



(51) International Patent Classification:

A61M 5/42 (2006.01) A61B 17/34 (2006.01)
A61B 17/30 (2006.01)

(21) International Application Number:

PCT/IB2014/058974

(22) International Filing Date:

13 February 2014 (13.02.2014)

(25) Filing Language:

Italian

(26) Publication Language:

English

(30) Priority Data:

EN2013A000002 13 February 2013 (13.02.2013) IT

(72) Inventor; and

(71) Applicant : CASSATA, Giovanni [IT/IT]; Viale
Michelangelo, 91, I-90145 Palermo (IT).

(74) Agent: MARINO, Ranieri; Contrà Paolo Lioy, 24, I-
36100 Vicenza (IT).

(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, BN, BR, BW, BY,
BZ, CA, CH, CL, 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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))

(54) Title: TOOL FOR THE INDUCTION OF THE PNEUMOPERITONEUM AND ASSEMBLY COMPRISING THE TOOL

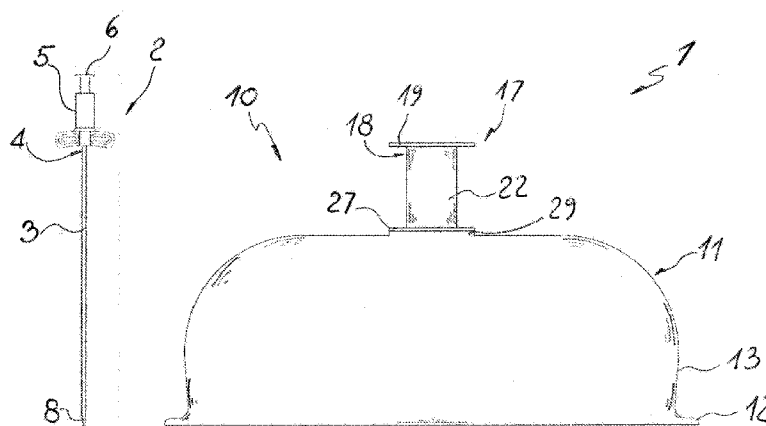


FIG. 1

(57) Abstract: A tool for the induction of the pneumoperitoneum comprises a bowl- shaped element (11, 111) having an open end (12, 112) adapted to adhere with the skin of a patient at the abdominal wall, the bowl-shaped element (11, 111) having an outer surface (13, 113), an inner surface (15, 115) and at least one hole (14, 114) with an inner diameter (ϕ) at least equal to the outer diameter (d_e) of the needle (2) used in combination, for the passage thereof. The bowl-shaped element (11, 111) is made of an elastically yieldable material to elastically deform and move, in response to a pressure exerted by an operator on its outer surface (13, 113), from an undeformed condition wherein the inner surface (15, 115) is spaced apart from the skin to a deformed condition wherein the inner surface (15, 115) is close to the abdominal wall or in at least partial contact therewith to produce an at least partial vacuum upon its elastic return in the undeformed condition, for lifting the abdominal wall.



TOOL FOR THE INDUCTION OF THE PNEUMOPERITONEUM AND
ASSEMBLY COMPRISING THE TOOL

Description

Technical Field

5 The present invention relates to the surgical instruments and in particular has as object a tool adapted to be used during induction of the pneumoperitoneum, generally during laparoscopy.

The invention also relates with an assembly comprising the above tool and a laparoscopy needle, adapted to be used in combination with each other.

10 State of the art

The induction of the pneumoperitoneum is a technique used in surgery, particularly in laparoscopic surgery, whose aim is to insufflate a gas inside the abdominal cavity, usually carbon dioxide, to distance the abdominal wall from the internal organs and create in this way a "work chamber", i.e. a zone having a volume suitable to allow the
15 insertion of surgical tools.

One of the possible way of induction of pneumoperitoneum provides the use of a special needle with a variable length, called Veress needle, adapted to be introduced into the abdominal cavity realizing a small incision on the skin after having induced the pneumoperitoneum.

20 In most cases, the lifting of the abdominal wall is performed by grasping the same with both hands, being thus particularly inconvenient and difficult to perform.

Therefore, the rate of operations carried out using the Veress needle or similar tools is rather low, in particular close to 20%.

From the state of the art some accessories are known whose aim is to facilitate the
25 lifting of the abdominal wall to make it easier and safer for the subsequent step of insertion of the needle.

For example CN201542695 discloses a pincer type tool whose object is to allow the gripping of the abdomen and the lifting of the abdominal wall.

30 However, this tool, in addition to provide an uncomfortable handling, is absolutely not safe and can easily cause damage and injury to the abdominal tissues.

Other solutions, disclosed for example in WO2011/128713, US2008/0058851, US2004/0049127, provide the use of a suction device having a bowl-shaped element substantially hemispherical or cap-shaped adapted to be placed in contact with its open edge on the skin of the patient.

The bowl-shaped element has a first center-offset opening and connected with vacuum means adapted to create a vacuum thereinside to promote the adhesion of the skin with the internal wall of the bowl-shaped element and a second opening having an axis coincident with the central axis of the bowl-shaped element and designed to allow the introduction of the needle.

A tool as disclosed above and provided with a rigid bowl-shaped element is also disclosed in WO2009/015030.

A first drawback of these solutions is represented by the presence of the inlet ducts connected to the first opening of the bowl-shaped element, which can represent an obstacle for the operator.

Moreover, the need to have a system for aspirating air, in addition to the need of providing the connection of the inlet with the bowl-shaped element at the beginning of each operation, makes these devices not of immediate use, as well as particularly expensive.

As a consequence such devices can be used only in premises that are suitably equipped and provided with suitable suction means.

A further drawback is represented by the fact that the introduction of the needle must be carried out with the same always in axial position, in practice perfectly orthogonal to the abdominal wall, thus requiring a not natural movement of the arm of the operator.

US2010210915 also shows a suction device of the type disclosed above but with a bowl-shaped element having a decentralized opening for the insertion of a surgical tool. In this case, however, in addition to the above drawbacks relating the aspiration, the introduction of the tool is not guided and therefore it requires a particular manual skill by the operator in order to not injure the internal organs.

Therefore, these drawbacks are not useful to contribute to the perception of the operation of induction of pneumoperitoneum as a safe procedure, thus not helping its diffusion.

Not least, in the tool according to the state of the art, the presence of a rigid structure, with an integral bowl-shaped element which has possibly a gripping and manipulation rod formed integrally thereto, does not allow to modify the configuration of the tool in order to adapt to the operative conditions preferred by the operator in turn using it or to change it in the light of further operational needs.

Scope of the invention

An object of the present invention is to overcome the above drawbacks, realizing a tool

for the induction of pneumoperitoneum which is simple and quick to use and which is also cost-effective.

A particular object is to provide a tool for the induction of pneumoperitoneum adapted to be used in combination with a needle for laparoscopy, such as a Veress needle or the like, which tool being easy to be handled and at the same time allowing the needle to be handled in a natural and safe way.

Still another object is to provide a tool for the induction of pneumoperitoneum which has low encumbrance.

A further object of the invention is to provide a tool for the induction of pneumoperitoneum which may be used in any kind of premise, without the need of auxiliary equipments.

Still another object is to provide a tool for the induction of pneumoperitoneum which is particularly safe for the patient undergoing the operation, be it human or animal.

A further object is to provide a tool for the induction of pneumoperitoneum which is customizable in its configuration to suit the operational needs of the patient and/or the operator carrying out the operation.

Not last object of the present invention is to provide a tool for the induction of pneumoperitoneum allowing the stroke of the needle to be adjusted to control the depth of penetration into the peritoneum.

These objects, as well as others which become more apparent hereinafter, are provided by a tool for inducing pneumoperitoneum which, according to claim 1, comprises a bowl-shaped element having an open end edge designed to come into contact relationship with the skin of a patient at the abdomen wall thereof, said bowl-shaped element having an outer surface, an inner surface designed to come at least partially into contact with the abdominal wall of a patient and at least one through-hole with an inner diameter at least equal to the outer diameter of the needle used in combination, for the passage thereof.

The bowl-shaped element is made of an elastically yieldable material to elastically deform and change, upon a pressure exerted by an operator on said outer surface, from an undeformed condition wherein said inner surface is spaced apart from the skin to a deformed condition wherein said inner surface is close to the abdominal wall to promote an at least partial vacuum upon its elastic return into said undeformed condition to lift the abdominal wall.

Thanks to this combination of features, the tool may be quickly and easily used without

it being necessary to provide special auxiliary equipments, such as air intake means.

Moreover, the elasticity of the bowl-shaped element will allow the same to adapt to the anatomy of the peritoneum during its deformation, subsequently creating a depression area which will promote the not traumatic lift of the tissue, ensuring high safety for the

5 whole operation.

Suitably, the bowl-shaped element may have the form of substantially hemispherical or spherical cap with a central axis of symmetry and the hole may have a central axis substantially parallel to the symmetry axis or inclined with respect to the same with an angle of inclination less than 45° and preferably between 1° and 5° .

10 The latter configuration will have the advantage of allowing the introduction of the needle into the peritoneum in a slightly inclined position, making easy the natural positioning of the arm by the operator.

Advantageously, the tool may comprise a substantially cylindrical guide rod having a free proximal end and the opposite distal end connected to said bowl-shaped element at
15 said hole, said rod having an axial passage substantially coaxial with said hole for the guided insertion of the needle.

With this further feature, the needle will be guided during all the insertion step through the hole, providing a greater sense of safety.

In the text, the words “proximal” and “distal” are referred to the position of the portion
20 to which they relates with respect of the operator handling the tool and the assembly.

Therefore, the word “proximal” relates to the portion closer to the operator and thus far from the abdomen of the patient, while the word “distal” relates to the opposite portion.

Further, the rod may have adjustable end-stroke means adapted to define an adjustable abutment for the needle for varying the stroke thereof.

25 By this way the tool may be always used in association with a needle of the same kind, regardless from the total length of the rod, but allowing the depth of insertion inside the peritoneum to be controlled, without it be necessary to provide a series of needle different for their useful lengths.

In a first configuration, the outer surface of said bowl-shaped element may have an
30 annular projection arranged peripherally to said hole and having an inner peripheral wall with an inner diameter substantially corresponding to the outer diameter of said substantially cylindrical rod, said connecting means being of the screw and nut type and being associated with said inner wall of said projection and to the outer surface of said rod at said distal connection end.

According to an alternative embodiment, the guide rod may instead include or be constituted by a female tubular element and a male tubular element coupled to one another via their insertion into said hole of said bowl-shaped element from opposite sides with respect to the same.

- 5 Suitably, said male and female elements may present respective countershaped means for their mutual coupling, such as screw and nut means complementary with each other for the mutual coupling by screwing, each of said elements having a radial flange adapted to abut on axially opposite faces of a same circular portion of said bowl-shaped element peripheral with respect to said central hole, for tightening said rod thereon.
- 10 In both embodiments it will be possible to remove the rod if necessary, for example for sanitizing it separately from the bowl-shaped element, or to replace it with a rod having different size so as to adapt its configuration to the specific needs of the operator and/or patient.

Suitably, said male tubular element may be externally threaded, while said central hole
15 of said bowl-shaped element may have a peripheral wall counter-threaded to allow the anchoring by screwing of said male element even in the absence of said tubular female element, so as to allow also the screwing of the female element to be adjusted and to vary the total height of the rod, adapting it to the length of the needle and/or the depth of penetration thereof selected each time by the operator.

- 20 Suitably, a plurality of guide rods may be arranged which are removably and selectively anchorable to said bowl-shaped element at said central hole and which are differentiated in size with each other.

In one of those variants, said rod of said plurality may comprise respective male tubular elements and female tubular elements adapted to be mutually coupled, said male
25 elements, respectively female, being mutually differentiated by the length and/or the outer and/or inner diameter.

Suitably, the male and/or female elements may be provided with corresponding radial circular flanges for tightening said rod on said bowl-shaped element which flanges having a maximum outer diameter differentiated with respect to the flanges of the other
30 male and/or female elements to vary the degree of deformability of said bowl-shaped element.

According to a further aspect of the invention an assembly for the induction of pneumoperitoneum is provided, which comprises, according to claim 15, an internally hollow needle having a substantially cylindrical elongated body with a gripping

proximal end adapted to be handled by an operator and a pointed or sharpened opposite distal end adapted to penetrate into the abdominal cavity of a patient through the abdominal wall and a tool according to claim 1 adapted to be placed in contact with the patient's skin at its abdominal wall to lift the same and promote the insertion of said

5 needle into the abdominal cavity.

Advantageous forms of the invention are achieved according with the dependent claims.

Brief disclosure of the drawings

Further features and advantages of the invention will become more apparent in the light of a detailed description of two preferred but not limiting embodiments of a tool for
10 induction of the pneumoperitoneum according to the invention, shown as not limiting examples with the aid of the appended drawings wherein:

FIG. 1 is a front view of the tool of the invention in a first preferred embodiment associated with a Veress needle;

FIG. 2 is a cross section view of the tool of Fig. 1;

15 FIG. 3 is an upper view of the tool of Fig. 1;

FIG. 4 is an exploded front view of a particular of the tool of Fig. 1;

FIG. 5 is a cross section view of the particular of Fig. 4 in assembled condition;

FIG. 6 is a front view of the tool of the invention in a second preferred embodiment associated with a Veress needle;

20 FIG. 7 is an upper view of the assembly of Fig. 6;

FIG. 8 is a cross section front view of the assembly of Fig. 6;

FIG. 9 is an exploded front view of the assembly of Fig. 6;

FIG. 10 is a cross section front view of the assembly of the invention in a third preferred embodiment.

Best mode of carrying out the invention

With reference to the above figures, an assembly used in laparoscopic surgery for the induction of pneumoperitoneum is shown.

In its most general embodiment the assembly, generally indicated by 1, comprises a laparoscopic needle 2, of the Veress type or the like, adapted to be used in combination
30 with a tool according to the present invention adapted to allow the lifting of the abdominal wall of a patient to promote the operation of insertion of the needle 2 and the subsequent induction of pneumoperitoneum according to traditional techniques.

The needle 2 may be any laparoscopic needle commercially available and generally it will comprise an elongated body 3 substantially cylindrical and internally hollow with a

predetermined maximum outer diameter d_e .

The elongated body 3 will have a gripping proximal end 4 provided with a shaped handle 5 adapted to be handled by an operator and also having a connector 6 to connect the tubular cavity 7 to a source of CO₂ or other fluid to be injected into the peritoneum,

5 not shown since of the known type.

The opposite distal end 8 of the elongated body 3, which is also open, will be appropriately pointed or sharpened to penetrate into the abdominal cavity of the patient through the abdominal wall.

Fig. 1 shows a first preferred but not exclusive embodiment of a tool according to the invention, generally designated by 10, which essentially comprises a bowl-shaped element 11 having an open end edge 12, substantially circular or shaped as a closed loop, designed to come into contact with the skin of a patient at the abdominal wall to be lifted.

The bowl-shaped element 11 has a substantially hemispherical or spherical cap shape with an outer surface 13 defining a central axis of symmetry X and which is provided with at least one hole 14 with an inner diameter ϕ at least equal to the outer diameter d_e of the needle 2 to be use in combination, for the passage thereof towards the skin.

The bowl-shaped element 11 is made of an elastically yielding material to elastically deform and move, in response to a pressure exerted by an operator on its outer surface 13 from the undeformed condition shown in Fig. 1, wherein it has an inner surface 15 spaced from the skin to a deformed position wherein the inner surface 15 is brought into close proximity or in partial adhesion to the skin.

In this way, the bowl-shaped element 11 will act as a suction cup, following the expulsion of air through the hole 14 and/or the edge 12, and at the time of its elastic return in the undeformed position will produce an at least partial vacuum in the chamber 16 between the abdominal wall and the inner surface 15, promoting the lifting of the abdominal wall and allowing the needle 2 to penetrate the same through the hole 14 without risk of damaging the internal organs.

The material used for the bowl-shaped element 11 may be rubber or other polymeric material with sufficient elastic yielding and porosity sufficient to adhere with the skin at its open edge 12, so as to create a chamber 16 wherein an at least partial vacuum is present. Preferably, the material will be biologically compatible and can be hot and/or cold sterilized.

Moreover, the material may be either opaque or transparent or translucent to allow the

viewing of the abdominal wall during the entire operation.

In this first embodiment, shown in Figs. 1 to 5, and more clearly visible from the section of Fig. 2, the hole 14 may have a central axis Y substantially coincident with the central axis of symmetry X.

- 5 Furthermore, the hole 14 has a diameter ϕ substantially greater than the outer diameter d_e of the needles typically used for such operations in order to allow the coupling of the bowl-shaped element 11 with a guide rod 17 whose function will also be that of allowing the manipulation of the bowl-shaped element 11 and the exertion of the pressure required for the deformation thereof.
- 10 The guide rod 17 is substantially cylindrical with a free proximal end 18, provided with a grip ring 19, more clearly shown in Fig. 3, adapted to make safer the grip of the rod 17 by the operator, and the distal end 20 connected to the bowl-shaped element 11 in correspondence of the hole 14.

The rod 17 is crossed for all its length by an axial passage 21 open at both ends and
15 substantially coaxial with hole 14, for the guided insertion of the needle 2.

Fig. 4 shows the particular configuration of the rod 17, formed by a female tubular element 22 and a male tubular element 23 adapted to be coupled with each other through their insertion into the hole 14 from opposite sides with respect thereto.

As shown in Fig. 5, the female element 22 and male element 23 are removably
20 couplable with each other by means of respective complementary shaped screw and nut means associated with each other for the mutual screwing.

In particular, the female element 22 has a through cavity 24, with an inner diameter d_i preferably not larger than the diameter ϕ of the hole 14 and even more preferably slightly lower than the same, whose inner peripheral surface 25 is threaded.

25 The male element 23, in turn, is provided with the above passage 21 for the needle 2 and has an outer peripheral surface 26 counter-threaded with respect to the inner surface 25 of the female element 22.

Moreover, the female and male elements 22, 23 have each a radial flange 27, respectively 27 and 28, adapted to abut on axially opposite faces of a same circular
30 portion 29 of the bowl-shaped element 11 peripheral to the central hole 14, for tightening the rod 17 thereon.

According to the shown embodiment, the central hole 14 has a substantially smooth peripheral wall 30 and the anchoring of the rod 17 will be obtained through the mutual tightening of the two flanges 27, 28 on the circular portion 29.

According to a not shown variant, the peripheral wall 30 of the hole may be counter-threaded with respect to the outer peripheral surface 26 of the male element 23 to allow the removable anchoring thereof by screwing to the bowl-shaped element 11 even in the absence of the tubular female element 22.

- 5 This latter may be subsequently screwed to the male element 23 with adjustable screw depth to adjust the overall length l of the rod 17.

Alternatively, the same male element 23 may be associated with different female elements 22 differentiated with each other in the axial length and/or in its outer diameter.

- 10 In both the two variants of the first shown embodiment disclosed above, it will be possible to provide a series of guide rods 17 adapted to be selectively and removably anchored to the bowl-shaped element in correspondence of the central hole 14.

The rods 17 of the series may be differentiated with each other for one or more dimensions (length, inner diameter, outer diameter) of the respective tubular female elements 22 and male elements 23.

According to a particular variant, the female 22 and/or male elements 23 of the rods 17 of the series may be differentiated with respect to the female 22 and/or male elements 23 of the other rods 17 in the outer diameter of the respective circular tightening flange 27, 28.

- 20 In this way it will be possible to vary the deformability degree of the bowl-shaped element as a function of the vacuum degree to be obtained and consequently of the lifting degree of the abdominal wall.

As matter of fact, this parameter is also selected according to the depth of penetration of the needle 2 in the abdominal wall, also determined by the operator based on anatomical characteristics of the patient.

In particular, in the case where it is necessary to penetrate the abdominal wall in a limited way, it is preferable to keep the same more spaced apart from the inner surface 15 of the bowl-shaped element.

- Therefore it is necessary to produce a lower vacuum degree and to this end it is possible to use a female element 22 and/or male element 23 having a flange 27, 28 of small diameter, so as to produce a smaller deformation of the bowl-shaped element 11 and a lower vacuum degree.

In contrast, the flanges 27, 28 of larger diameter will allow to obtain the most greater deformation of the bowl-shaped element 11 and therefore also a higher degree of

vacuum.

Fig. 6 shows a second embodiment of a tool according to the invention, generally designated by 110, having a bowl-shaped element 111 with a deformable outer surface 113 shaped as a spherical cap, an open peripheral edge 112 and an inner surface 113 designed to be brought in proximity to the abdominal wall, possibly in at least partial contact therewith, at the time of deformation so as to induce an at least partial vacuum in the inner chamber 116 in response to the elastic return in the undeformed position.

The bowl-shaped element 111 has a central hole 114 with a central axis Y substantially parallel to the central axis of symmetry X of the outer surface 113.

Although, as shown in Fig. 8, the central hole 114 may have an inner diameter ϕ substantially corresponding to the outer diameter d_e of the cylindrical body 3 of the needle 2, due to the elasticity of the bowl-shaped element 111, in the undeformed position the hole 114 may also have an inner diameter ϕ less than the outer diameter d_e of the needle 2.

As matter of fact, in this case the pointed end 8 of the latter may still cause the enlargement, allowing the easy passage of the elongated body 3 toward the skin of the abdominal wall.

The bowl-shaped element 111 will also be fastened to a substantially cylindrical guide rod 117 having a free proximal end 118 and the distal end 120 connected to the bowl-shaped element 111 at the hole 114.

In particular, the rod 117 will be crossed for all its length by an axial passage 121 open at both ends and substantially coaxial with the hole 114, for the guided insertion of the needle 2.

The bowl-shaped element 111 differs from the bowl-shaped element 11 of the first embodiment above disclosed in particular for the provision of an annular projection 130 arranged peripherally to the hole 114 and having an inner peripheral wall 131 with a diameter D_i substantially corresponding to the outer diameter D_e of the substantially cylindrical rod 117.

As shown in Fig. 9, the distal end 120 of the rod 117 is connected with the bowl-shaped element 111 by removable connection means of the screw and nut type, defined by a thread 125 formed on the inner wall 131 of the annular projection 130 and a counter-thread 126 formed on the outer surface 132 of the rod 117, in correspondence of the same distal end 120.

Moreover a sealing washer 133 may be interposed between the latter and the outer

surface 113 of the bowl-shaped element 111.

Analogously to the first embodiment shown in Fig. 1, the tool 110 may be provided with a series of rods 117 mutually differentiated in their lengths.

5 In a not shown variant, the bowl-shaped element 111 and the rod 117 may instead be integral with each other and not adapted to be uncoupled.

According to further variants of the two disclosed embodiments, also not shown, the rod 17, 117 may have adjustable end-stroke means adapted to define an adjustable abutment for the needle 2 so as to adjust the axial stroke and consequently the depth of penetration.

10 For example, the end-stroke means may include a slider adapted to axially slide on the rod 17, 117 or with respect thereto to interact with a part of the needle 2, for example with the handle 6 or with a counter abutment, not shown, associated with the elongated body 3, limiting or increasing the maximum stroke of the needle 2.

Fig. 10 shows a further variant of the tool 110 of the invention which differs from the embodiment of Fig. 6 essentially for the fact that the inner passage 121 of the rod 117 has an axis of development Z inclined with respect to the central axis of symmetry X with a predetermined inclination angle α .

Preferably, the angle of inclination α will be less than 45° and even more preferably between 1° and 5° .

20 In this case, the central hole 114 may have substantially elongated shape in plan and not more circular and therefore its central axis Y will also be inclined with the same angle of inclination α .

A further variant, not shown, the rod 17, 117 is provided with a transverse auxiliary channel in fluidic communication with the axial passage 21, 121 and adapted to allow the draining of air at the time of deformation of the bowl-shaped element 11, 111, in particular in the case in which the axial passage 21, 121 is clogged by the operator's hand.

From the foregoing it appears evident that the invention achieves the intended objects and in particular to provide a tool for the induction of pneumoperitoneum, which is of simple and immediate use, which is particularly safe and economical and which does not require special equipment auxiliary to be used.

30 The tool and the assembly according to the invention are susceptible of numerous modifications and variations, all falling within the inventive concept expressed in the appended claims. All the details may be replaced with other technically equivalent

elements, and the materials may be different depending on requirements, without departing from the scope of protection of the present invention.

Although the tool and the assembly have been disclosed with particular reference to the appended drawings, reference numbers used in the description and in the claims are
5 used to improve the intelligence of the invention and do not constitute any limitation to the claimed scope of protection.

Claims

1. A tool for the induction of the pneumoperitoneum, adapted to be used in combination with a laparoscopy needle (2), such as a Veress needle or the like, having a substantially tubular elongated body (3) with a predetermined maximum outer diameter
5 (d_e), which tool (10, 110) comprises a bowl-shaped element (11, 111) having an open end edge (12, 112) adapted to adhere with the skin of the patient at the abdominal wall, said bowl-shaped element (11, 111) having an outer surface (13, 113), an inner surface (15, 115) and at least one hole (14, 114) with an inner diameter (ϕ) at least equal to the outer diameter (d_e) of the needle (2) used in combination, for the passage thereof;
10 characterized in that said bowl-shaped element (11, 111) is made of an elastically yieldable material to elastically deform and move, in response to a pressure exerted by an operator on said outer surface (13, 113), from an undeformed condition wherein said inner surface (15, 115) is spaced apart from the skin to a deformed condition wherein said inner surface (15, 115) is close to the abdominal wall or in at least partial contact
15 therewith to produce an at least partial vacuum upon its elastic return in said undeformed condition, for lifting the abdominal wall.
2. Tool as claimed in claim 1, characterized in that said bowl-shaped element (11, 111) is substantially hemisphere-shaped or spherical cap-shaped with a central symmetry axis (X), said hole (14) having a central axis (Y) substantially parallel to said
20 central symmetry axis (X).
3. Tool as claimed in claim 1, characterized in that said bowl-shaped element (11, 111) is substantially hemisphere-shaped or spherical cap-shaped with a central symmetry axis (X), said hole (14, 114) having a central axis (Y) inclined with respect of said central symmetry axis (X) with an inclination angle (α) lower than 45° and
25 preferably between 1° and 5° .
4. Tool as claimed in claim 2 or 3, characterized by comprising a substantially cylindrical guide rod (17, 117) having a free proximal end (18, 118) and the opposite distal end (20, 120) fastened to said bowl-shaped element (10) at said hole (14, 114), said rod (17, 117) having a passage (21, 121) substantially co-axial with said hole (14,
30 114) for the guided insertion of the needle (2).
5. Tool as claimed in claim 4, characterized in that said rod (17, 117) is fastened to said bowl-shaped element (11, 111) by removable connecting means.
6. Tool as claimed in claim 5, characterized in that said outer surface (113) of said bowl-shaped element (111) has an annular projection (130) arranged peripherally to said

hole (114) and having an inner peripheral wall (131) with an inner diameter (D_i) substantially equal to the outer diameter (D_e) of said substantially cylindrical rod (117), said connecting means being of the nut and screw type (125, 126) and being associated with said inner peripheral wall (131) of said projection (130) and to the outer surface (132) of said rod (117) at said connection distal end (120).

7. Tool as claimed in claim 5, characterized in that said guide rod (17) comprises a female tubular element (22) and a male tubular element (23) adapted to be coupled with each other by their insertion into said central hole (14) of said bowl-shaped element (11) from opposite sides with respect of the same.

8. Tool as claimed in claim 7, characterized in that said female element (22) and male element (23) of said guide rod (17) has corresponding nut and screw means (25, 26) complementary shaped with each other for the mutual coupling by screwing, each of said elements (22, 23) having a radial flange (27, 28) adapted to abut against axially opposite faces of a same circular portion (29) of said bowl-shaped element (11) arranged peripherally with respect of said central hole (14), for tightening said rod (17) thereon.

9. Tool as claimed in claim 8, characterized in that said tubular male element (23) is externally threaded, said central hole (14) of said bowl-shaped element (11) having a counter-threaded peripheral wall (30) to allow the anchoring by screwing of said male element (23) even in absence of said tubular female element (22).

10. Tool as claimed in any claim 4 to 9, characterized in that said rod (17, 117) has an auxiliary transverse channel in fluidic communication with said axial passage (21, 122) and adapted to allow the drainage of air upon the deformation of said bowl-shaped element (11, 111).

11. Tool as claimed in any claim 4 to 10, characterized in that said rod (17, 117) has adjustable end-stroke means adapted to define an adjustable abutment for the needle (2).

12. Tool as claimed in any claim 4 to 11, characterized by comprising a plurality of guide rods (17, 117) adapted to be removably and selectively coupled with said bowl-shaped element (101, 111) at said central hole (14, 114).

13. Tool as claimed in any claim from 5 to 10 and according to claim 12, characterized in that said rods (17) of said plurality comprise respective male tubular elements (23) and tubular female elements (22) reciprocally coupable, said male elements (23), respectively female (22), being differentiated with each other in their lengths and/or outer and/or inner diameter.

14. Tool as claimed in claim 8 and 13, characterized in that said rods (17) of said plurality comprise respective pairs of tubular male elements (23) and tubular female elements (22) coupable with each other, the male elements (23) an/or female elements (22) of said pairs being differentiated with each other in the maximum outer diameter of the corresponding tightening flanges (27, 28) to adjust the degree of deformability of said bowl-shaped element (11).

15. Assembly for the induction of the pneumoperitoneum, comprising:

- a needle (2) having a substantially tubular elongated body (3) with a proximal gripping end (4) adapted to be handled by an operator and an opposite sharpened distal end (8) adapted to penetrate into the abdominal cavity of a patient through the abdominal wall;

- a tool (10, 110) adapted to be placed into contact with the skin of a patient at its abdominal wall for lifting it and promote the introduction of said needle (2) in the abdominal cavity;

characterized in that said tool (10, 110) is according to one or more of the preceding claims.

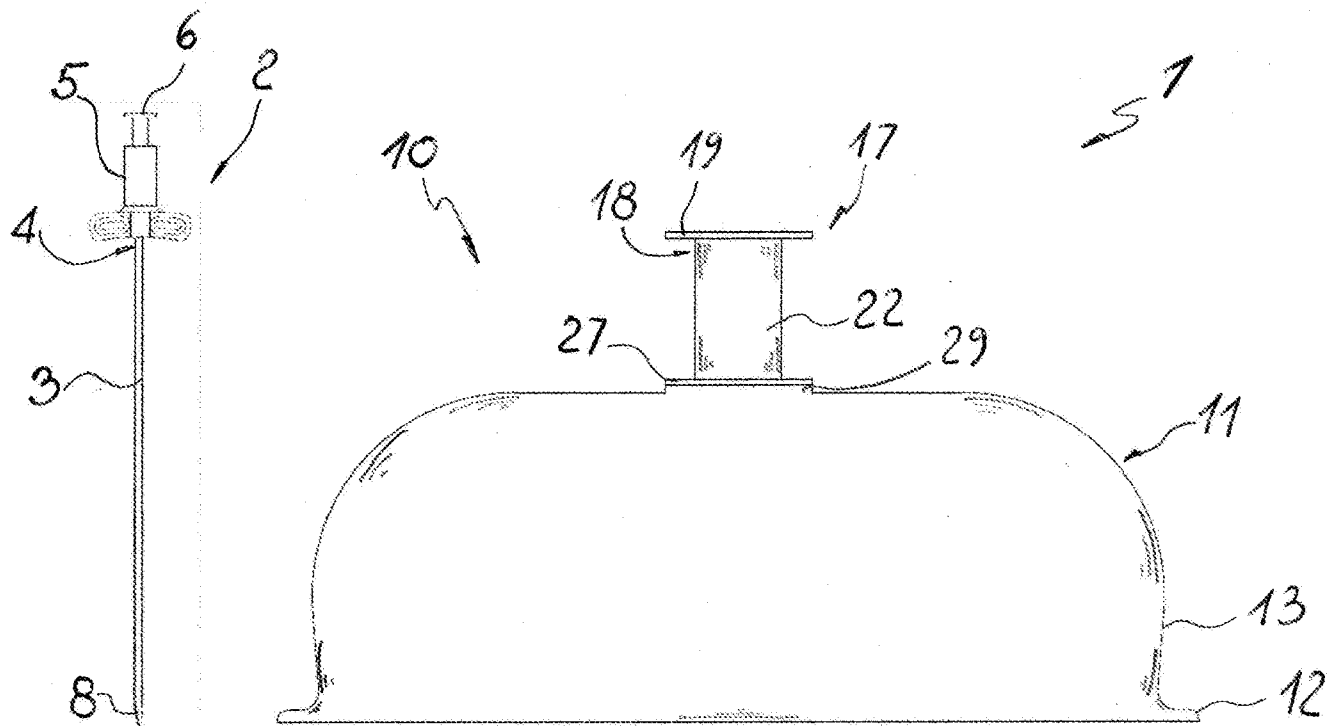


FIG. 1

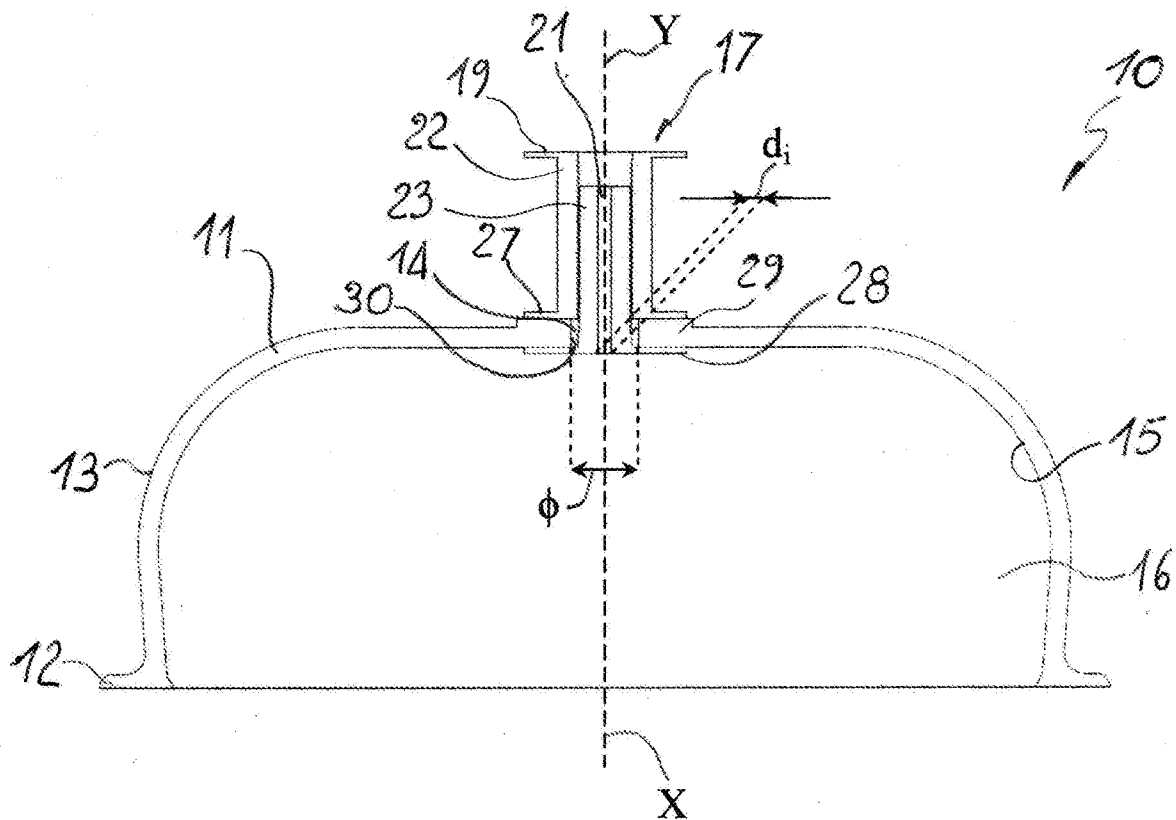


FIG. 2

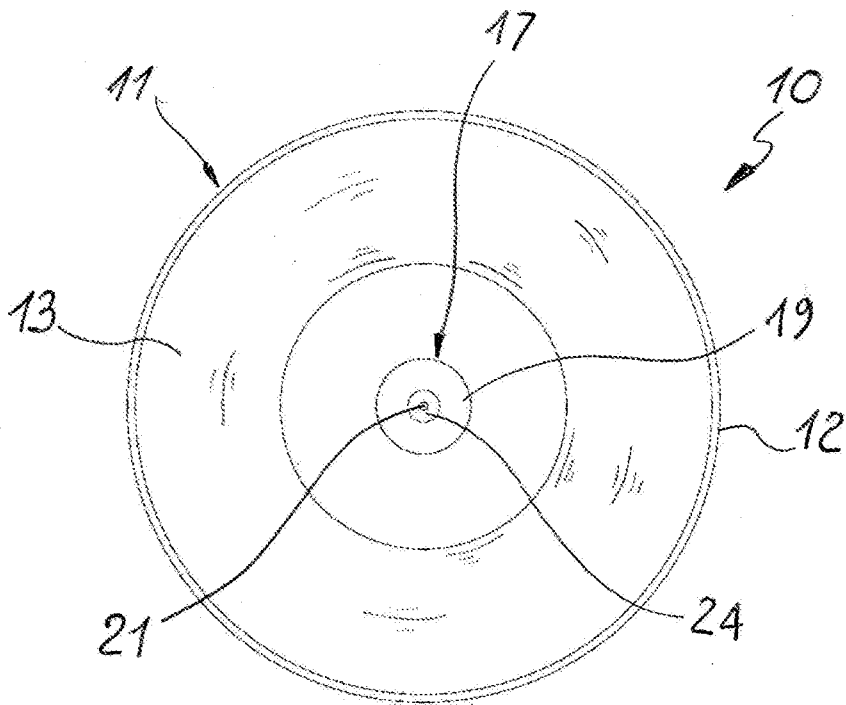


FIG. 3

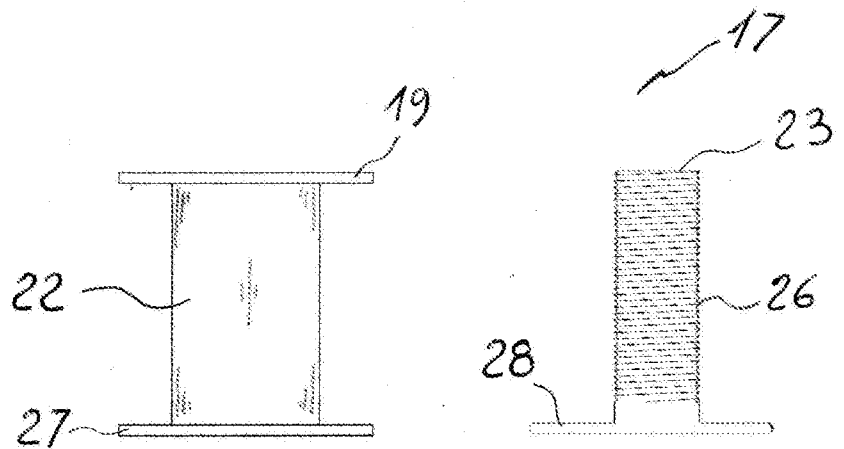


FIG. 4

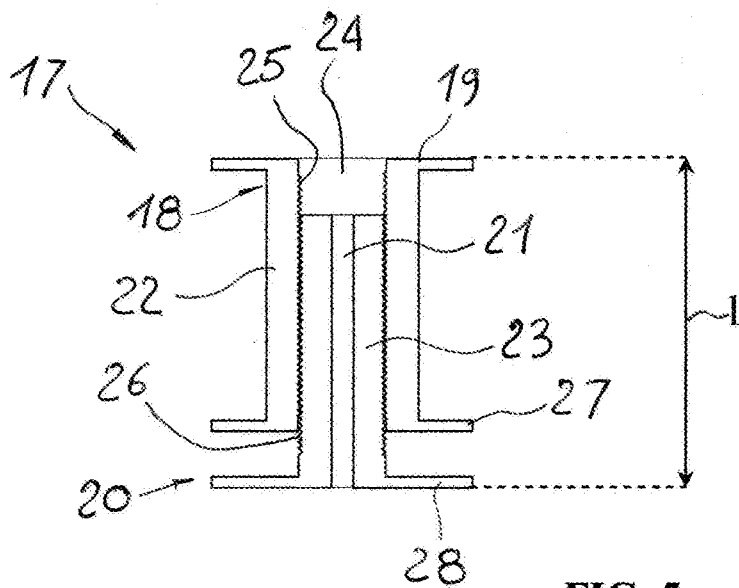


FIG. 5

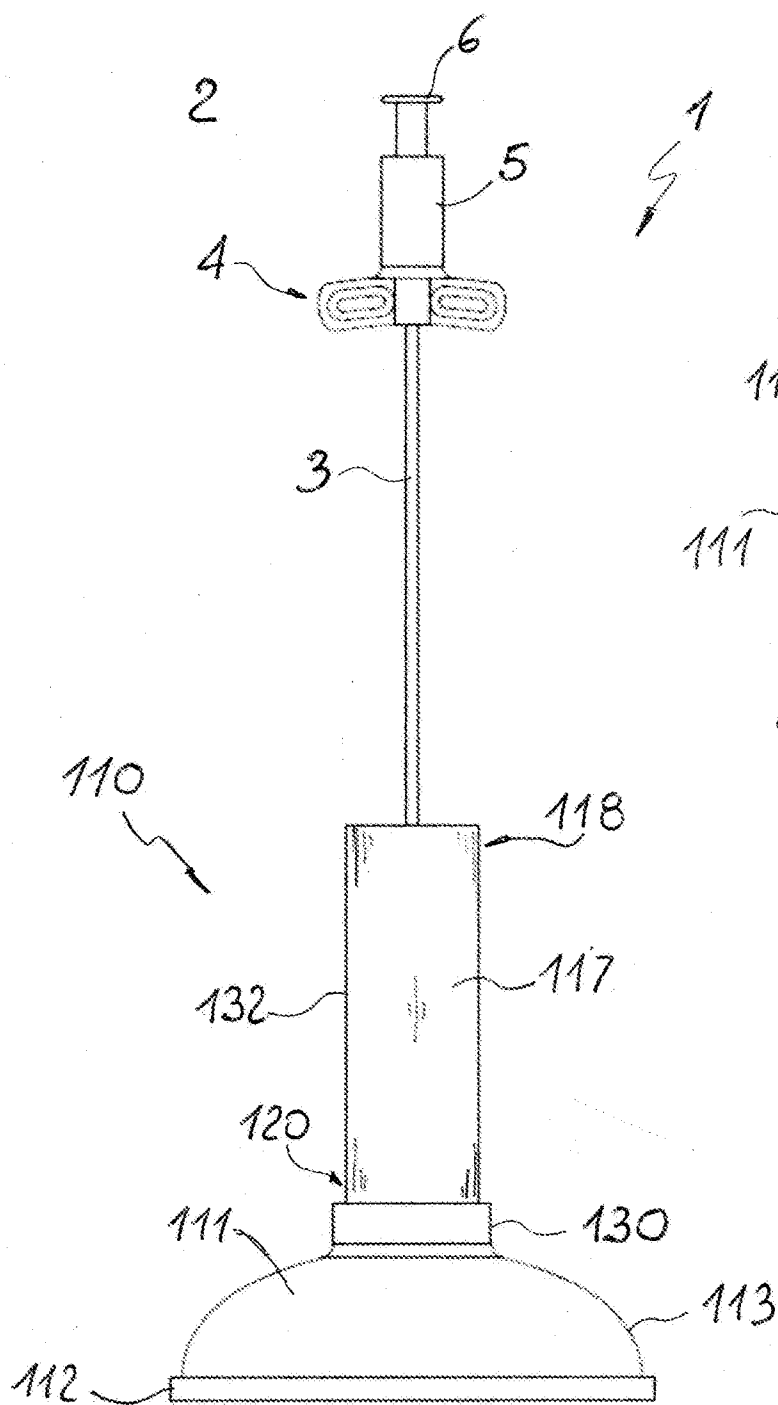


FIG. 6

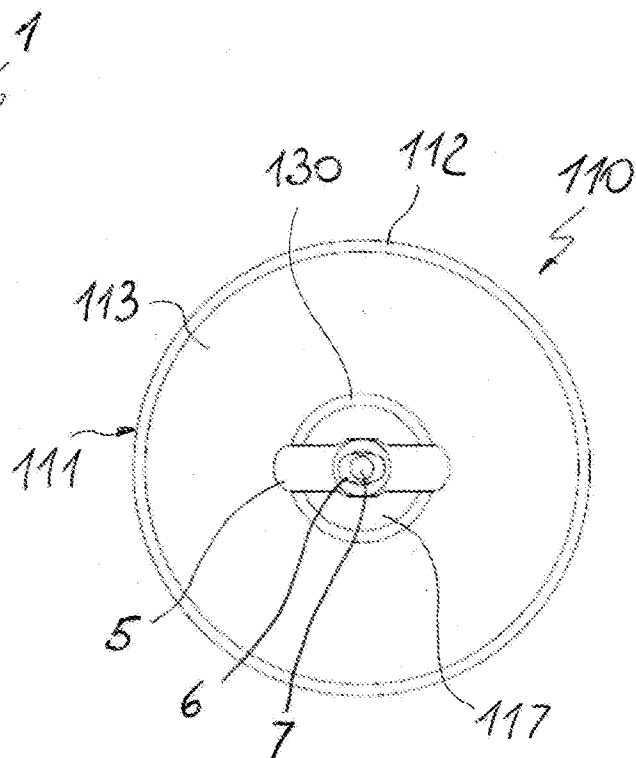


FIG. 7

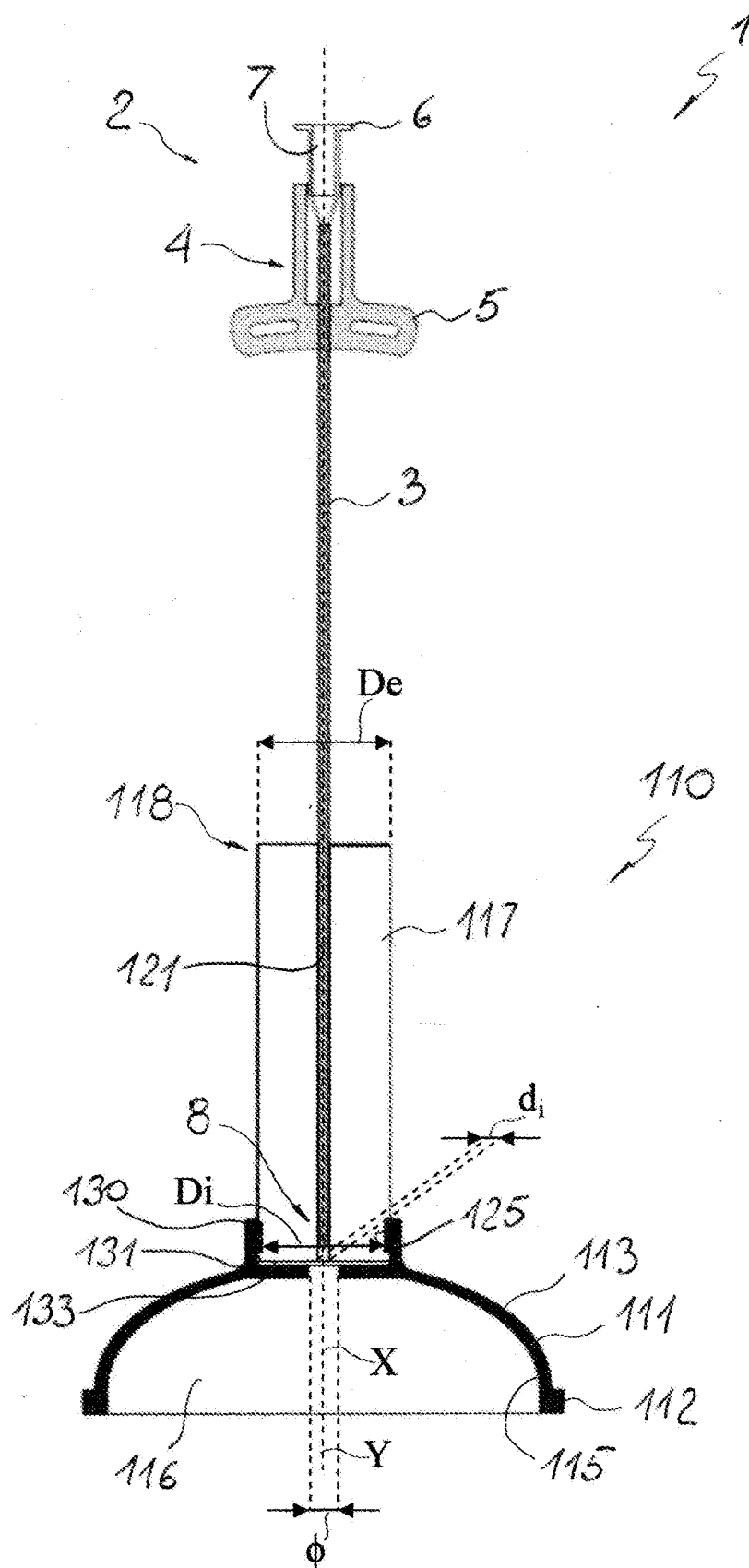
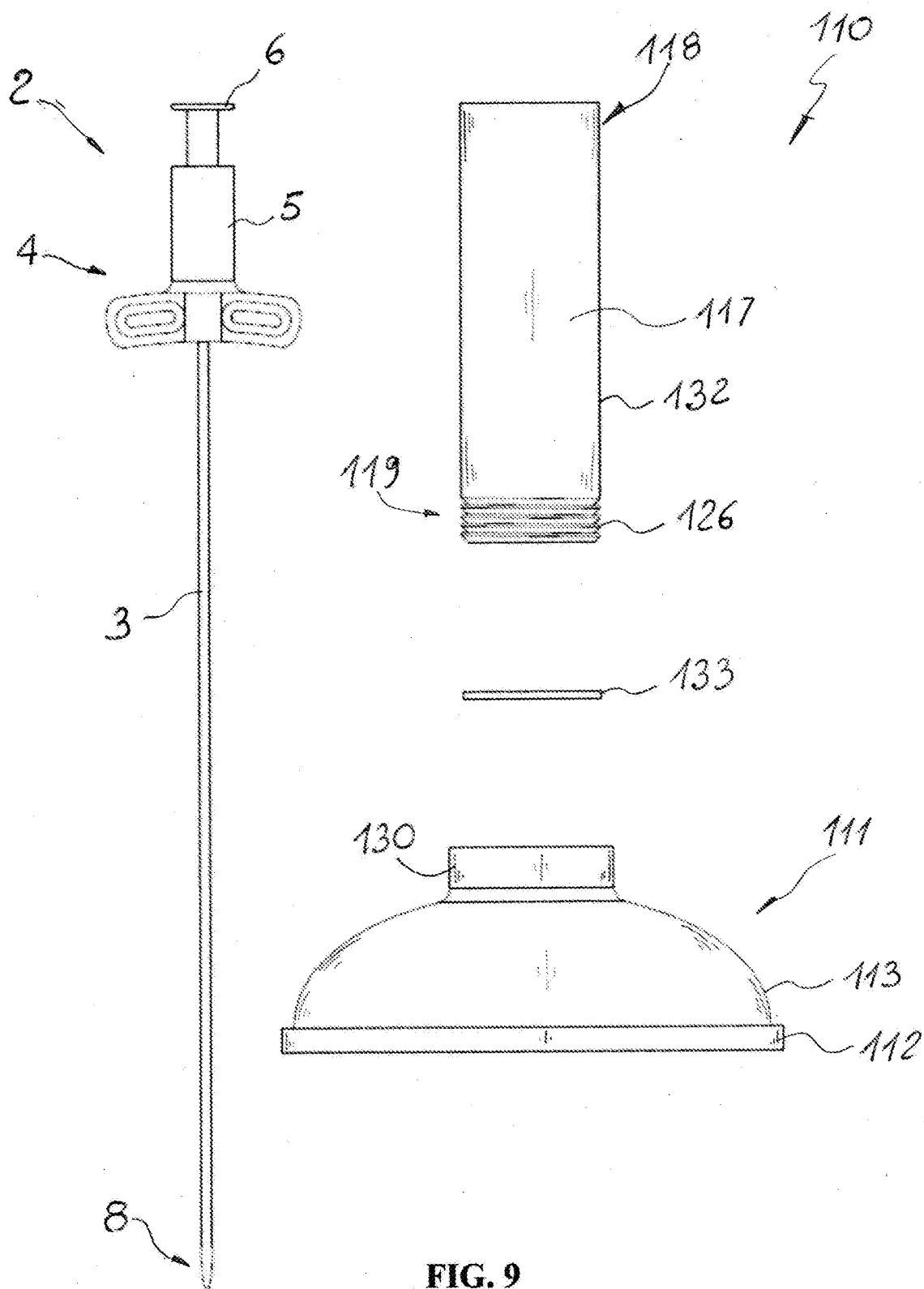


FIG. 8



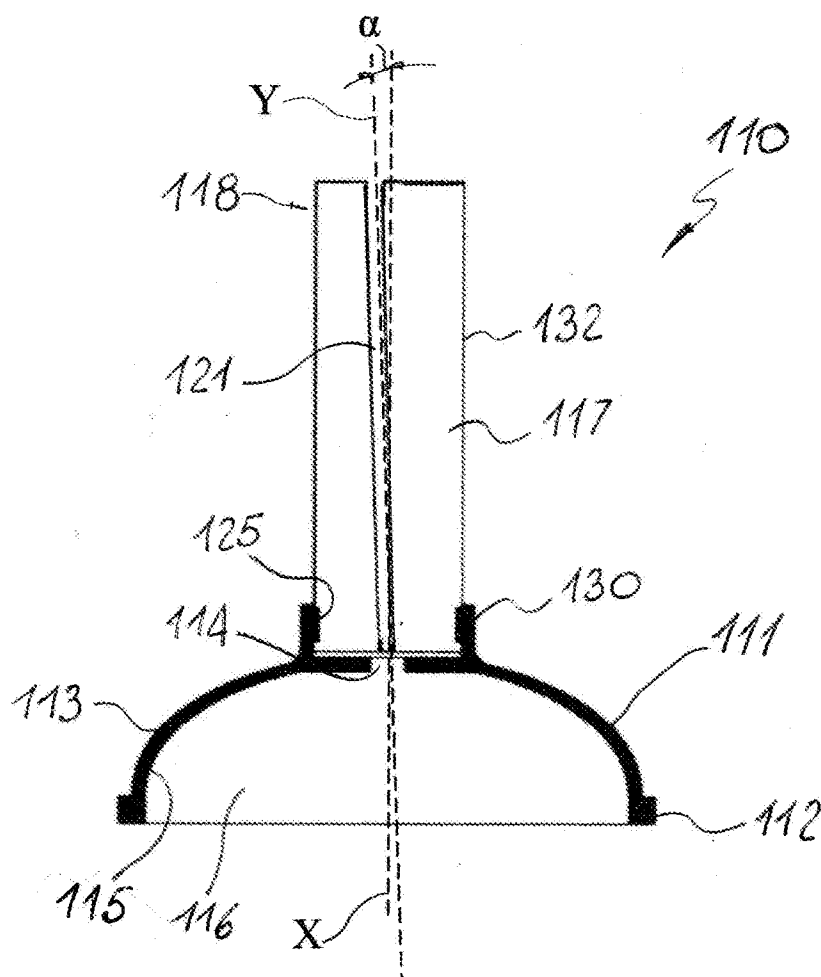


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/058974

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/42
ADD. A61B17/30 A61B17/34

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 practicable, search terms used)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2009/015030 A1 (ARAGON SURGICAL INC [US]) 29 January 2009 (2009-01-29)	1-7, 10-12,15
A	page 10 - page 13; figures 4a, 4b -----	8,9
Y	WO 2007/047813 A2 (AMS RES CORP [US]; BUYSMAN JASON J [US]; LUND ROBERT E [US]) 26 April 2007 (2007-04-26) paragraph [0054]; figure 15 -----	1-7, 10-12,15
A	WO 97/26828 A1 (GENTILLI SERGIO [IT]; VELARDOCCIA MAURO [IT]; BELFORTE GUIDO [IT]) 31 July 1997 (1997-07-31) figure 5 -----	3
A	GB 2 489 492 A (SURGICAL INNOVATIONS LTD [GB]) 3 October 2012 (2012-10-03) figures 5-6 ----- -/--	3



Further documents are listed in the continuation of Box C.



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 application or patent 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

19 May 2014

Date of mailing of the international search report

31/07/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Hausmann, Alexander

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/058974

Box No. 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
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 No. 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. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
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.:
1-12, 15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2014/058974

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 779 788 A1 (BRAINLAB AG [DE]) 2 May 2007 (2007-05-02) figure 1	5,6
Y	----- US 5 882 344 A (STOUDER JR ALBERT E [US]) 16 March 1999 (1999-03-16) figure 7 -----	11,12

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-12, 15

A tool for establishing pneumoperitoneum according to claim 7 comprising an elastically yieldable bowl-shaped element having a hole and an open end edge adapted to apply a vacuum to the skin. The tool further comprising a female tubular element and a male tubular element adapted to be coupled with each other by their insertion into the hole from opposite sides solving the problem of providing an alternative way of aligning the needle with the hole.

2. claims: 13, 14

A tool for establishing pneumoperitoneum according to claim 7 comprising an elastically yieldable bowl-shaped element having a hole and an open end edge adapted to apply a vacuum to the skin. The tool further comprising male tubular elements and female tubular elements reciprocally couplable to each other varying in their diameter or comprising tightening flanges solving the problem of providing the possibility to adjust the degree of deformability of the bowl-shaped element.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2014/058974

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009015030 A1	29-01-2009	US 2008058851 A1 WO 2009015030 A1	06-03-2008 29-01-2009
WO 2007047813 A2	26-04-2007	US 2008281269 A1 WO 2007047813 A2	13-11-2008 26-04-2007
WO 9726828 A1	31-07-1997	AU 1544397 A IT T0960033 A1 WO 9726828 A1	20-08-1997 22-04-1996 31-07-1997
GB 2489492 A	03-10-2012	EP 2691039 A1 GB 2489492 A US 2014018822 A1 WO 2012131343 A1	05-02-2014 03-10-2012 16-01-2014 04-10-2012
EP 1779788 A1	02-05-2007	EP 1779788 A1 US 2007123774 A1	02-05-2007 31-05-2007
US 5882344 A	16-03-1999	NONE	