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(54) Title: RETRACTOR DEVICE

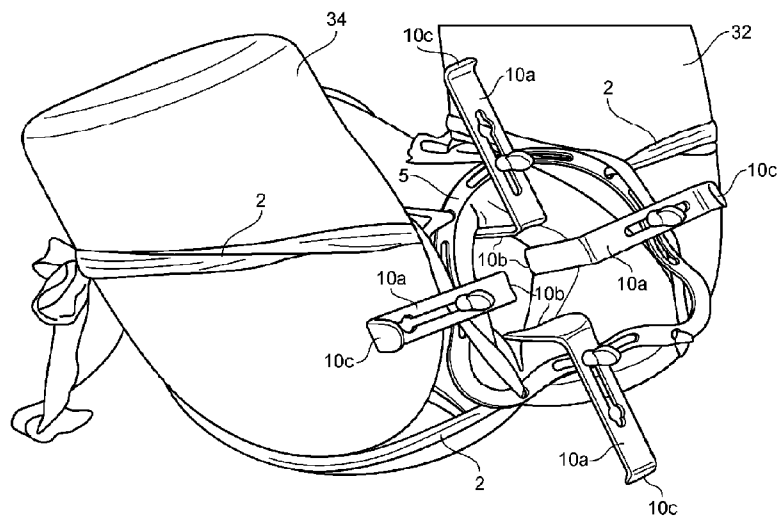


FIG. 3

(57) Abstract: A retractor device for retracting the vaginal walls of a patient comprising a main frame (5); a plurality of retractor elements (10) which are mountable on the main frame (5) and which are adapted, in use, to be inserted into the vagina of the patient; and attachment means (2) comprising a first strap and a second strap for securing the main frame to the thighs of the patient.

RETRACTOR DEVICE

The invention relates to a medical device in the gynaecological field, and in particular to a vaginal retractor device for vaginal examinations and/or surgery.

During vaginal examinations and/or surgery, retraction of the vagina is needed because the vaginal walls are normally closed together so that visual observation is practically impossible.

In order to induce a widening of the vagina, it is necessary for a surgeon to be assisted by other personnel who retract and hold the vaginal walls. The task of holding a retractor is very difficult and tiring because it must be held in place from thirty minutes to over an hour. Furthermore, difficulties can arise because of the crowded conditions resulting from a number of personnel sitting and working between the patient's legs. Personnel are also tied up in the performances of retraction so that they are unable to serve their usual tasks, such as sponging, placing of sutures, etc., during the surgery.

Accordingly, there is a need in the art for a vaginal retractor device that can maintain itself in position during vaginal examinations and/or surgery without the need for any assistance, thereby providing the surgeon with relatively free access to the patient. This need is addressed by the present invention, which solves one or more of the above-mentioned problems.

Thus, in one aspect of the present invention, there is provided a vaginal retractor device comprising:

- a main frame that is capable of being positioned against the pubic bone area of a patient;

- a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and

- at least one attachment means for attaching the main frame to the body of the patient.

The device removes the need for personnel to assist the surgeon in keeping the vaginal walls retracted, and therefore advantageously frees up the operating area for the surgeon. Moreover, the device is designed to cause little if any discomfort to the patient.

More specifically, there is provided a vaginal retractor device comprising:

- a main frame that is capable of being positioned against the pubic bone area of a patient;

- a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and

- attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.

In one embodiment, the vaginal retractor device consists of:

- a main frame that is capable of being positioned against the pubic bone area of a patient;

- a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and

- attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.

In another aspect, there is provided a kit for performing vaginal retraction, wherein the kit comprises:

- a main frame that is capable of being positioned against the pubic bone area of a patient;

- a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and

attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.

In one embodiment, the kit for performing vaginal retraction consists of:

- a main frame that is capable of being positioned against the pubic bone area of a patient;

- a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and

- attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.

In use, the main frame fits between the legs of the patient so that it is positioned against the pubic bone area. The attachment means consist of one or more straps that are capable of directly attaching to the legs, e.g. the thighs, of the patient. They help to hold the vaginal retractor device securely in place, providing the surgeon with relatively free access to the patient.

In one embodiment, the attachment means consist of a first strap and a second strap. Each strap may be tied around one of the patient's legs to hold the frame in place. Thus, there is no need for any other attachment means, such as a belt. Each strap may be made up of two pieces that are joined together when the strap is tied around one of the patient's leg.

The dimensions of the strap and the material it is made from can be adjusted to the individual subject's requirements. In one embodiment, the straps are e.g. an elastic strap. The strap may be constructed from a thermoplastic elastomer such as Hytrel® or other durable polymer such as Zytel® ST. In another embodiment, the straps are made from disposable surgical material, and may be e.g. surgical ties or gauze.

In one embodiment, the attachment means is coated in or made of a material which increases frictional resistance with the skin of the human subject. Its surface may be coated in or made of a soft adhesive or 'tacky' material which easily adheres to the surface of the subject's skin. This ensures that the correct position of the vaginal retractor device is maintained during use.

The attachment means can have a permanent fixation or they can be releasably attached to the main frame. In one embodiment, the attachment means are secured to the main frame by means of one or more (e.g. one, two, three, four, five, six, seven, eight) fasteners, notches, holes, clefts, clips or clamps, or any combination thereof in or on the main frame. In one embodiment, the attachment means are attached to the main frame via one or more holes defined within the main frame. Accordingly, the main frame may comprise one or more, e.g. four, holes so that the attachment means may be attached thereto.

One of ordinary skill in the art will readily appreciate that the main frame of the vaginal retractor device may take on a variety of shapes that are convenient for holding the retractor elements during gynaecological procedures. Thus, in one embodiment, the main frame forms any geometric shape that is convenient for positioning it against the pubic bone of the patient, e.g. a circle, an oval, a triangle, a quadrilateral. In a further embodiment, the main frame is ergonomically designed to fit between the patient's legs. In this regard, the edges of the main frame may be smooth and/or rounded to ensure safety.

In one embodiment, the main frame also contains mounting means on which the retractor elements may be adjustably and removably mounted. The mounting means permit the retractor elements to be releasably mounted on the main frame and also to be easily set to the desired position. Thus, the skilled person will appreciate that the main frame may comprise any means by which a retractor element can be adjustably and removably mounted to the main frame of the device.

For example, in one embodiment, the main frame comprises at least one slot, (e.g. one, two, three, four, five, six, seven, eight), upon which the retractor elements may be adjustably and removably mounted. The retractor elements may be secured to the main frame with an adjustable tensionable fastener such as a screw and nut combination, for example a wing nut, a locking nut or similar fastener.

In another embodiment, the main frame comprises at least one track or groove, e.g. a track or groove for each retractor element, along which the retractor elements may be adjustably and removably mounted. In another embodiment, the main frame may have a corrugated edge to which the retractor elements may be adjustably and removably mounted.

In yet a further embodiment, suture material and/or surgical tools (other than retractor elements) can also be secured to the main frame. Thus, the main frame may comprise one or more securing means (e.g. one, two, three, four, five, six, seven, eight), such as a fastener, a notch, a hole, a cleft, a clip or a clamp, or any combination thereof, in which or on which it is possible to secure suture material and surgical tools. The suture material and/or surgical tools may then be released when desired. This feature is particularly advantageous for a surgeon, for example, when performing a vaginal hysterectomy since these procedures typically require an assistant to hold the cervix tissue with a surgical tool so that the surgeon can make an incision. In this embodiment, the securing means would allow the surgeon to fix the surgical tool holding the cervix tissue onto the main frame and make the required cut without the need for any further assistance.

In one embodiment, the retractor elements are generally L-shape, each comprising a handle substantially perpendicular (such as about 60° to about 120°, for example about 75° to about 105°, e.g. about 75° or 90°) to a retractor blade.

The retractor blade may be shaped in the form of a shallow trough and/or may be curved as desired, e.g. the retractor blade might curve away from the vaginal cavity created by the retractor blade. The retractor blade can also be hollow, thereby enabling it to carry optical fibres for lighting purposes. This could greatly improve the visual field without causing any additional obstruction.

The handle can be polygonal, with grooves or rails. It may comprise one or more securing means (e.g. one, two, three, four, five, six, seven, eight), such as a fastener, a notch, a hole, a cleft, a clip or a clamp, or any combination thereof, in which or on which it is possible to attach suture material and surgical tools for a surgical operation. The handle may also have an upturned or a downturned end portion. The handle may additionally be labelled so as to indicate its positioning on the main frame.

Typically, two, three or four retractor elements may be used but other numbers may also be used in accordance with embodiments of the invention. In one embodiment, four retractor elements are used, including an anterior retractor element, a posterior retractor element, a left lateral retractor element and a right lateral retractor element.

The retractor elements are adapted to be mounted on the main frame. The retractor elements can have a permanent fixation or they can be dismountable, for adjustment to each different case. In one embodiment, the retractor elements each comprise a slot in their handles that allow the retractor elements to be adjustably mounted onto the main frame. The retractor elements may be secured to the main frame, and more particularly to a corresponding slot on the main frame, with an adjustable tensionable fastener, for example a screw and nut combination such as a wing nut, a locking nut or similar fastener. In addition, or in the alternative, the retractor elements can each comprise a one-way ratchet mechanism, whereby the retractor elements may be readily set to any desired position, and the position maintained until released by manual operation of a latch. A ratchet

mechanism allows the angle of the retractor blade with respect to the main frame to be adjusted.

In a further embodiment, the vaginal retractor device is predominantly constructed from durable materials, e.g. plastics or metal. Such materials provide the advantage of being light weight, strong, durable and resistant to rust. In one embodiment, the vaginal retractor device is composed of surgical stainless steel or an equivalent material suitable for repeated sterilization. In another embodiment, the vaginal retractor device is composed of a plastic material that is comfortable temperature-wise for the patient. The edges of the device are smooth and/or rounded to ensure safety and integrity of the sterile fields.

According to another aspect, there is provided a method of securing the vaginal retractor device as hereinbefore defined to a patient comprising:

- (a) positioning the main frame against the pubic bone area of the patient;
- (b) securing the main frame to the patient by attaching the one or more straps to the legs of the patient; and
- (c) mounting one or more retractor elements on to the main frame.

In a further embodiment, step (b) comprises securing the main frame to the patient by tying the first strap of the attachment means around one leg of the patient and tying the second strap of the attachment means around the other leg of the patient. Each strap may be made up of two pieces that are joined together when the strap is tied around one of the patient's leg.

The attachment means can have a permanent fixation or they can be releasably attached to the main frame. In one embodiment, the attachment means are secured to the main frame by means of one or more (e.g. one, two, three, four, five, six, seven, eight) fasteners, notches, holes, clefts, clips or clamps, or any combination thereof in or on the main frame. In one embodiment, the attachment means are attached to the main frame via one or more (e.g. four) holes defined within the main frame.

In a further embodiment, the retractor elements are secured to the main frame, and more particularly to the corresponding slot on the main frame, with an adjustable tensionable fastener, for example a screw and nut combination such as a wing nut, a locking nut or similar fastener.

In another aspect, there is provided a method of retracting the vaginal walls of a patient comprising:

- (a) securing the vaginal retractor device as hereinbefore defined to the patient; and
- (b) retracting the vaginal walls with the one or more retractor elements.

The invention will now be described, by way of examples only, with reference to the accompanying drawing in which:

Figures 1-3 show a vaginal retractor device according to one embodiment of the present invention.

The vaginal retractor device generally comprises a main frame 5, which is ergonomically shaped, retractor elements 10, and straps 2 for attaching the device to the patient.

The main frame 5 defines four slots 5a 5b 5c 5d which permit each retractor element 10 to be readily applied to, or removed from, the main frame 5 and also to be easily set to the desired position in use. The main frame 5 further defines four holes 52, 54, 56, 58, through which the straps 2 pass. The main frame 5 is preferably made from surgical stainless steel.

The distal end of each retractor element 10 forms a retractor blade 10b that is shaped in the form of a shallow trough. In other embodiments (not shown), the distal end of the retractor blade 10b has a slight curvature. The proximal end of each retractor element 10 forms a handle 10a that is bent about 75° or 90° to the axis of the retractor blade 10b. Thus, the retractor element 10 is generally L-shaped. In some embodiments, the handle 10a of the retractor

element 10 also has an upturned or downturned end portion 10c. The retractor elements 10 are preferably made from surgical stainless steel.

The handle 10a of each retractor element 10 defines a slot that receives an adjustable tensionable fastener 15 made up of a screw and locking nut combination that extends through the corresponding slot in the main frame 5. The retractor elements 10 are secured on the main frame 5 using the screw and locking nut 15. This allows the retractor elements 10 to be adjustably mounted to the main frame 5 of the vaginal retractor device 1 and positioned as desired.

The vaginal retractor device 1 is sterilized prior to use. To deploy the vaginal retractor device 1, the patient's legs 32, 34 are flexed in the lithotomy position. The patient's feet may be placed in stirrups or otherwise supported in an elevated position. The main frame 5 is fitted between the thighs of the patient bearing against the pubic bone area. The main frame 5 is secured in position by the attachment means. The first strap 2 is passed through holes 52, 54 and is wrapped around the patient's thigh 32, and the second strap 2 is passed through holes 56, 58 and is wrapped around the patient's other thigh 34.

In other embodiments (not shown), the first strap is made up of two pieces, one of which is attached to hole 52 and the other of which is attached to hole 54. The pieces are wrapped around the patient's thigh 32 and tied together. The second strap is made up of two pieces, one of which is attached to hole 56 and the other of which is attached to hole 58. The pieces are wrapped around the patient's thigh 34 and tied together.

The retractor elements 10 are sequentially inserted into the vagina of the patient and secured to the main frame 5 by the adjustable tensionable fasteners 15 that pass through the slots defined within the main frame 5 and retractor elements 10. The retractor elements 10 can be adjusted up, down and side to side as necessary before or during the procedure. As will be appreciated, the particular order of insertion of the retractor elements 10 may be adjusted according to the nature and progress of the surgery.

CLAIMS

1. A vaginal retractor device comprising:
 - a main frame that is capable of being positioned against the pubic bone area of a patient;
 - a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and
 - attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.
2. A kit for performing vaginal retraction, wherein the kit comprises:
 - a main frame that is capable of being positioned against the pubic bone area of a patient;
 - a plurality of retractor elements which are mountable on the main frame and which are adapted, in use, to be inserted into the vagina of the patient; and
 - attachment means comprising one or more straps that are capable of attaching to the legs of the patient so as to secure the main frame to the patient, wherein the attachment means do not comprise a belt.
3. The device of claim 1 or the kit of claim 2, wherein the attachment means comprise a first strap for attachment to one leg of the patient and a second strap for attachment to the other leg of the patient.
4. The device or kit of claim 3, wherein the first and second straps are attachable to the main frame via one or more holes defined within the main frame.
5. The device or kit of claim 3, wherein the first and second straps are attachable to the main frame via four holes defined within the main frame.

6. The device or kit of any preceding claim, wherein the main frame is ergonomically designed.
7. The device or kit of any preceding claim, wherein the main frame further comprises mounting means for the retractor elements.
8. The device or kit of claim 7, wherein the main frame defines at least one slot for releasably mounting the retractor elements.
9. The device or the kit of any preceding claim, wherein the main frame further comprises at least one fastener, notch, hole, cleft, clip or clamp.
10. A method of securing the vaginal retractor device of any of claims 1 and 3-8 to a patient comprising:
 - (a) positioning the main frame against the pubic bone area of the patient;
 - (b) securing the main frame to the patient by attaching the one or more straps to the legs of the patient; and
 - (c) mounting one or more retractor elements on to the main frame.
11. The method of claim 10 comprising:
 - (a) positioning the main frame against the pubic bone area of the patient;
 - (b) securing the main frame to the patient by tying the first strap of the attachment means around one leg of the patient and tying the second strap of the attachment means around the other leg of the patient; and
 - (c) mounting one or more retractor elements on to the main frame.

1/3

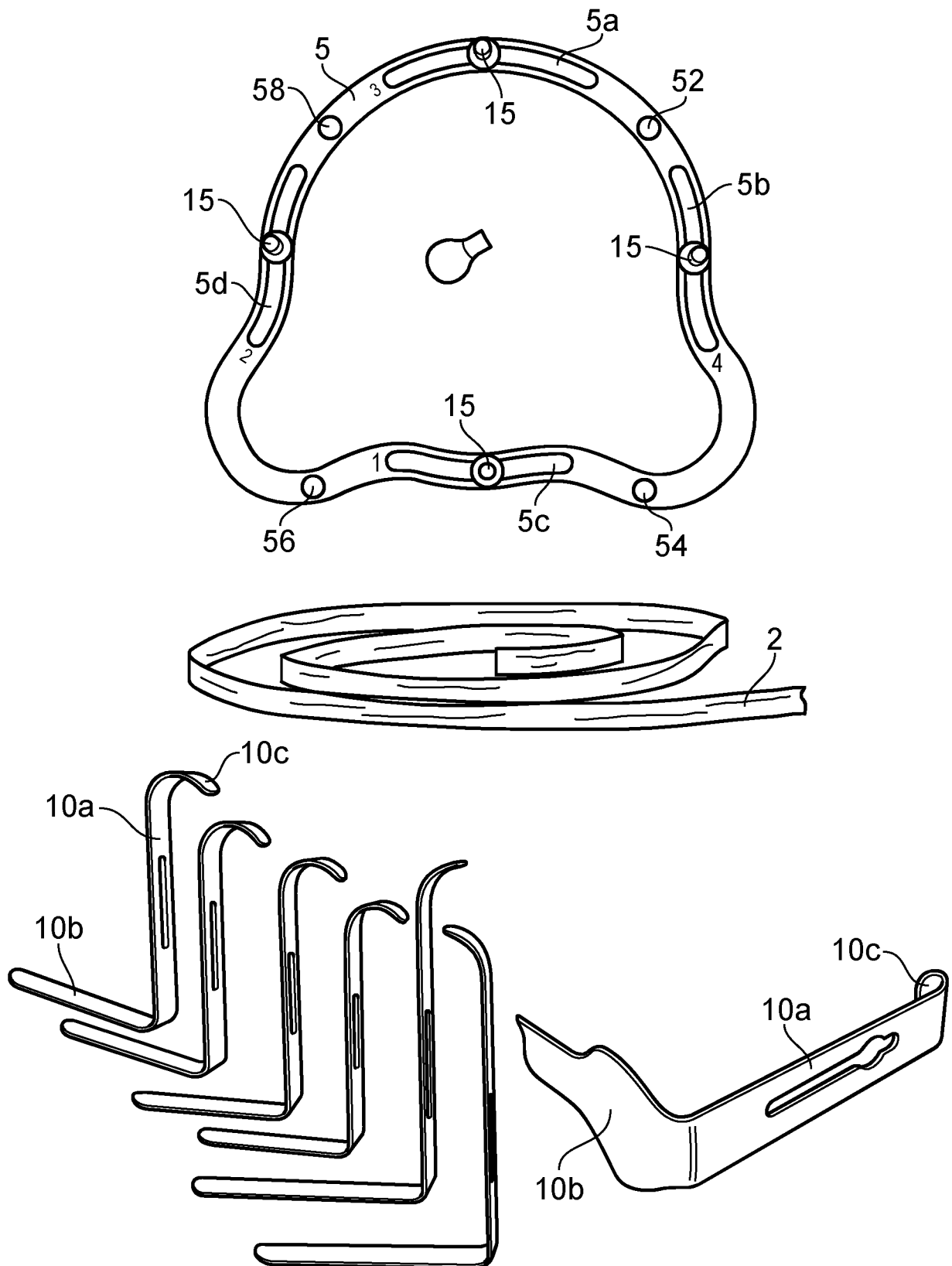


FIG. 1

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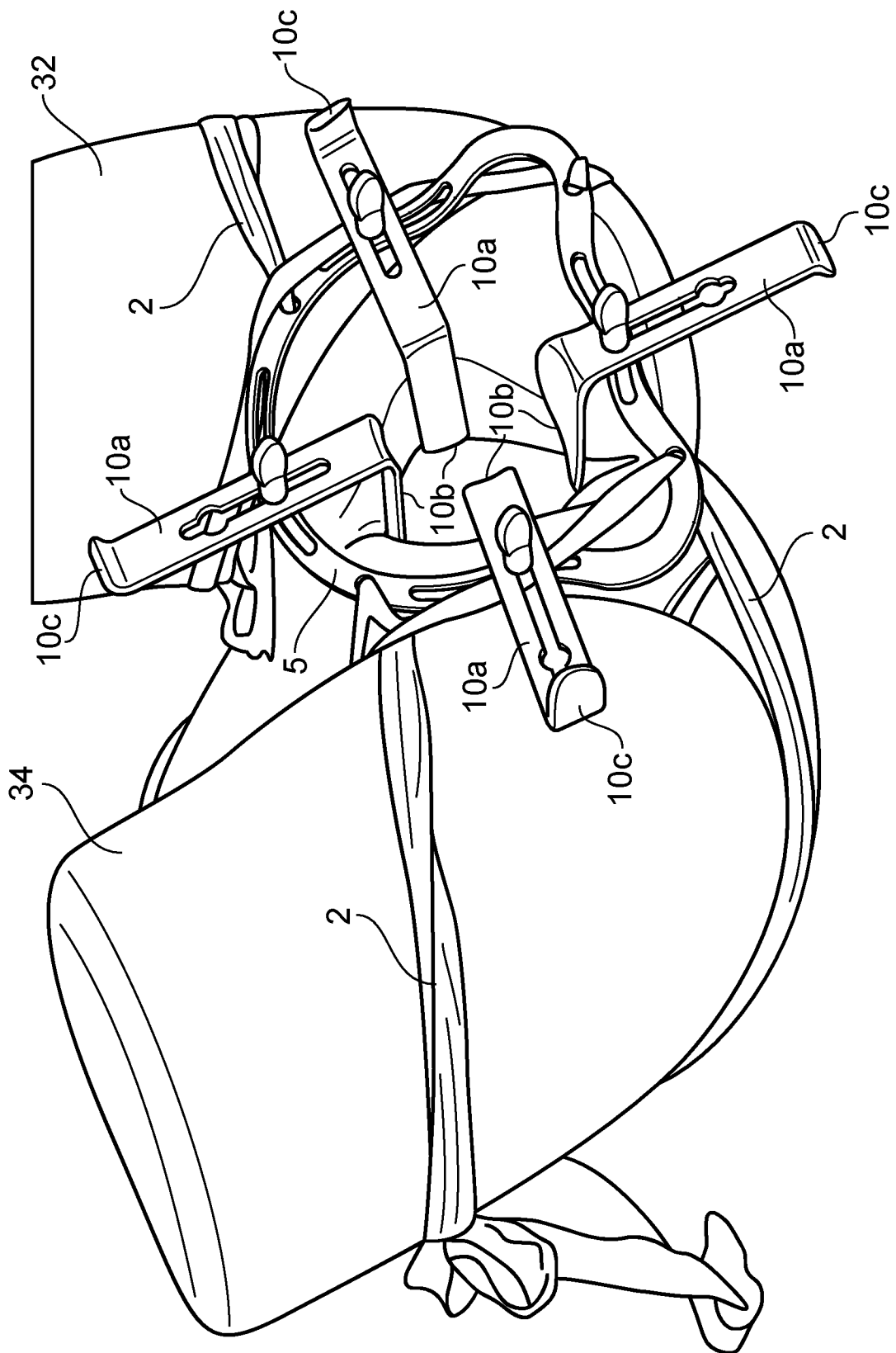


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2011/051150

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/02 A61B1/32
ADD.

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

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	US 497 064 A (M. E. VAN METER) 9 May 1893 (1893-05-09) the whole document	1-10
X	FR 2 841 458 A1 (KIRSCH FREDERIQUE NOIR [FR]) 2 January 2004 (2004-01-02) page 5, line 20 - page 6, line 16	1-4,6-10
A	US 2004/059193 A1 (FANOUS REFAAT S [US]) 25 March 2004 (2004-03-25) the whole document	1



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2011/051150

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 497064	A	NONE	

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US 2004059193	A1	25-03-2004	US 2006149138 A1 06-07-2006
