a resilient shroud or seal at its proximal end to protect against foreign materials entering the chest cavity, and for instrument stabilization. Once inserted into a free space in the chest cavity, through an incision, the threaded port is turned clockwise until securely seated in the tissue. The obturator can be removed and an endoscope can be inserted. The threaded port will grip tissue to reduce slippage during instrument manipulation.

In accordance with this aspect of the invention, a surgical drain is inserted through the port, rather than an endoscope. In a preferred but optional arrangement, a device in accordance with any of the previous aspects is used to secure the drain with respect to the patient, and to facilitate this the port may be provided with at least one eyelet through which the suture material may pass. This provides security for both the drain and the port. Multiple devices may be used, with corresponding eyelets, to improve security.

Such a port facilitates pleural drain insertion., and is a more reliable alternative technique for achieving definitive pleural decompression.

In one embodiment of such a port, there is incorporated one way flap valve within the port, which extends its use in spontaneously ventilating patients and may obviate the need for an inter-costal drain.

The invention extends to novel port configurations as described above, and to the use of the port.

As a stand alone device for pleural decompression in positively ventilated patients, such an arrangement is more reliable than needle thoracocentesis (decompression) and there is less potential haemorrhage than with finger thoracostomy. The arrangement is quick, safe (as there are no sharp objects in the chest cavity, cheap, secure and requires little skill.

In a modification of this arrangement, additionally or alternatively to securing the port by means of a suture device as described above, an inflatable bladder is provided on the drain which is passed into the port, this bladder being inflated after insertion of the drain, so as to assist in retaining the drain in position.

Some embodiments of the invention will now be described by way of example only, and with reference to the accompanying diagrammatic drawings, in which:

Figure 1 is a first embodiment of a device in accordance with the invention;

Figure 2 is a detailed view of part of the device of Figure 1;

Figure 3 is a cross section through the part of Figure 2;

Figures 4a to 4c show the device of Figure 1 in use;

Figure 5 shows an alternative embodiment of a device in accordance with the invention;

Figures 6(a) to 6(c) show the use of the device of Figure 5;

Figure 7 shows a further embodiment of a device in accordance with the invention;

Figure 8 shows the device of Figure 7 in use;

Figure 9 shows a further embodiment of a device in accordance with the invention;

Figures 10 (a) to 10 (c) show the device of Figure 9 in use to secure a drain;

Figures 11 (a) to 11 (c) show the device of Figure 9 in use to close a wound;

Figures 12 (a) and 12 (b) shows a modified arrangement for securing the drain, for use with a small diameter drain;

Figure 13 shows a port for use in another embodiment of the invention;

Figures 14 (a) to (c) show steps in the use of the embodiment of Figure 13;

Figures 15(a) and 15(b) shows a modification of the arrangement of Figures 14 (a) to 14 (c); and

Figures 16 (a) and 16 (b) show a modified arrangement for the use of a port and a drain.

In the following description, like components in different embodiments will be given the same reference numbers.

Figure 1 shows a first embodiment of a device 1 for use in securing a drain to the tissue of a patient. The device 1 comprises a length of suture material 2 joined at one end to the mid point of a first terminating element in the form of an elongate rigid cross member 3. At the other end of the suture material, it is joined to the mid point of a second terminating element in the form of a second elongate rigid cross member 4. The member 4 is joined at one end, indicated by dotted line 5 to an integral, axially extending needle portion 6 which then curves round and ends in a point 7. The needle

portion 6 can be separated from the member 4 by snapping at the junction 5, where there is a point of weakness. Also provided on the suture 2 are a slidable plastic bead 8 and a crimpable metallic collar 9. In alternative arrangements other fasteners could be used and the bead could have an integral fastening function, for example being crimpable directly to the suture. In some arrangements, the bead 8 and collar 9 may be omitted.

Figure 2 shows part of the terminating member 4 of Figure 1, with the needle portion 6 omitted. The suture 2 is secured to the member 4 at its mid point 20. From that mid point to the end remote from the needle portion 6, the member 4 is provided with an open channel 21, which receives the suture as shown in Figure 3.

Figure 4a shows a first stage for closing a wound 10 in the tissue 11 of a patient. The needle 6 is passed through the tissue, with the integral terminating element 4, bringing the suture 2 as well. The needle portion 6 is then snapped off and this sharp end discarded. It will be appreciated that the first terminating element 3 serves to assist in manipulation, and to retain the bead 8 and collar 9 on the suture. As it does not pass through or engage the skin in this embodiment, it could have a number of alternative configurations. In the absence of the bead and collar, it would engage the tissue of the patient.

As shown in Figure 4b, the wound is closed by pushing the wound together, using the securing bead 8 which engages against the skin of the patient. On the other side of the wound, the member 4 forms a T shape with the suture 2 ,and engages flat against the skin. The wound is held closed by crimping the collar 9 to hold the bead 8 in place.

In Figure 4c, a drain 12 has previously been placed in position before the wound is closed as in Figure 4c. and the free end of the suture 2, with the terminating member 3, is secured to the drain under tension and held in place with a cable tie 13. The wound is now closed, and the drain secured, without the use of any knots. In an alternative arrangement, not shown, the bead 8 is not engaged against the skin of the patient, but instead is positioned above the cable tie with the collar 9 to stop movement of the cable tie along the suture.

Figure 5 shows an alternative device 14. Members 4 and 6 are as in the previous embodiment, i.e. a terminating element frangibly connected to a needle. However, attached to the mid point of member 4 is a loop 15 of suture material. Figure 6a shows this alternative device 14 in use. A percutaneous drain 12 passing through a puncture site in tissue 11. The needle portion 6, member 4 and some of the loop 15 are pulled through the tissue, and the needle portion 6 is snapped off. The member 4 is then passed through the free end of the loop 15 as shown in Figure 6b, and tightened so as to secure the suture to the tissue of the patient. As shown in Figure 6c, the free end of the suture loop 15 is then secured to the drain 12 with a cable tie 13.

Figure 7 shows an alternative device 16. A terminating element 3 is attached at its mid point to a loop 15 of suture material, to which a small secondary loop 17 of suture material is linked. The secondary loop 17 is connected to the end of a needle 18. As shown in Figure 8, the needle 18 has been passed through the tissue 11, leaving the loop 15 passing through the tissue and terminating in member 3. The secondary loop 17 is then cut, for example with a scalpel, and the needle 18 detached and discarded. The device can then be used in a manner analogous to that shown in Figures 6a to 6c.

Figure 9 shows a device 19 which is a modification of the device 16, in which loop 15 is provided with bead 8 and collar 9 in addition to the terminating member. This device may be used as shown in Figures 10a to 10c.

In the embodiments of both Figures 7 and 9, the terminating member does not pass through the skin and can have various configurations such as a flat terminating disc, button, rectangle or other shape, a terminating bead , a ring to put a finger through to assist manipulation, and so forth. It directly prevents the suture passing below the tissue surface or all of the way through the tissue of the patient in the embodiment of Figure 7, and in Figure 9 it achieves this indirectly by keeping the bead and collar on the suture and engaging them.

As shown in Figure 10a, a drain 12 passes through a puncture site in the tissue 11 of a patient. the needle 18 has been passed through the tissue 11, leaving the loop 15 passing

through the tissue and terminating in member 3. The secondary loop 17 is then cut, for example with a scalpel, and the needle 18 detached and discarded. As shown in Figure 10b, the cable tie 13 passes around the drain 12 and through the loop 15 of suture. Figure 10c shows how the bead 8 and crimpable metal collar 9 are used to pull the suture tight and to bring the cable tie 13 to the surface of the tissue 11.

Figures 11a to 11c show an alternative way in which the device 19 may be used in order to close a wound. As shown in Figure 11a, the needle 18 has been passed through the tissue 11, leaving the loop 15 passing through the tissue. The secondary loop 17 is then cut, for example with a scalpel, and the needle 18 detached and discarded. As shown ion Figure 11b, the member 3 is then passed through the loop of suture 15. Finally, as shown in Figure 11c, the suture 15 is tightened by pulling on member 3 to close the wound 10, the bead 8 is slid into contact with the tissue 11 of the patient and the collar 9 is crimped to hold the bead 8 in place and the wound closed. This provides a very effective way of closing a wound without the use of knots. In addition the free end of the loop of suture 15, with the member 3, may be used to secure in place a drain passing through the wound 11, in a manner analogous to that shown in Figure 4c or 6c, for example.

Figures 12a and 12b show how a rubber cuff 22 can be placed round a narrow drain 23 to facilitate the use of the cable tie 13.

Figure 13 shows a thoracic port 24 comprising a threaded sleeve 25 having a head 26 provided with one, or as shown two or more, eyelets 27 although in the broadest context these are optional. The sleeve can be of rigid or flexible plastics. Passing into the sleeve 25 is a trocar 28, with a blunt end 29, passing through a rubber seal 30 in the head 26 of the port. As shown in Figure 14a, the port 24 is screwed in between the ribs 31 of a patient, passing through skin 32, fat 33, muscle 34 and pleura 35.

As shown in Figure 14b, the trocar 28 is removed and a drain 12 is passed through the seal 30 in head 26, and through the threaded portion 25, into the chest. The seal 30 creates an airtight seal on the drain.

Such an arrangement is an affective alternative use for a thoracic port. Optionally, the drain 12 and the port 24 are secured to the tissue of the patent by means of a device 1 as shown in Figure 1, for example, although in this case the bead 8 and collar 9 have been omitted. The needle 6 has been passed through the tissue of the patent until the member 3 lies against the tissue. The needle 6 and attached suture 2 is passed through eyelet 27 and the needle 6 is then detached from member 4. The suture 2 is then clamped to drain 12 by cable tie 13, member 4 being used to pull the arrangement tight. In the optional arrangement as shown in Figure 14c, two devices 1 are used so that there are two lengths of suture 2 passing through respective eyelets 27 and being secured to drain 12 by the cable tie 13.

Figure 15a shows an arrangement analogous to that of Figure 14b, but in this case a device 19 as shown in Figure 9 has been used. The needle 17 is passed through the tissue of the patient and through an eyelet 27. The loop 17 is then cut by means of a scalpel, for example, and the loop 17 and needle 18 discarded. The cable tie 3 is then passed through suture loop 15 and around drain 12. The arrangement is pulled tight by means of member 3, bead 8 is slid to engage the tissue of the patient, and the collar 9 is crimped to hold the bead 8 in place. Figure 15b shows an optional arrangement in which two devices 19 have been used so that there are two loops of suture 15 passing through two eyelets 27 and secured to the cable tie 13 and drain 12.

Figures 16a and 16b show an alternative arrangement for use in locating a drain using the thoracic port 24. The insertion of the port 24 and the removal of the trocar 28 are as described with reference to Figures 13, 14a and 14b. However, in place of drain tube 12, there is a modified drain tube 36. At its distal end, drain 36 is provided with an annular inflatable bladder 37 around its outer circumference. An air tube 38 passes from the bladder 37, through the wall of the drain 36, along the drain, and out through the wall of the drain 36, terminating in a connector 39 for an inflation pump, which could be electrical or manually operated. The drain 36 is inserted through the port with the bladder in a deflated condition, as shown in Figure 16a. Once the drain 36 is in position, the bladder 37 is inflated by passing air thought the connector 39 and air tube 38. The drain may be sufficiently stable in this condition, but optionally one or more sutures are

also used in conjunction with optional eyelets 27, in an arrangement as described with reference to any of Figures 14b to 15b.

In the described embodiments, there are therefore disclosed improved suture devices and modes of their use, for use in closing wounds or securing implements such as drains in place. Experience with tying suture knots is not necessary in order to close a wound and / or fasten a drain or other item. There is also disclosed a new use of a thoracic port to locate a drain, which optionally may be used in conjunction with the new suturing devices, or with an alternative locating means using a bladder, or with a combination of the two.

CLAIMS

1. A suture device comprising a longitudinally extending portion of flexible suture material attached to a central region of a laterally extending, substantially rigid terminating element, the device also comprising a tissue piercing component which is removably attached to the terminating element.

2. A device as claimed in claim 1, wherein the tissue piercing component is connected directly to the terminating element.

3. A device as claimed in claim 2, wherein the tissue piercing component is an elongate extension from an end of the terminating element.

4. A device as claimed in claim 3, wherein the tissue piercing element and the terminating element are connected with a frangible portion so that the tissue piercing element can be snapped off of the terminating element.

5. A device as claimed in any of claims 2, 3 and 4, wherein the suture material is in the form of a loop.

6. A device as claimed in any of claims 2, 3 or 4, wherein the suture material is an elongate filament attached at one end to the terminating element and at the other end to additional terminating means.

7. A device as claimed in claim 6, wherein the additional terminating means is a laterally extending, substantially rigid second terminating element, the point of attachment of the suture material to the second terminating element being in a central region.

8. A device as claimed in any preceding claim wherein the terminating element is an elongate member.

9. A device as claimed in any of claims 2 to 7, wherein the terminating element is an elongate member formed with an elongate groove for containing part of the suture material, the groove extending from the point of attachment of the suture material to the terminating element to the end of the terminating element remote from the tissue piercing component.

10. A device as claimed in any preceding claim, wherein the suture material is also provided with a sliding tissue engaging portion and fastening means to hold the tissue engaging portion in position.

11. A device as claimed in claim 1, wherein the tissue piercing component is connected to the terminating element by being connected to the suture material.

12. A device as claimed in claim 11, wherein the suture material is in the form of a primary loop connected to the terminating element, and the tissue piercing component is connected to a secondary loop of material which is interlinked with the primary loop and can be severed to detach the secondary loop and the tissue piercing component from the primary loop.

13. A device as claimed in claim 10, wherein the primary loop is provided with a sliding tissue engaging portion and fastening means to hold the tissue engaging portion in position.

14. A device as claimed in claim 11, 12 or 13 wherein the terminating element is an elongate member.

15. The combination of a device as claimed in any preceding claim, with an elongate surgical drain and means for attaching the suture material to the drain.

16. The combination of a device as claimed in any of claims 1 to 14 with a surgical drain, a thoracic port in which the drain may be located, and means for attaching the suture material to the drain.

17. A combination as claimed in claim 16, wherein the thoracic port has a head with means for receiving the suture material.

18. A combination as claimed in claim 16 or 17, wherein the thoracic port is provided with a trocar for use during insertion of the port into a patient, the trocar being removable after insertion to permit the drain to be received by the port.

19. The combination of a device as claimed in any of claims 1 to 14 with a surgical drain, a thoracic port in which the drain may be located, and means for attaching the suture material to the thoracic port.

20. A suture device comprising: a longitudinally extending portion of flexible suture material attached at one end to a central region of a first laterally extending, substantially rigid elongate terminating element; a tissue piercing component which is directly attached to the first terminating element as an elongate extension from an end thereof, the tissue piercing element and the first terminating element being connected by a frangible portion so that the tissue piercing element can be snapped off of the first terminating element; and a laterally extending, substantially rigid elongate second terminating element, the suture material being attached at its other end to a central region of the second terminating element.

21. A suture device as claimed in claim 20, further comprising: a sliding tissue engaging portion on the suture material between the first and second terminating elements; and means for retaining the tissue engaging portion in position.

22. A suture device comprising: a loop of flexible suture material attached to a central region of a laterally extending, substantially rigid elongate terminating element; and a tissue piercing component which is directly attached to the first terminating element as an elongate extension from an end thereof, the tissue piercing element and the terminating element being connected by a frangible portion so that the tissue piercing element can be snapped off of the terminating element.

23. A suture device comprising: a primary loop of flexible suture material attached to a central region of a laterally extending, substantially rigid elongate terminating element; a secondary loop of material linked to the primary loop of suture material; and a tissue piercing component which is attached to the secondary loop of material.

24. A suture device as claimed in claim 23, further comprising: a sliding tissue engaging portion on the primary loop of suture material; and means for retaining the tissue engaging portion in position.

25. A method of closing a wound of a patient using a device as claimed in any preceding claim, comprising passing the tissue piercing component of the device through the tissue of the patient, securing the suture material to the tissue of the patient, and separating the tissue piercing component from the remainder of the device.

26. A method of securing a surgical implement to a patient, using a device as claimed in any of claims 1 to 24, comprising passing the tissue piercing component through the tissue of the patient, securing the suture material to the tissue of the patient, separating the tissue piercing component from the remainder of the device, and attaching the remainder of the device to the surgical implement.

27. A process as claimed in claim 26, wherein the surgical instrument is a drain.

28. A process as claimed in claim 27, wherein the drain passes through a thoracic port and the device further secures the port to the tissue of the patient.

29. A surgical drain in combination with a thoracic port having a tubular portion adapted to receive the drain, the drain comprising an elongate tubular member having adjacent its distal end an external inflatable bladder, there being a gas supply conduit extending from the bladder to adjacent the proximal end of the drain, through which gas can be introduced into, or released from, the bladder so as to selectively inflate or deflate the bladder.

30. A combination as claimed in claim 29, wherein the thoracic port has an enlarged head provided with means for receiving a suture for securing the port and the drain to a patient.

31. A combination as claimed in claim 30, further including at least one suture device as claimed in any of claims 1 to 24.

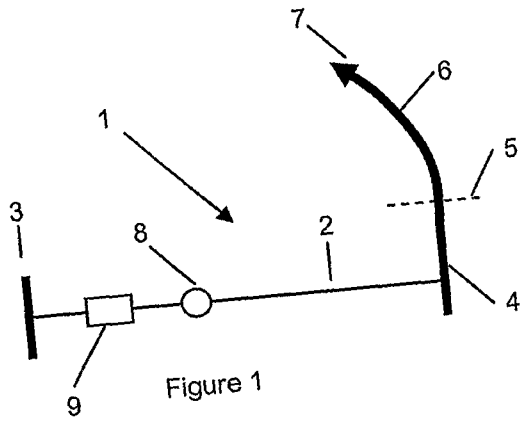


Figure 1

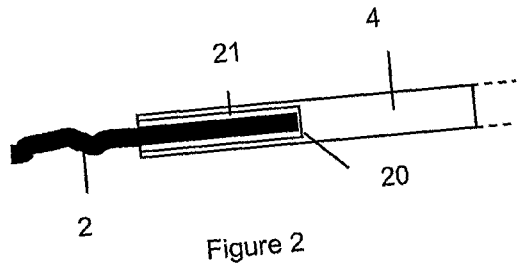


Figure 2

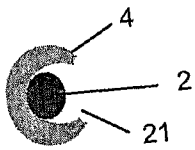


Figure 3

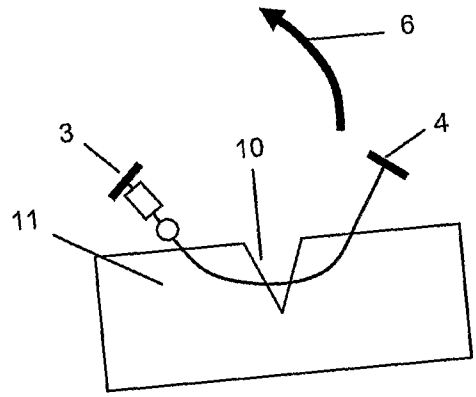


Figure 4a

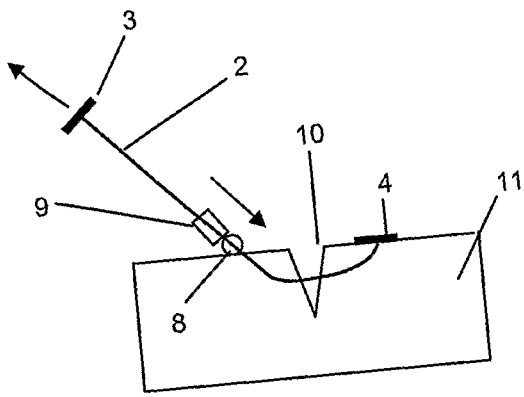


Figure 4b

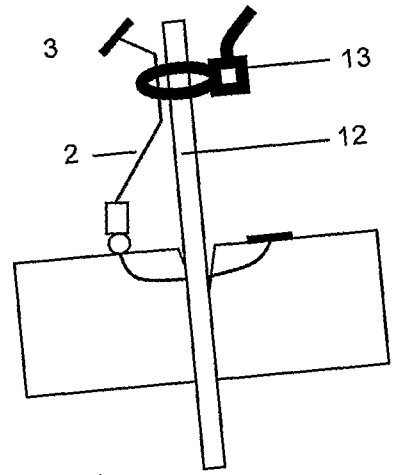


Figure 4c

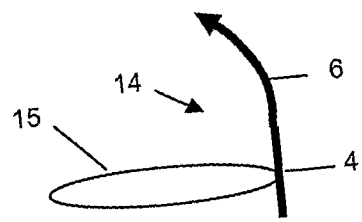


Figure 5

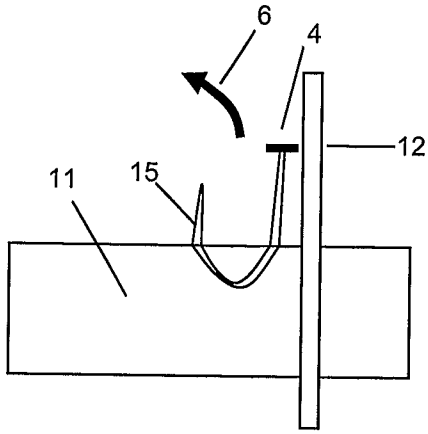


Figure 6a

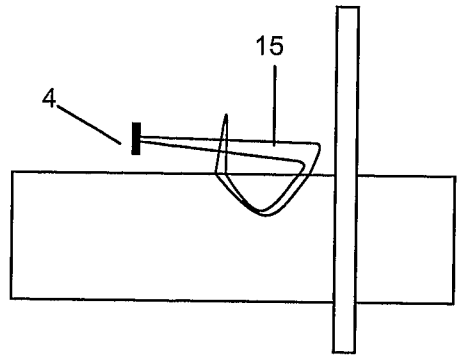


Figure 6b

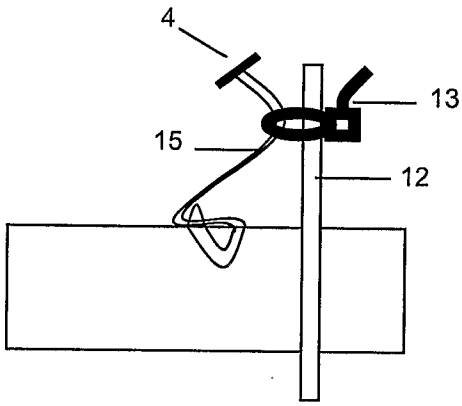


Figure 6c

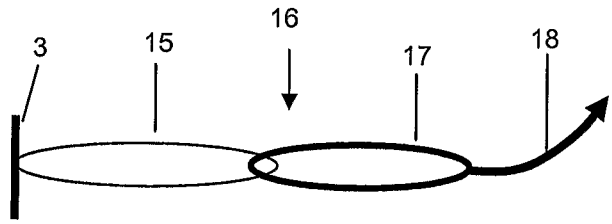


Figure 7

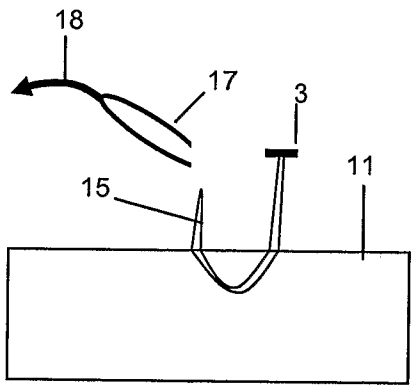


Figure 8

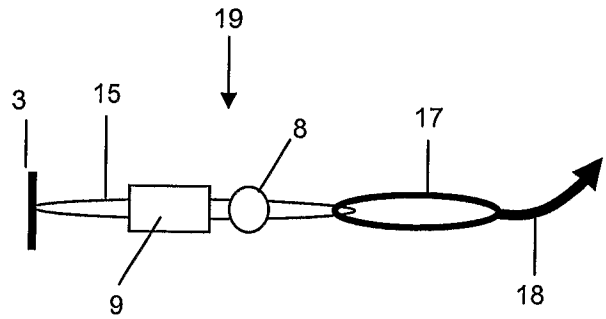


Figure 9

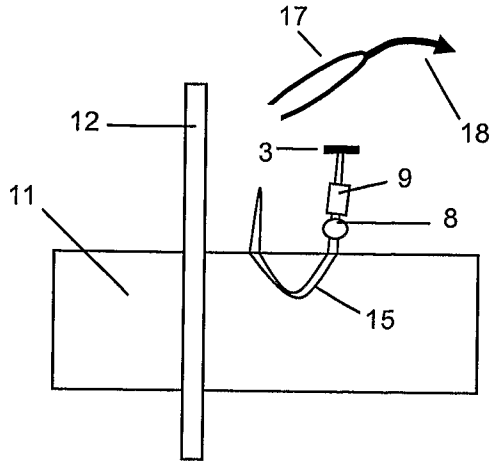


Figure 10a

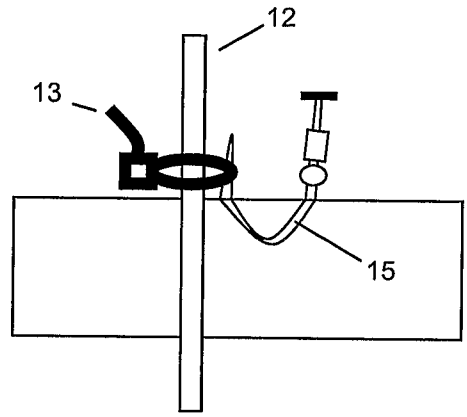


Figure 10b

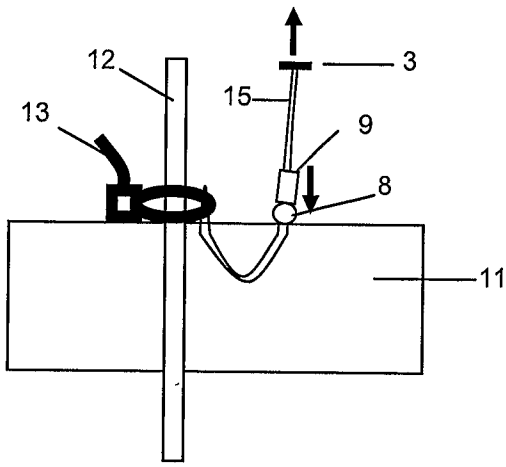


Figure 10c

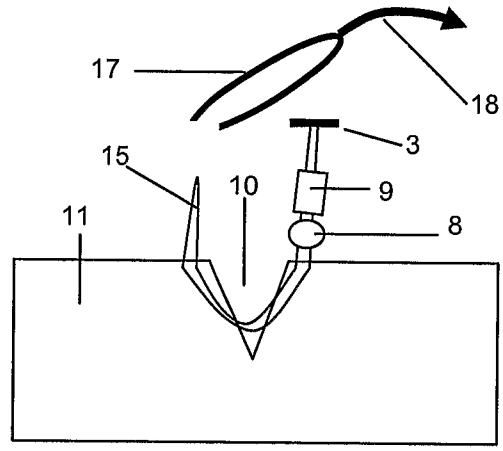


Figure 11a

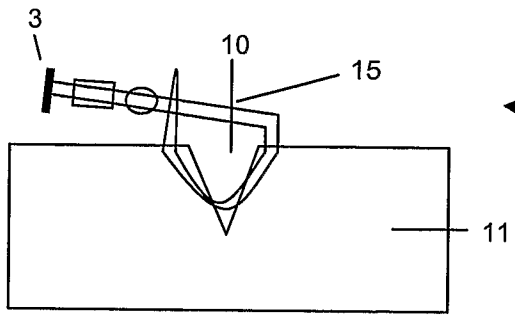


Figure 11b

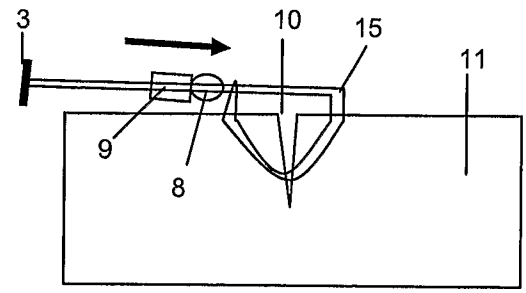


Figure 11c

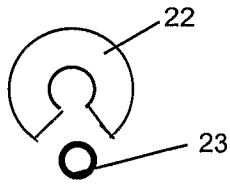


Figure 12a

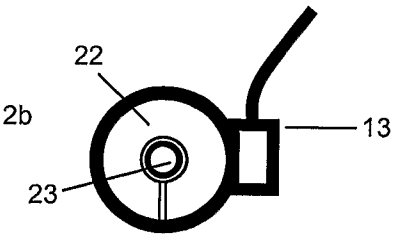


Figure 12b

Figure 13

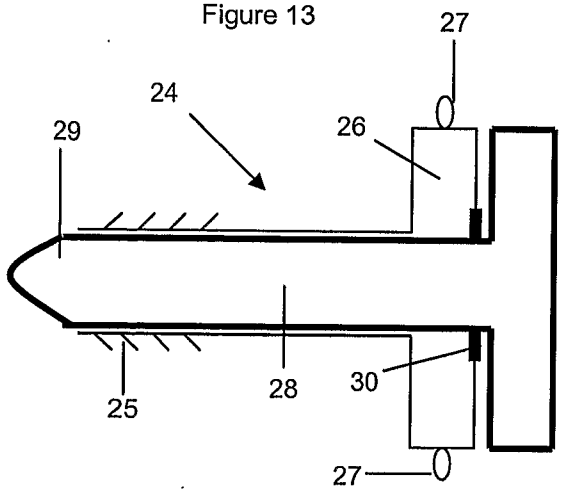
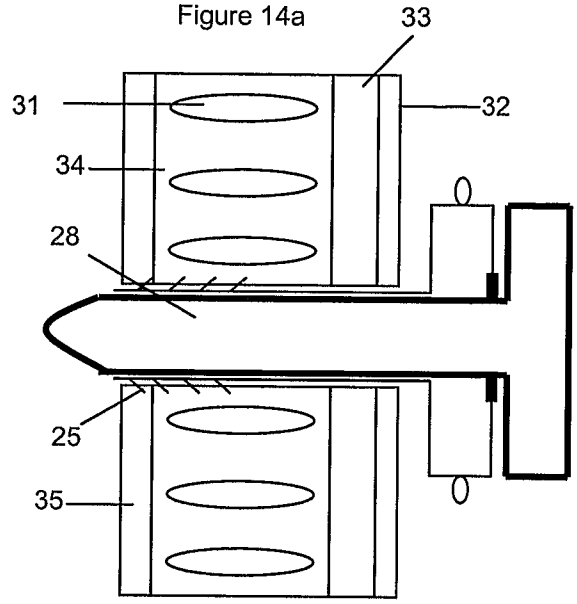


Figure 14a



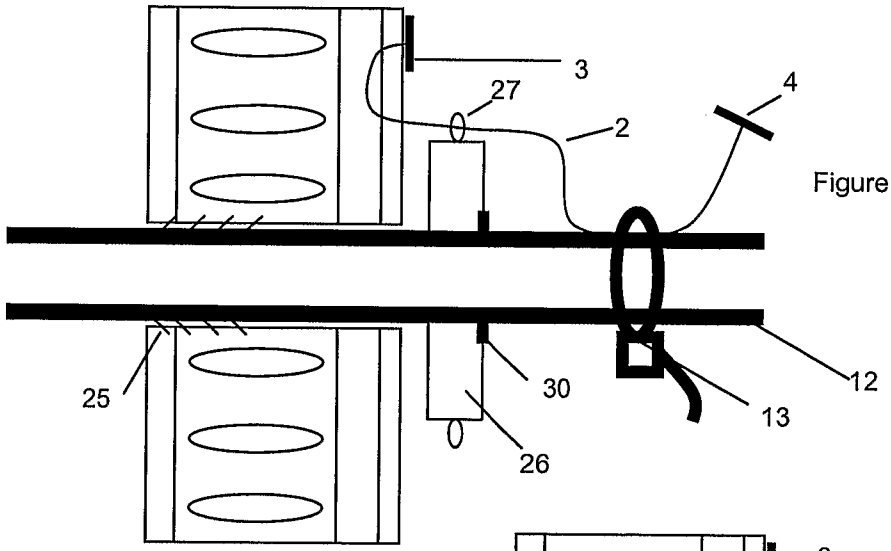


Figure 14b

Figure 14c

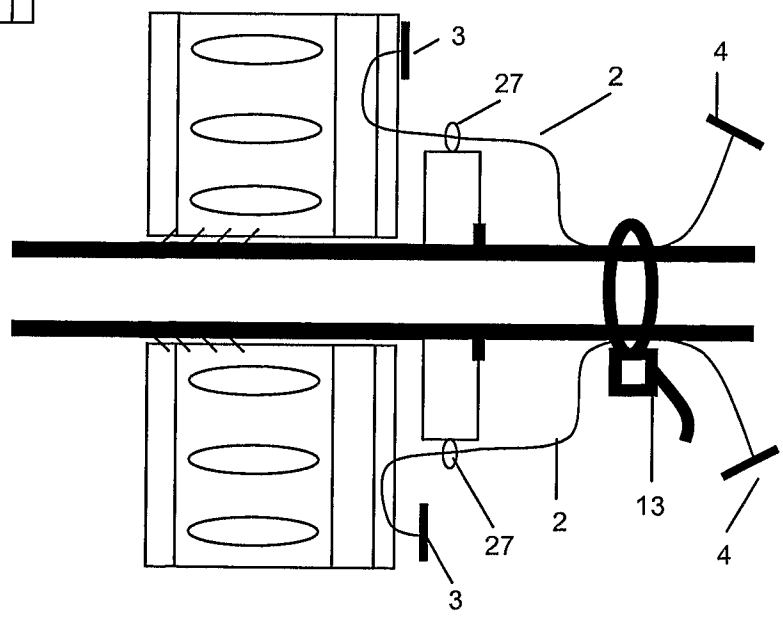


Figure 15a

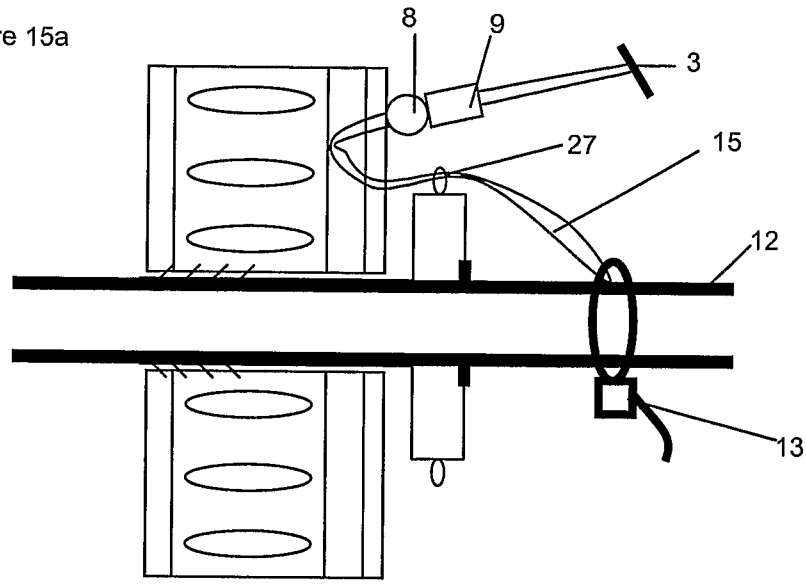


Figure 15b

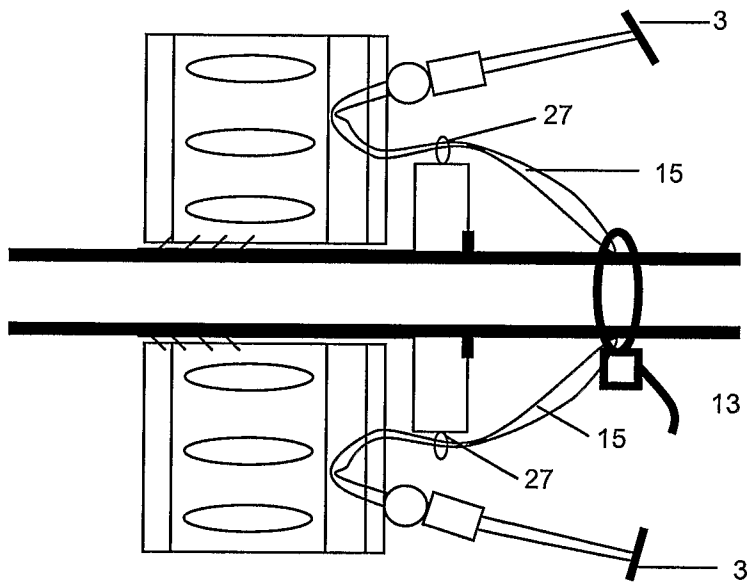


Figure 16a

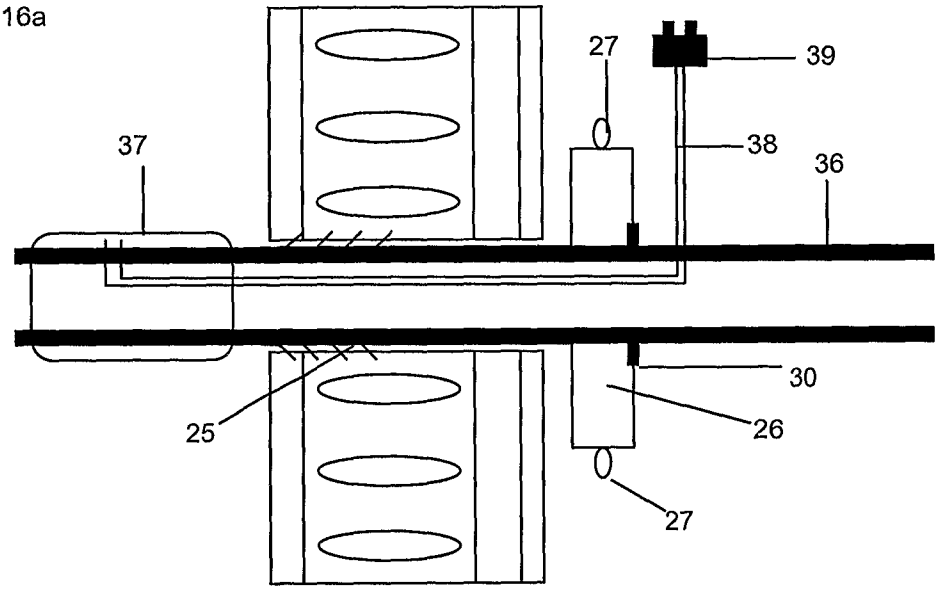
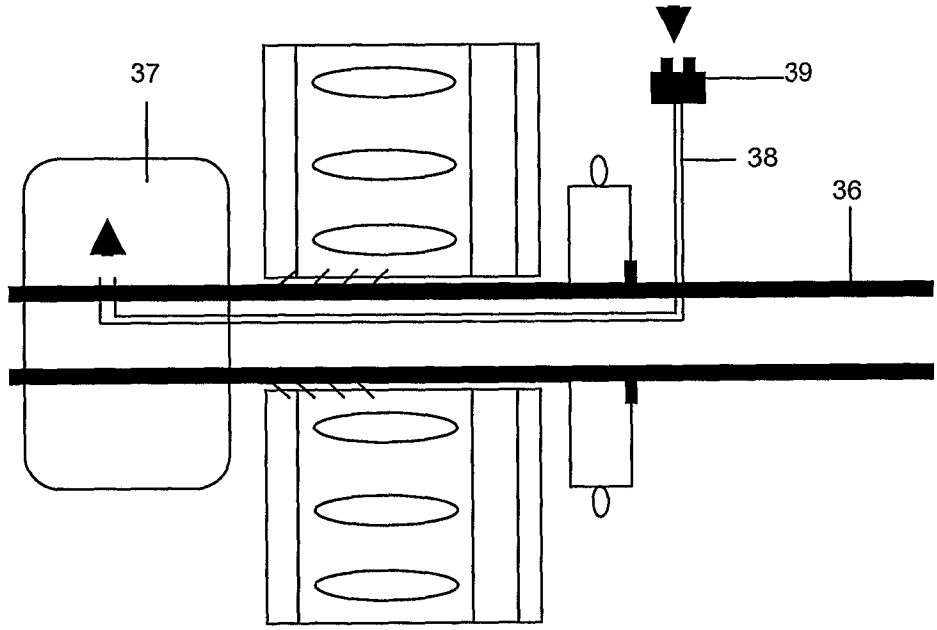


Figure 16b



INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/000233

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61B17/06 A61M1/00 A61M25/04 A61M25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	FR 2 826 253 A1 (SOFRADIM PRODUCTION [FR]) 27 December 2002 (2002-12-27) page 9, line 15 - line 18; figure 14	1-4,6-8, 20,22 15-19
X A	EP 1 199 036 A2 (ETHICON INC [US] DEPUY MITEK INC [US]) 24 April 2002 (2002-04-24) the whole document	23 1,11-16, 19-23
X A	US 5 891 168 A (THAL RAYMOND [US]) 6 April 1999 (1999-04-06) the whole document	23 1,15,16, 19,20,22
A	US 5 941 899 A (GRANGER RICHARD N [US] ET AL) 24 August 1999 (1999-08-24) abstract; figure 1	1,9,20, 22,23

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 April 2007	07/05/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hansen, Soren

3

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/000233

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/116963 A1 (LATTOUF OMAR M [US]) 17 June 2004 (2004-06-17) abstract; figure 3	1,5,11, 20,22,23
A	WO 96/09005 A (ABBOTT LAB [US]) 28 March 1996 (1996-03-28) abstract; figures 27,28	1,10, 20-24
Y	EP 0 807 450 A (REDMOND ANTHONY DAMIEN [GB]) 19 November 1997 (1997-11-19)	29-31
A	the whole document	15-19
Y	WO 98/44980 A (COOK UROLOGICAL INC [US]) 15 October 1998 (1998-10-15) abstract; figures 2,3	29-31
A	US 3 730 187 A (REYNOLDS V) 1 May 1973 (1973-05-01) the whole document	15,16, 19,29

3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/000233

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 25-28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

A suture device comprising a longitudinal extending portion of flexible suture material attached to a central region of a laterally extending, ridgid terminating element, the device also comprising a tissue piercing component which is removably attached to the terminating element.

---

2. claims: 23,24

A suture device comprising: a primary loop of flexible suture material attached to a central region of a laterally extending, ridgid elongate terminating element; a secondary loop of material linked to the primary loop of suture material; and a tissue piercing component which is attached to the secondary loop of material.

---

3. claims: 29-31

A surgical drain in combination with a thoratic port having a tubular portion adapted to receive the drain, the drain comprising an elongate member having adjacent its distal end an external inflatable bladder, there being a gas supply conduit extending from the bladder to adjecent the proximal end of the drain, through which gas can be introduced into, or released from, the bladder so as to selectively inflate or deflate the bladder.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2007/000233

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2826253 A1	27-12-2002	EP 1406543 A1	14-04-2004
		WO 03000140 A1	03-01-2003
		JP 2004530492 T	07-10-2004
		US 2004153102 A1	05-08-2004
EP 1199036 A2	24-04-2002	AT 354313 T	15-03-2007
		AU 759346 B2	10-04-2003
		AU 8143501 A	02-05-2002
		CA 2359158 A1	18-04-2002
		JP 2002177285 A	25-06-2002
		US 2003023268 A1	30-01-2003
		US 2003171778 A1	11-09-2003
		US 6527795 B1	04-03-2003
US 5891168 A	06-04-1999	AU 714085 B2	16-12-1999
		AU 3820097 A	25-08-1998
		CA 2273875 A1	06-08-1998
		EP 0951237 A1	27-10-1999
		JP 3683590 B2	17-08-2005
		JP 2001509711 T	24-07-2001
		WO 9833439 A1	06-08-1998
		US 5709708 A	20-01-1998
US 5941899 A	24-08-1999	NONE	
US 2004116963 A1	17-06-2004	NONE	
WO 9609005 A	28-03-1996	AT 246473 T	15-08-2003
		AU 702525 B2	25-02-1999
		AU 1977395 A	09-04-1996
		CA 2196074 A1	28-03-1996
		DE 69531455 D1	11-09-2003
		DE 69531455 T2	12-08-2004
		DK 782411 T3	17-11-2003
		EP 0782411 A1	09-07-1997
		ES 2204943 T3	01-05-2004
		JP 3589466 B2	17-11-2004
		JP 10505777 T	09-06-1998
		NZ 282604 A	24-10-1997
		PT 782411 T	31-12-2003
		US 5531699 A	02-07-1996
		US 5531678 A	02-07-1996
EP 0807450 A	19-11-1997	GB 2313315 A	26-11-1997
WO 9844980 A	15-10-1998	AU 742942 B2	17-01-2002
		AU 6891198 A	30-10-1998
		CA 2281885 A1	15-10-1998
		DE 69821342 D1	04-03-2004
		DE 69821342 T2	02-12-2004
		DK 973574 T3	26-04-2004
		EP 0973574 A1	26-01-2000
		ES 2214704 T3	16-09-2004
		JP 2001518818 T	16-10-2001
US 3730187 A	01-05-1973	NONE	