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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 October 2009 (22.10.2009)

PCT

(10) International Publication Number
WO 2009/128811 A1

(51) International Patent Classification:
A61M 39/02 (2006.01)

(21) International Application Number:
PCT/US2008/011592

(22) International Filing Date:
8 October 2008 (08.10.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/124,066 14 April 2008 (14.04.2008) US
12/220,248 23 July 2008 (23.07.2008) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, 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, LY, MA, MD, ME, 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, ST, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, 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 (Art. 21(3))*

(54) **Title**: IMPROVED CONICAL LAPAROSCOPIC APPARATUS FOR MINIMALLY INVASIVE SURGERY

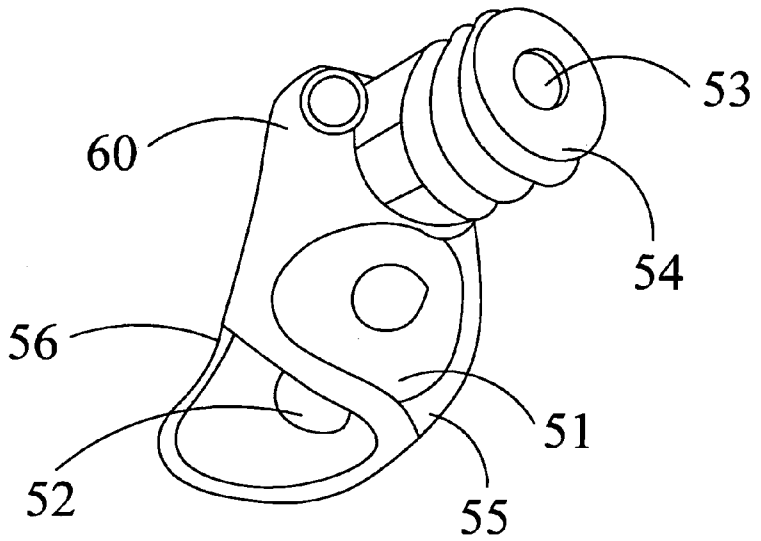

Figure 11

(57) **Abstract**: A single body port or body flange access device having an oval shape and associated stabilizer anchor for performing laparoscopic surgery is disclosed. The device is slipped into the body anchor stabilizer first so that the anchor stabilizer lifts up fat and peritoneum inside the body thereby keeping the operating area clear and acting to hold the body flange in place. The device further has a plurality of crisscrossing conduits assuming the shape of a cone through which surgical instruments may be inserted. The instruments are manipulated so that triangulation is obtained using one patient body flange while standard surgical procedures are performed on the patient. Due the oval shape of the device, the device minimally rotates while instruments are manipulated. [Figure 11]

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IMPROVED CONICAL LAPAROSCOPIC APPARATUS FOR MINIMALLY INVASIVE SURGERY

Technical Field of the Invention

This device and method relate to laparoscopic surgical procedures and in particular to an improved device and method for minimally invasive surgical procedures.

Background of the Invention

Minimally invasive surgery has improved patient care by decreasing pain, shortening hospital stays, offering a faster recovery time and much smaller scars. In fact the surgical procedure is much shorter than standard procedures and offers less chance of infection, etc. These laparoscopic procedures are proving popular with the patient.

During minimally invasive procedures for the abdominal surgeries such as:

laparoscopic appendectomy (removal of the appendix);
laparoscopic cholecystectomy (removal of the gallbladder);
laparoscopic colectomy (removal of part or all of the colon);
laparoscopic fundoplication (corrects severe or persistent acid reflux);
laparoscopic hysterectomy (removal of the uterus); or
laparoscopic ventral hernia repair (repair of an abnormal bulging of the abdominal wall often at the site of a previous surgical incision),

the surgeon makes a series of three to five small, dime-sized incisions in the patient's abdomen. Carbon dioxide gas is used to inflate the abdomen and create a working space between the internal organs and the skin. A small video camera, or scope, then is placed in one of the incisions, providing the surgeon with a magnified view of the patient's internal organs on a television monitor in the operating room. In some procedures, like MIP for colon conditions, a slightly larger incision may be needed.

Thus, the procedure requires body access devices, which are utilized to introduce visualization equipment and operative instruments rather than a standard incision to access a required part of the body. Nonparallel instrumentation is necessary to create a "depth of field" (3-dimensional vision) and introduce a variety of instrumentation. This concept is commonly known as triangulation.

In the past multichannel devices have been used by the surgeon using narrow parallel channels (within the single multichannel access device). These narrow parallel channels have

been found to limit the field of view and reduce depth perception. Thus, multichannel devices have not met the needs of the surgical community and are rarely used.

Nonparallel multiple access devices would allow the surgeon to introduce numerous types of instruments with triangulation through one body access opening. This concept would preserve triangulation and create the required field and depth of view while allowing the surgeon to utilize **one** body flange for multiple simultaneous tasks, which would be required to complete an operation on any applicable body area or space.

The current state of the art utilizes entry devices (body flanges) that have a similar cross-section as a silver dollar and incorporate a control head (gas in fusion port and sealing systems for insertable surgical instruments that have almost double cross-section as the part of the flange that attaches to the abdominal wall or body entry port. This means that large incisions will be used when operating on obese patients to allow for the large control head.

Wilk in U.S. Patent 5,183,471 discloses a "Laparoscopic Cannula" that has a central conduit with a side crossing conduit that passes through the central conduit thereby creating an obstacle within the central conduit. The disclosure teaches a means to facilitate the temporary insertion of an extra laparoscopic instrument without having to make another perforation of the abdomen. The side crossing conduit will require that the central conduit be large; otherwise, a standard instrument would not be able to pass through the central conduit. The central conduit will allow a surgical instrument to "look" vertically downward over the operation point while the side crossing conduit will pass an instrument to one side of the operation point. Wilk continues to teach a second body flange for illumination and vision and does not discuss triangulation.

Wilk in U.S. Patent 5,269,772 discloses a "Laparoscopic Cannula Assembly and Associated Method" which essentially is two parallel swiveling conduit passing through the same body opening and is a continuation-in-part of his '471 disclosure examined above. The parallel conduits do not cross over each other; however, the device will allow one instrument to be to one side of the operation point while the other instrument may be to the other side. The swiveling assembly will require a rather large opening in the abdomen wall. As in his '471 disclosure, he continues to teach a second body flange for illumination and vision and does not discuss triangulation.

Yoon in U.S. Patent 6,066,090 discloses a "Branched Endoscope System" which discusses a single body flange having a plurality of tubes passing through the conduit for

various surgical instruments. Yoon shows an embodiment in which the inside section of the body flange splits in two parts each having a bend thereby allowing a tube to overlook the other tube. The Yoon '090 device is designed to pass through the current art body flange having a single conduit.

Yoon in U.S. Patent 6,277,064 discloses a "Surgical Instrument with Rotatably Mounted Offset Endoscope." The apparatus is a variation of the '090 device and is designed to pass through the current art body flange having a single conduit.

Wenner et al. in U.S. Patent 6,440,061 disclose a "Laparoscopic Instrument System for Real-Time Biliary Exploration and Stone Removal." This device has multiple ports within its system, but, like Yoon, is designed to pass through the current art body flange having a single conduit.

Bimbo et al. in U.S. Patent 6,551,270 disclose a "Dual Lumen Access Port." The device is essentially a current state of the art body flange with parallel entry ports that open into a single conduit which will accept two surgical tools through one body flange without ensuring a three dimensional field of view. Bimbo teaches multiple instruments through a single conduit but does not explore the concept of a single body flange replacing surgical procedures using multiple body flanges.

Piskun in U.S. Patent 6,454,783 discloses "Laparoscopic Instruments and Trocar Systems for Trans-umbilical Laproscopic (sic) Surgery." Piskun discloses an instrument system that markedly increases the work space between the hands of the surgeon. The system includes s-shaped laparoscopic tools and associated curved trocars (sealable conduit passing through the umbilicus). The disclosure goes further to propose at least one curved trocar contained within an inflatable unit for placement through the umbilicus – essentially an inflatable body flange.

The inventors in their earlier application, of which this is a continuation-in-part, disclosed a body flange or body anchor system which provided an apparatus and method that would allowed the surgeon to perform minimally invasive operations with body flanges having a smaller overall cross-section while allowing for triangulation within the patient. Such a device and method will result in fewer incisions for body access openings thus further decreasing the pain caused by surgery and further decreasing the recovery time and further reducing the risk of infection. However, as their device was developed it was discovered that a perfectly round shape tended to swivel in the umbilicus and tended to lift out of the

umbilicus in spite of the sutures.

It was discovered that if the shape of the anchor was modified to be oval in shape then the anchor would not as easily rotate. At the same time it was discovered that if a stabilizer extension (shaped somewhat like the toe of a boot) was added to the lower inside part of the anchor the tendency to lift out of the umbilicus was further reduced. The stabilizer extension added one further advantage to the body anchor in that it tended to elevate fat and peritoneum inside the patient's body thereby keeping the internal opening clear for surgical instruments.

During further experimentation with the crisscrossed anchor employing the "boot" stabilizer, it was discovered that a substantial improvement in the ease of instrument positioning with the body cavity would occur if the conduit passages were "bored-out" into the shape of a cone either above or below the point in the anchor where it passes into the body. As a part of this discovery, it was noted that the conical conduit must be angled away from each other substantially like bicycle spokes while maintaining a crisscross pattern (for three-dimensional viewing) resulting in trajectories that may be nonparallel or parallel which may of may not crisscross within the actual anchor itself.

Further development lead to a concept to allow for a fourth conduit about the outside of the anchor without significantly increasing the "diameter" of the anchor. At the same time it was realized that if the conduit passages were made of a flexible material, then the overall triangulation could be substantially increased.

Summary of the Invention

The invention consists of a "body flange" or "trans-axis-uniport" ("TAU") which is anchored to the body with a standard suture anchoring points or a twin hexagonal tie-down. In turn, the body anchor contains a crisscrossed plurality of conduits which allow nonparallel introduction of equipment and/or instruments. The conduits may be parallel, nonparallel, straight or curved, but enter the body through one body opening. (It may be necessary during some procedures to have additional body openings.)

Rather than use the current art round body flange shape, the device is slightly oval (or elliptical if viewed from beneath). In a further embodiment the perimeter of the flange at the point inside the body is less than the perimeter outside the body thereby providing a further circumferential oval shape. A stabilizer extension shaped somewhat like the toe of a boot is added to the lower (inside the body) perimeter of the flange. The stabilizer extends along an

axis that joins the foci of the ellipse.

The conduit extending through the anchor are "bored-out" or enlarged either preferably above the point in the anchor where it passes through the body or below the point. This allows the surgical instrument to freely move back and forth within the body (in a circular pattern) thereby increasing the "fulcrum" (movement of the instrument tip) within the body. In an alternate version the conical shapes of the conduit are combined into one cone which follows the outside conical shape of the anchor. A rubberized-malleable seal is placed within the cone or cones of the conduit and in one alternate the seals may be placed at the bottom (inside the patient) side of the anchor. The bottom placement of seals allows for more freedom of movement of the surgical instruments and removes the chance of seal bumping against one another.

Brief Description of the Drawings

Figure 1 shows isometric view of the body anchor of the instant invention showing how the conduit apertures cross over (criss-cross) within the anchor and showing the anchor stabilizer.

Figure 2 shows a side view of the instant invention.

Figure 3 shows a side view of the instant invention rotated 180-degrees from the illustration in Figure 2.

Figure 4 is a top view of the instant invention

Figure 5 is a bottom view of the instant invention.

Figure 6 shows a side view of the instant device in place within the body of the patient illustrating how the anchor stabilizer functions.

Figure 7 shows a twin hexagonal suture tie-down.

Figure 8 shows the art disclosed in an earlier application by the inventors on which this application continues in part.

Figure 9 identifies three simulated instruments (as A, B, and C) and indicating where (in this case within the device) the crisscross occurs.

Figure 10 is a side view of the further improved anchor showing two simulated instruments crisscrossing, one inside the anchor and the other outside the anchor, but still positioned by the anchor.

Figure 11 is a top view of the further improved anchor showing four conduit, two utilizing a flexible wall (with seals at the bottom), one using a fixed conduit (with a normal seal) and one passing through the edge of the anchor. Also shown is an inflation conduit.

Figure 12 is a bottom view of the further improved anchor clearly showing the two lower seals, the fixed conduit exit, the side channel and the inflation opening.

Figure 13 is a side view of the further improved anchor showing the flexible side.

Figure 14 is the same as Figure 13, but rotated 180-degrees.

Description of the Preferred Embodiment

In reading this disclosure, the reader should understand that the term body flange generally means the entire device used to temporarily seal an incision in a patient. Thus, the body flange would include the body anchor – the section of the device that fits within the abdominal wall and is temporality sutured to the abdominal lining, any passageways extending through the body anchor (both above and below), any seals or other apparatus that is required to form the complete temporary entry closure.

Turning now to Figure 1, the improved body anchor is shown as item **5**. The overall shape is somewhat like a boot, in that the upper perimeter, **7**, and lower perimeter, **8** are elliptical. The anchor stabilizer, **6**, extends from the lower perimeter following an axis which passes through the foci of the elliptical lower perimeter, **8**. Crisscrossing instrument conduit, **1** and **2** are shown. It should be noted that these conduit need not crisscross to take advantage of the improved body anchor utilizing the defined shapes and stabilizer and in fact such condition would be an alternate embodiment. A further straight conduit, **3**, is shown passing behind the crisscrossing conduit as is an inflation passage, **4**.

It should be noted that the oval shaped body flange and stabilizer can function with only one conduit and the illustration of Figure 1 must not be construed to require a plurality of conduit; thus, the illustration of Figure 1 should not be construed as a limitation. Figures 2 and 3 serve to illustrate side views of the improved body anchor further showing and claiming the anchor stabilizer, **6**. Also shown is the suture guide, **9**.

Likewise Figures 4 and 5 are top and bottom views of the improved body anchor further showing and claiming the anchor stabilizer, **6**.

Figure 6 shows the device in place within the body of a patient and clearly illustrates how the anchor stabilizer acts to hold the anchor in place while lifting fat and peritoneum within the body.

Figure 7 shows the twin hexagonal suture anchor (or tie-down point). This set of twin posts could be flat (to each other), triangular (with the apex of each triangle touching), round, or possibly any geometric shape. The tie-down point operates very simply by tightly holding the suture between the two posts. The preferred shape is hexagonal, but an octagonal shape may also be employed. Also shown in Figure 7 are two conduits with standard "outer" seals, **21** and **22**. That is to say the seal between the surgical instrument and the conduit is standard and is located "outside" the conduit. Compare this concept to a further improvement to be

described in paragraph 46.

Figure 8 shows the prior art multi-channel body flange, **1'**, described in the inventors' parent application serial number 11/710,388 and illustrating two crisscrossing conduit, **2'**.

Figure 9 shows the conical form of the crisscrossing conduit with three simulated instruments passing through the body flange, **5**. The figure shows clearly the "bicycle-spoke" arrangement that the surgical instruments, **A**, **B**, and **C**, will assume when passing through the body flange. The instruments may now be readily and easily manipulated over a large arc within the body while maintaining the critical three-dimensional view.

Figures 10 through 14 show additional embodiments of the instant device. An external crisscross passage, **60**, has been placed in the outer wall of the body anchor, **5**. A simulated surgical instrument, **59**, is shown passing through the passage. There is no seal shown, however, flexible rubber may be placed in the passage, which would seal against the instrument: the human body will provide the remaining seal. Also shown is the air inflation passage, **70**.

Figure 11 shows the inside crisscrossing conduit, **51** and **52**. It would be possible to slightly enlarge these conduits to assume the conical shape; however, this may result in a large (overall) diameter flange. Note the flexible external membranes in these conduits, **55** and **56**. If and when the surgeon manipulates the instruments within these conduits and needs more movement, the two flexible walls will distend.

Figure 12 clearly shows the instrument seal, **50**, placed on the bottom of the body flange (the bottom being defined as the portion of the anchor which is fully within the patient). This dual seal serves to seal passages, **51** and **52**. An alternate (standard) seal, **54**, is shown on passage **53**. The standard seal on passage **53** may be replaced with a bottom seal as shown by seal **50**.

It is the intent of the invention to reduce the overall body incision, thus the body flange of the instant invention (at the point where it is designed to penetrate the abdominal wall) to a minimum. Note that, as the instruments are manipulated within the flange, the instrument trajectories may range from nonparallel to parallel crisscrossing. The device is shown with a US dime for size comparison.

In the current series of prototype model body flanges, the overall (penetration point) diameter is about 15mm and allows for three instruments having diameters of 5, 5, and 3 mm respectively. Another prototype has been developed that allows for laparoscopic spleen

surgery using instruments having diameters of 5, 5, and 12 (stapler) mm respectively. The overall diameter of this prototype is about 20 mm.

Because the instant devices are smaller (both in diameter and depth) over the current art, the body flange will easily accept flexible instruments, inflexible instruments, curved, straight, instruments with angled lenses, and etc.

Claims

We claim:

1. A multiple access body flange assembly for performing minimally invasive laparoscopic surgery on a body comprising:

a body access anchor adapted to be anchored to the body and having a lower section for placement within the body;

a first aperture;

a second aperture; and,

an anchor stabilizer formed within the lower section of said body access anchor, wherein both said first and second apertures passing through said body access anchor whereby when surgical instruments are passed through said apertures such instruments may be manipulated by the surgeon so that a triangular field of view is obtained.

2. The device of claim 1 wherein said first apertures crisscrosses, within said body anchor, said second aperture.

3. A body flange assembly for performing minimally invasive laparoscopic surgery on a body comprising:

a body access anchor adapted to be anchored to the body and having a lower section for placement within the body;

a first aperture; and,

an anchor stabilizer formed within the lower section of said body access anchor, wherein said first aperture passes through said body access anchor.

4. A multiple access body flange assembly for performing minimally invasive laparoscopic surgery on a body comprising:

a body access anchor adapted to be anchored to the body and having a lower section for placement within the body;

a first aperture;

a second aperture; and,

wherein both said first and second apertures pass through said body access anchor and are "bored-out" to assume a conical shape within the body flange and whereby when surgical instruments are passed through said apertures such instruments may be manipulated by the surgeon so that a triangular field of view is obtained.

5. The device of claim 4 wherein said first apertures crisscrosses, within said body anchor, said second aperture.

6. A multiple access body flange assembly for performing minimally invasive laparoscopic surgery on a body comprising:

a body access anchor adapted to be anchored to the body and having a lower section for placement within the body;

a first aperture;

a second aperture,

wherein both said first and second apertures pass through said body access anchor having flexible sides whereby when surgical instruments are passed through said apertures such instruments may be manipulated by the surgeon so that a triangular field of view is obtained.

7. The device of claim 6 wherein said first apertures crisscrosses, within said body anchor, said second aperture.

8. The device of claim 6 wherein a third passage is formed within the outer wall of said body access anchor.

9. The device of claim 7 wherein said passage and apertures crisscross each other within said body anchor.

10. The device of claim 8 wherein said passage and apertures crisscross each other within said body anchor.

11. The device of claim 6 wherein said apertures terminate at the distal end in a seal formed within the lower side of said body anchor.

12. The device of claim 6 wherein one or more of said apertures have distendable walls formed with said aperture and said body anchor.

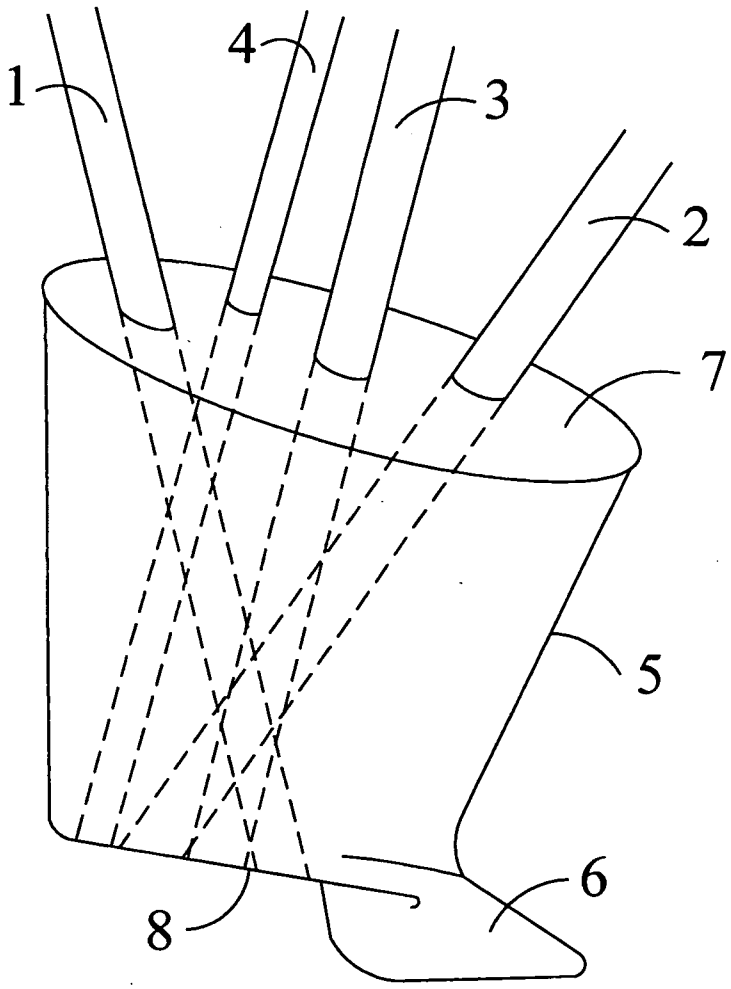

Figure 1

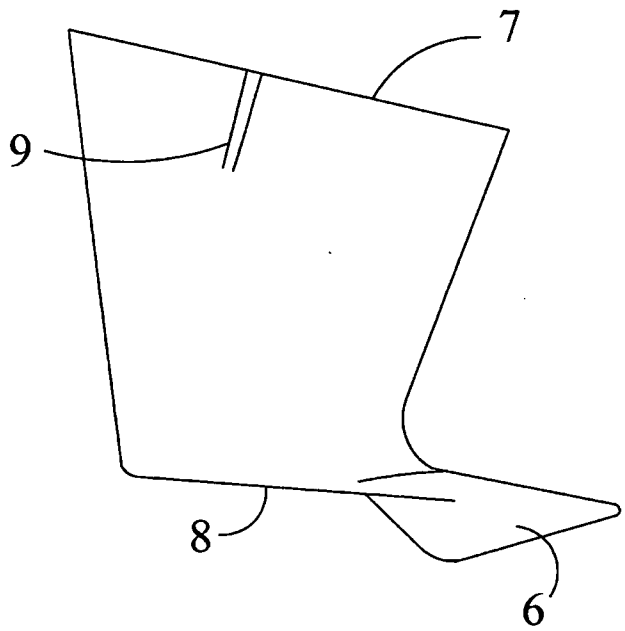

Figure 2

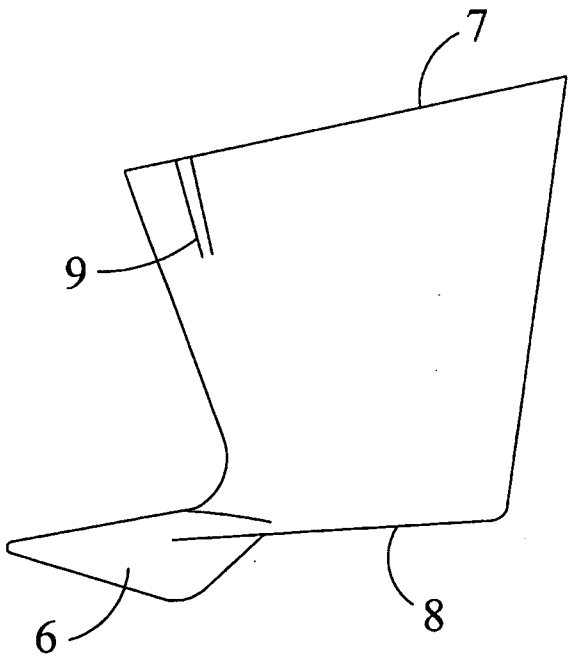

Figure 3

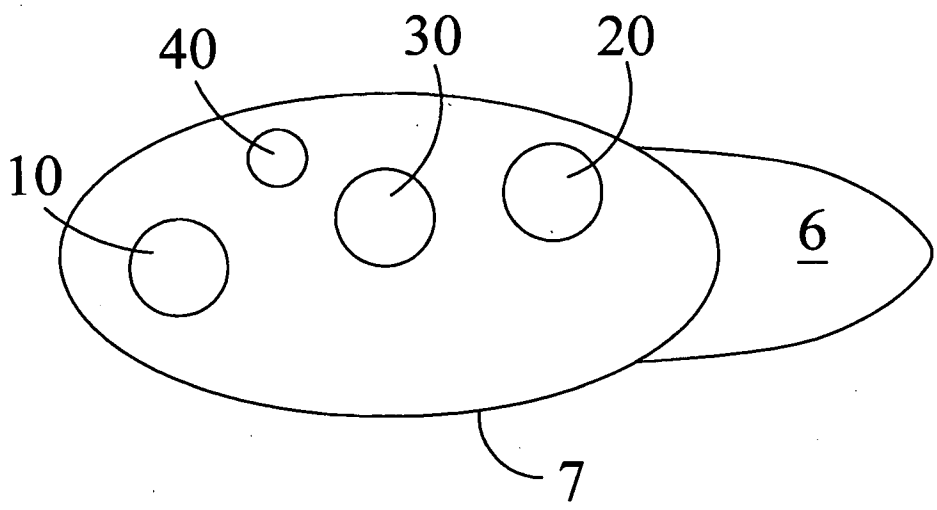

Figure 4

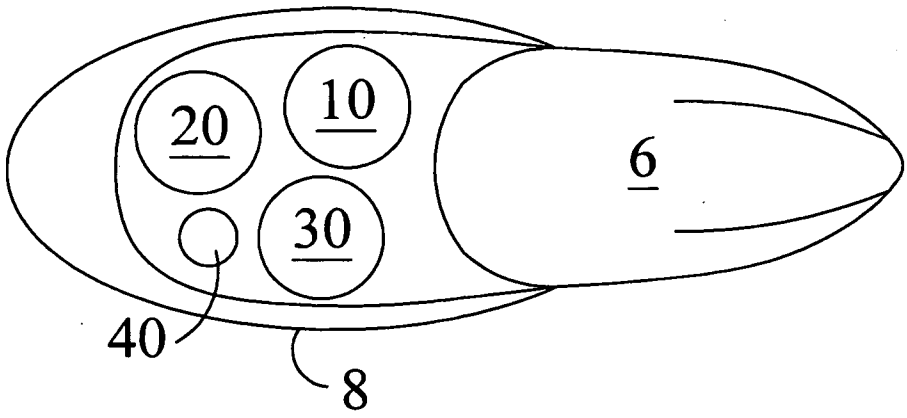

Figure 5

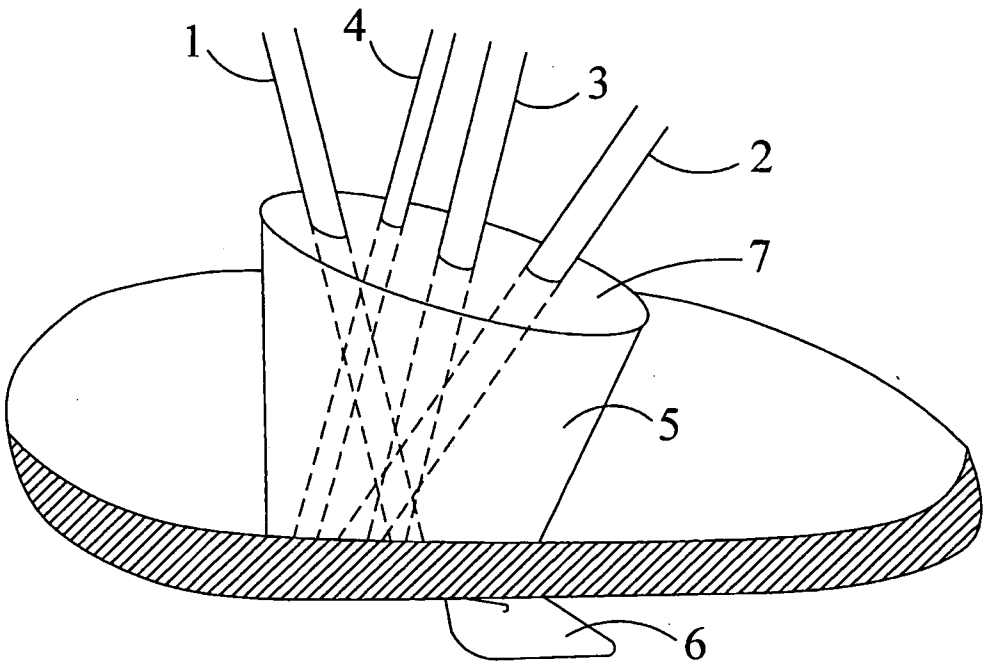

Figure 6

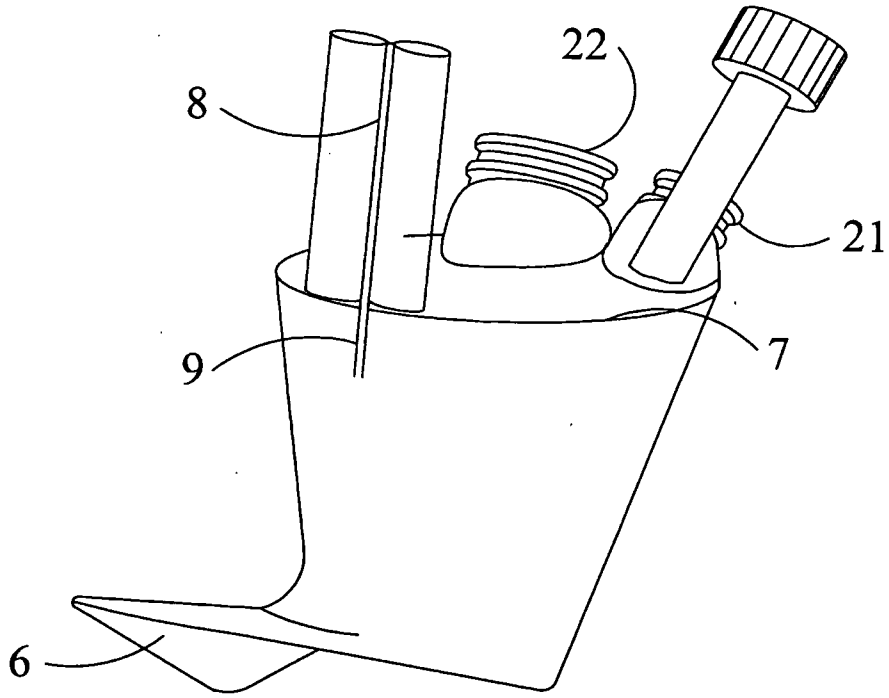

Figure 7

PRIOR ART

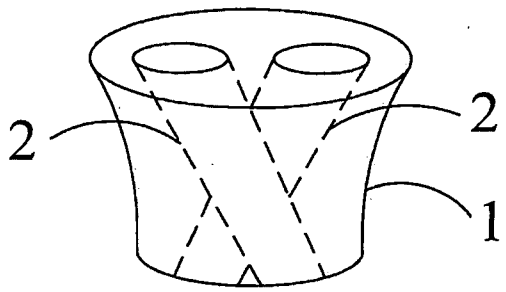

Figure 8

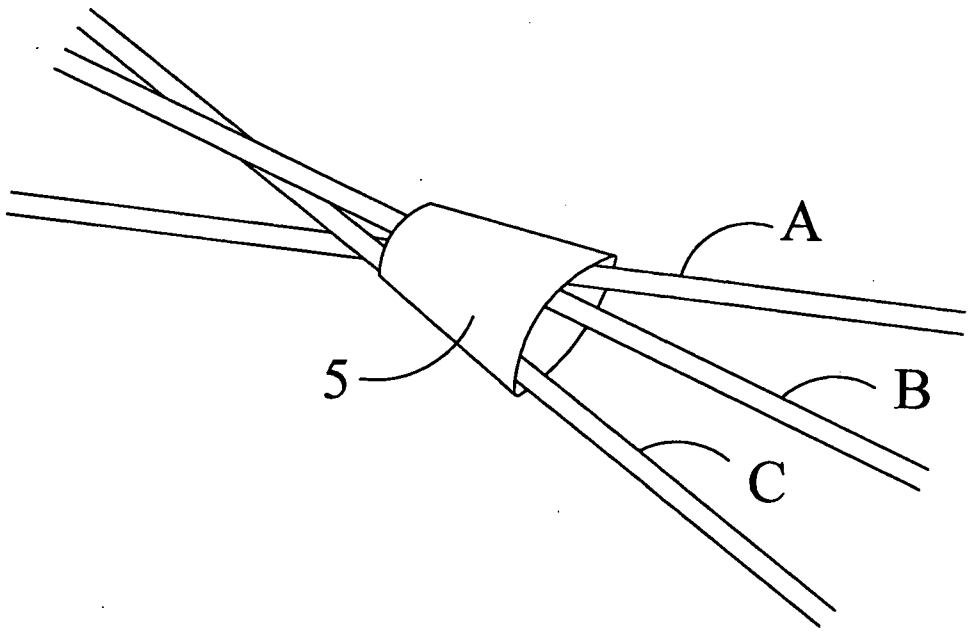

Figure 9

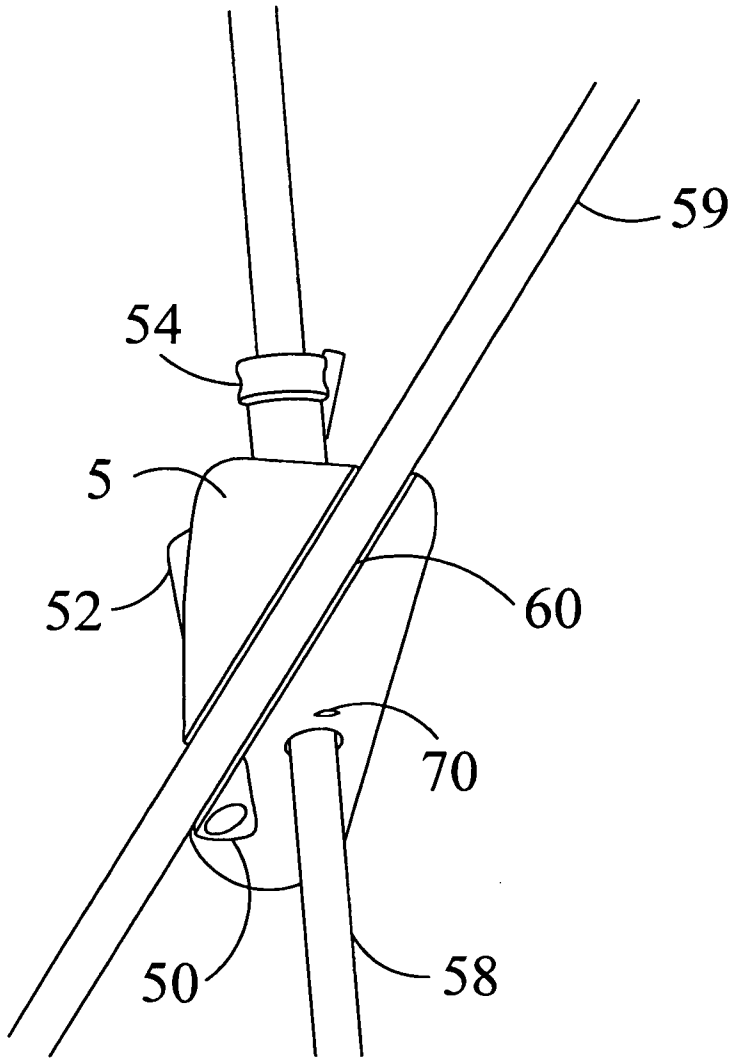

Figure 10

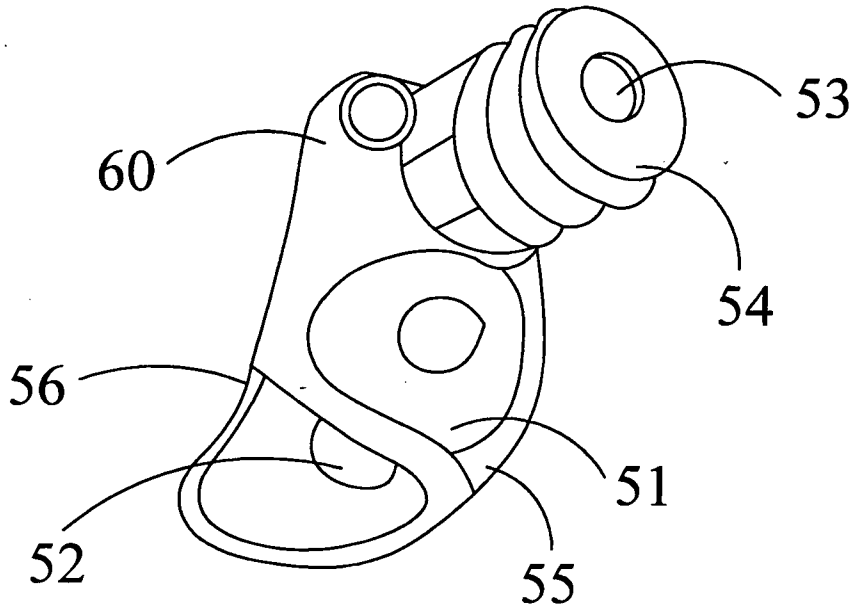

Figure 11

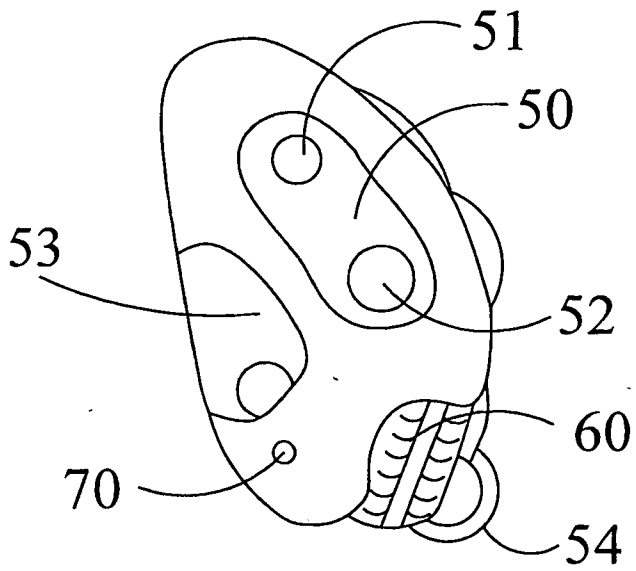

Figure 12

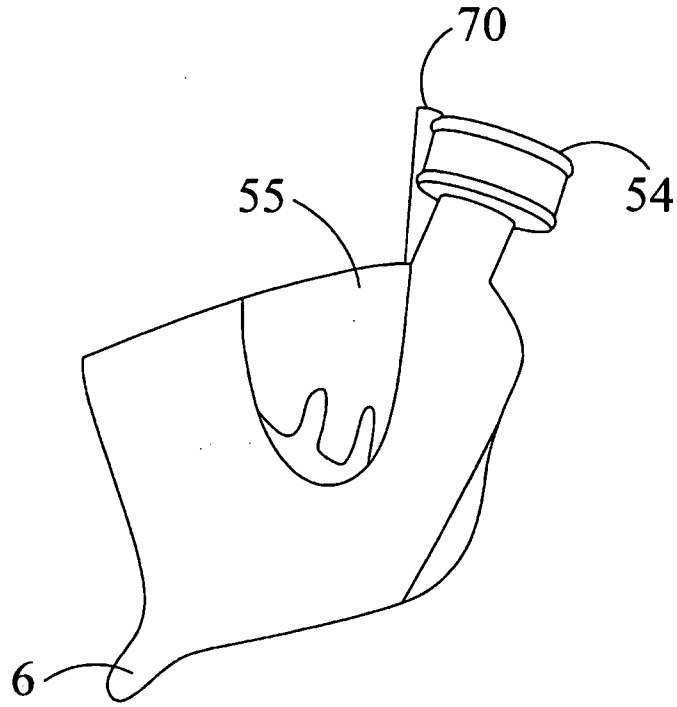

Figure 13

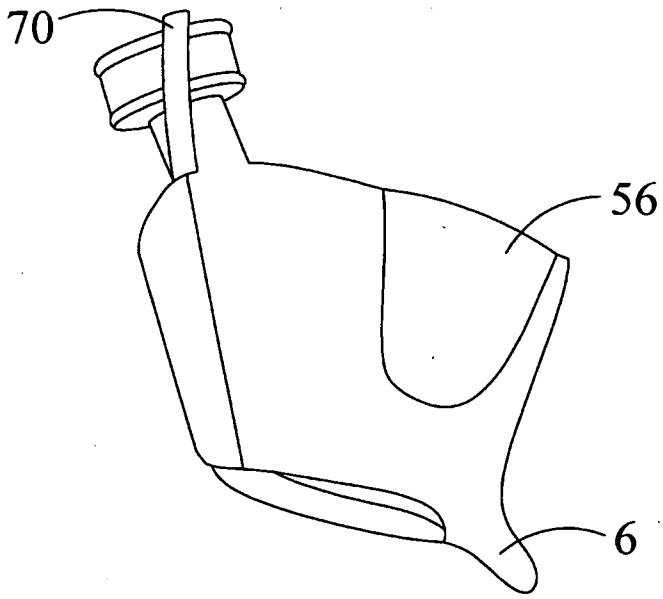

Figure 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/011592

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 39/02 (2008.04)
USPC - 604/43
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)
IPC(8) - A61M 25/00, 25/01, 25/06, 25/10, 29/00, 29/02, 39/00, 39/02 (2008.04)
USPC - 604/43, 83, 256, 264, 523; 606/194

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 practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0020241 (PISKUN et al) 26 January 2006 (26.01.2006) entire document	1-7, 9, 11, 12
Y		8, 10
Y	US 5,047,045 A (ARNEY et al) 10 September 1991 (10.09.1991) entire document	8, 10

☐ Further documents are listed in the continuation of Box C. ☐

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"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
16 December 2008	29 DEC 2008

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