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(54) Title: APPENDECTOMY MODEL

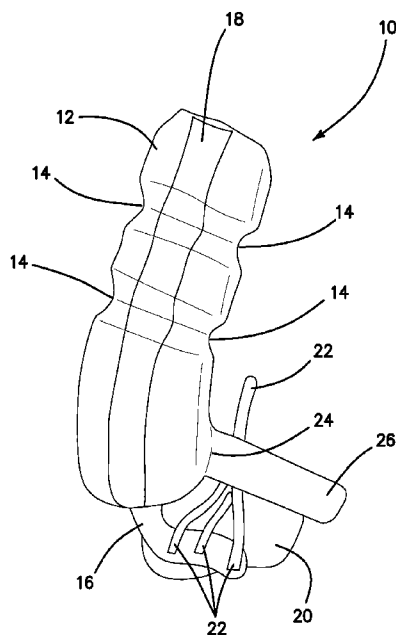


FIG. 1

(57) Abstract: An appendectomy model for surgical training is provided. The model includes a simulated large intestine with a central lumen interconnected with a lumen of an artificial appendix. The model also includes a simulated appendiceal artery, simulated mesoappendix and a simulated ileum. The simulated ileum made of white silicone is embedded between a first layer of pink silicone and a second layer of pink silicone to create a realistic anatomical landmark particularly suitable for laparoscopic appendectomy training.

APPENDECTOMY MODEL

Cross-Reference to Related Application

[0001] This patent application claims benefit and priority to U.S. Provisional Patent Application Serial No. 62/195,439 entitled "Appendectomy model" filed on July 22, 2015 incorporated herein by reference in its entirety.

Field of the Invention

[0002] This application is generally related to surgical training tools, and in particular, to simulated tissue structures and models for teaching and practicing various surgical techniques and procedures related but not limited to laparoscopic, endoscopic and minimally invasive surgery.

Background of the Invention

[0003] Medical students as well as experienced doctors learning new surgical techniques must undergo extensive training before they are qualified to perform surgery on human patients. The training must teach proper techniques employing various medical devices for cutting, penetrating, clamping, grasping, stapling, cauterizing and suturing a variety of tissue types. The range of possibilities that a trainee may encounter is great. For example, different organs and patient anatomies and diseases are presented. The thickness and consistency of the various tissue layers will also vary from one part of the body to the next and from one patient to another. Different procedures demand different skills. Furthermore, the trainee must practice techniques in various anatomical environs that are influenced by factors such as the size and condition of the patient, the adjacent anatomical landscape and the types of targeted tissues and whether they are readily accessible or relatively inaccessible.

[0004] Numerous teaching aids, trainers, simulators and model organs are available for one or more aspects of surgical training. However, there is a need for models or simulated tissue elements that are likely to be encountered in and that can be used for practicing endoscopic and laparoscopic, minimally invasive, transluminal

surgical procedures. In laparoscopic surgery, a trocar or cannula is inserted to access a body cavity and to create a channel for the insertion of a camera such as a laparoscope. The camera provides a live video feed capturing images that are then displayed to the surgeon on one or more monitors. At least one additional small incision is made through which another trocar/cannula is inserted to create a pathway through which surgical instruments can be passed for performing procedures observed on the video monitor. The targeted tissue location such as the abdomen is typically enlarged by delivering carbon dioxide gas to insufflate the body cavity and create a working space large enough to accommodate the scope and instruments used by the surgeon. The insufflation pressure in the tissue cavity is maintained by using specialized trocars. Laparoscopic surgery offers a number of advantages when compared with an open procedure. These advantages include reduced pain, reduced blood and shorter recovery times due to smaller incisions.

[0005] Laparoscopic or endoscopic minimally invasive surgery requires an increased level of skill compared to open surgery because the target tissue is not directly observed by the clinician. The target tissue is observed on monitors displaying a portion of the surgical site that is accessed through a small opening. Therefore, clinicians need to practice visually determining tissue planes, three-dimensional depth perception on a two-dimensional viewing screen, hand-to-hand transfer of instruments, suturing, precision cutting and tissue and instrument manipulation. Typically, models simulating a particular anatomy or procedure are placed in a simulated pelvic trainer where the anatomical model is obscured from direct visualization by the practitioner. Ports in the trainer are employed for passing instruments to practice techniques on the anatomical model hidden from direct visualization. Simulated pelvic trainers provide a functional, inexpensive and practical means to train surgeons and residents the basic skills and typical techniques used in laparoscopic surgery such as grasping, manipulating, cutting, tying knots, suturing, stapling, cauterizing as well as how to perform specific surgical procedures that utilized these basic skills.

[0006] Organ models for use with simulated pelvic trainers on which surgeons can train surgical techniques are needed. These organ models need to be realistic so that the surgeon can properly learn the techniques and improve their skills.

Summary of the Invention

[0007] According to one aspect of the invention, a simulated tissue structure for surgical training is provided. The simulated tissue structure includes a simulated large intestine having a tubular structure defining a central lumen extending along a longitudinal axis between a proximal end and a distal end. The simulated tissue structure includes a simulated appendix connected to the distal end of the simulated large intestine. A simulated teniae coli is connected to and extends longitudinally along the simulated large intestine. The simulated tissue structure includes at least one simulated artery having a middle portion between a proximal end and a distal end. The at least one simulated artery is connected to the simulated appendix. A silicone pocket substantially defines a cavity that encloses the simulated appendix and at least part of the simulated artery.

[0008] According to another aspect of the invention, a simulated tissue structure for surgical training is provided. The simulated tissue structure includes an appendectomy model. The appendectomy model includes a first layer of silicone having an inner surface defining a central lumen having a diameter. A second layer of silicone is provided. A strip of silicone is embedded between the first layer and the second layer. The strip of silicone has an inner surface, an outer surface, a length defined between a top edge and a bottom edge, and a width defined between a first side edge and a second side edge.

[0009] According to another aspect of the invention, a method of manufacturing a simulated tissue structure is provided. The method includes the steps of providing a mandrel and applying a first layer of wet silicone onto the mandrel. The first layer is cured to create a first tubular structure that defines a central lumen occupied by the mandrel. A narrow strip of silicone that is approximately less than half of the diameter of the central lumen is provided and applied longitudinally along the first tubular structure. A second layer of wet silicone is applied over the first tubular structure and narrow strip. After the second layer is allowed to cure, the combination of the first layer, second layer and narrow strip is removed from the mandrel.

Brief Description of the Drawings

[0010] FIG. 1 is a top view of an appendectomy model with the second layer of yellow silicone removed to show the simulated appendix and arteries according to the present invention.

[0011] FIG. 2 is top view of an appendectomy model with a second layer of yellow silicone forming a pocket with the first yellow silicone layer beneath to contain the simulated appendix arteries according to the present invention.

Detailed Description of the Invention

[0012] An appendectomy model for laparoscopic procedures is provided. The appendectomy model has been designed to teach surgeons and residents the anatomy and steps involved in an appendectomy procedure. The model is made of silicone, thermoplastic elastomer (TPE) and foam and contains all the important anatomical landmarks. The appendectomy model is placed inside a laparoscopic trainer concealed from direct observation with the naked eye so that laparoscopic surgical skills may be practiced while viewing the operation on a video monitor.

[0013] FIG. 1 illustrates an appendectomy model 10 according to the present invention. The model 10 includes a portion of a simulated large intestine 12 that includes a plurality of transverse folds 14. The distal end of the simulated large intestine 12 is integrally molded together with an appendix 16 by applying a first layer of wet silicone to a rotating mandrel. The mandrel has the shape of the simulated large intestine with the shape of the simulated appendix 16 connected to the end of the mandrel. The diameter of the simulated appendix 16 is smaller than the diameter of the simulated large intestine 12. The first layer of silicone is allowed to cure around the mandrel. The mandrel is rotated to allow an even layer to cure taking the shape of the mandrel. Then a white narrow strip 18 of pre-formed silicone is laid over along the longitudinal axis of the tubular simulated large intestine 12 as shown in FIGs. 1 and 2 to define a simulated teniae coli. Silicone adhesive may be used to attach the white narrow strip to the first layer of silicone. Then a second layer of wet silicone is applied to sandwich the white narrow strip 18 between the first layer and the second layer of

silicone. The narrow long white narrow strip 18 of silicone is substantially rectangular in shape. In another variation, the narrow strip 18 may have wider lateral portions interspersed with narrower lateral portions along the longitudinal length of the simulated large intestine 12. The wider portions of the narrow strip 18 are substantially spaced apart and aligned with the transverse folds 14 of the large intestine 12 before being attached and embedded between two layers of silicone. The cured silicone structure is removed from the mandrel.

[0014] Still referencing FIG. 1, a small thin first layer 20 of yellow silicone is attached to the bottom of the simulated large intestine 12 and may or may not be attached to the bottom of the appendix 16. One or more red silicone tubes 22 representing arteries are attached to the first layer 20 of yellow silicone along the middle of the simulated arteries such as a simulated appendiceal artery. The tubes 22 may be solid or hollow. The distal ends of the red artery tubes 22 are attached to the top of the appendix 16 with adhesive as shown. A hole 24 is formed near the distal end of the simulated large intestine 12 and a pre-formed tube 26 of silicone is inserted into the hole 24 to simulate the ileum. The proximal ends of the red tubes 22 are placed under the ileum as shown in FIG. 1. A thin second layer 28 of yellow silicone is then applied above the first layer 20 of silicone and attached to the lower edge of the yellow first layer 20 and to the artificial large intestine 12 to create a cave or pocket-like structure that covers and contains the appendix 16, part of the large intestine 12, red tubes 22 and part of the artificial ileum 26 as shown in FIG. 2. The whole model is attached to a red background sheet 30 of textured silicone. Hook-and-loop type fastening means may be used under the model 10 and, in one variation, under the background sheet 30 to attach and secure the model 10 to the inside of a laparoscopic trainer. In one variation, the background sheet 30 is made of high density ethylene vinyl acetate foam.

[0015] The practitioner will practice a laparoscopic appendectomy by placing the appendectomy model 10 inside a laparoscopic trainer. The model 10 is secured to the base of a trainer with the fastening means. A scalpel or other instrument is used to cut through the top yellow second layer 28 of silicone to open the pocket and visualize the arteries 22 beneath. The practitioner will then practice cutting through the red arteries 22 and retracting them. The appendix 16 will then be cut and removed.

[0016] In another variation, the model 10 is formed as part of another larger model or tissue structure such as an abdominal organ model or pelvic model and is sized and configured to be placed inside a simulated laparoscopic environment such as a surgical training device which will now be described.

[0017] A surgical training device that is configured to mimic the torso of a patient such as the abdominal region. The surgical training device provides a body cavity substantially obscured from the user for receiving simulated or live tissue or model organs or training models of the like described in this invention. The body cavity is accessed via a tissue simulation region that is penetrated by the user employing devices to practice surgical techniques on the tissue or practice model found located in the body cavity. Although the body cavity is shown to be accessible through a tissue simulation region, a hand-assisted access device or single-site port device may be alternatively employed to access the body cavity. An exemplary surgical training device is described in U.S. Patent No. 8,764,452 entitled "Portable Laparoscopic Trainer" filed on September 29, 2011 and incorporated herein by reference in its entirety. The surgical training device is particularly well suited for practicing laparoscopic or other minimally invasive surgical procedures.

[0018] The surgical training device includes a top cover connected to and spaced apart from a base by at least one leg. A plurality of legs may be employed to space apart the top cover. The surgical training device is configured to mimic the torso of a patient such as the abdominal region. The top cover is representative of the anterior surface of the patient and the space between the top cover and the base is representative of an interior of the patient or body cavity where organs reside. The surgical trainer is a useful tool for teaching, practicing and demonstrating various surgical procedures and their related instruments in simulation of a patient undergoing a surgical procedure. Surgical instruments are inserted into the cavity through the tissue simulation region as well as through pre-established apertures in the top cover. Various tools and techniques may be used to penetrate the top cover to perform mock procedures on simulated organs or practice models placed between the top cover and the base. The base includes a model-receiving area or tray for staging or holding a simulated tissue model or live tissue. The model-receiving area of the base includes

frame-like elements for holding the model in place. To help retain a simulated tissue model or live organs on the base, a clip attached to a retractable wire is provided at locations. The retractable wire is extended and then clipped to hold the tissue model in position substantially beneath the tissue simulation region. Other means for retaining the tissue model include a patch of hook-and-loop type fastening material affixed to the base in the model receiving area such that it is removably connectable to a complementary piece of hook-and-loop type fastening material affixed to the model 10.

[0019] A video display monitor is hinged to the top. The video monitor is connectable to a variety of visual systems for delivering an image to the monitor. For example, a laparoscope inserted through one of the pre-established apertures or a webcam located in the cavity and used to observe the simulated procedure can be connected to the video monitor and/or a mobile computing device to provide an image to the user. Also, audio recording or delivery means may also be provided and integrated with the trainer to provide audio and visual capabilities. Means for connecting a portable memory storage device such as a flash drive, smart phone, digital audio or video player, or other digital mobile device is also provided, to record training procedures and/or play back pre-recorded videos on the monitor for demonstration purposes. Of course, connection means for providing an audio visual output to a screen larger than the monitor is provided. In another variation, the top cover 10 does not include a video display but includes means for connecting with a laptop computer, a mobile digital device or tablet and connecting it by wire or wirelessly to the trainer.

[0020] When assembled, the top cover is positioned directly above the base with the legs located substantially around the periphery and interconnected between the top cover and base. The top cover and base are substantially the same shape and size and have substantially the same peripheral outline. The internal cavity is partially or entirely obscured from view. The legs include openings to allow ambient light to illuminate the internal cavity as much as possible and also to advantageously provide as much weight reduction as possible for convenient portability. The top cover is removable from the legs which in turn are removable or collapsible via hinges or the like with respect to the base. Therefore, the unassembled trainer has a reduced height that makes for easier portability. In essence, the surgical trainer provides a simulated body

cavity that is obscured from the user. The body cavity is configured to receive at least one surgical model accessible via at least one tissue simulation region and/or apertures in the top cover through which the user may access the models to practice laparoscopic or endoscopic minimally invasive surgical techniques.

[0021] Any portion of the model can be made of one or more organic base polymer including but not limited to hydrogel, single-polymer hydrogel, multi-polymer hydrogel, rubber, latex, nitrile, protein, gelatin, collagen, soy, non-organic base polymer such as thermo plastic elastomer, kraton, silicone, foam, silicone-based foam, urethane-based foam and ethylene vinyl acetate foam and the like. Into any base polymer one or more filler may be employed such as a fabric, woven or non-woven fiber, polyester, nylon, cotton and silk, conductive filler material such as graphite, platinum, silver, gold, copper, miscellaneous additives, gels, oil, cornstarch, glass, dolomite, carbonate mineral, alcohol, deadener, silicone oil, pigment, foam, poloxamer, collagen, gelatin and the like. The adhesives employed may include but are not limited to cyanoacrylate, silicone, epoxy, spray adhesive, rubber adhesive and the like.

[0022] It is understood that various modifications may be made to the embodiments and variations disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

Claims

We claim:

1. A simulated tissue structure for surgical training comprising:
 - a simulated large intestine having a tubular structure defining a central lumen extending along a longitudinal axis between a proximal end and a distal end;
 - a simulated appendix connected to the distal end of the simulated large intestine;
 - a simulated teniae coli connected to and extending longitudinally along the simulated large intestine;
 - at least one simulated artery having a middle portion between a proximal end and a distal end; the at least one simulated artery being connected to the simulated appendix;
 - a pocket substantially enclosing the simulated appendix.
- 2 The simulated tissue structure of claim 1 wherein the simulated large intestine includes at least one transverse fold having a reduced diameter.
3. The simulated tissue structure of claim 2 wherein the simulated teniae coli includes at least one wider lateral portion along the longitudinal length of the simulated teniae coli; the at least one wider lateral portion is aligned with the at least one transverse fold.
4. The simulated tissue structure of claim 1 wherein the simulated teniae coli is a narrow strip of silicone.
5. The simulated tissue structure of claim 1 further including a simulated ileum wherein the simulated large intestine includes a hole near the distal end; the simulated ileum being inserted into the hole and connected to the simulated large intestine.

6. The simulated tissue structure of claim 1 wherein the simulated large intestine includes a first layer of silicone and a second layer of silicone wherein the simulated teniae coli is located between the first layer and the second layer.
7. The simulated tissue structure of claim 6 wherein the simulated teniae coli is a narrow strip of white silicone.
8. The simulated tissue structure of claim 1 wherein the pocket includes a lower layer of silicone and an upper layer of silicone; the simulated appendix and at least one simulated artery being located between the lower layer and the upper layer.
9. The simulated tissue structure of claim 8 wherein the middle portion of the at least one simulated artery being adhered to the lower layer and the distal end of the at least one simulated artery being adhered to the simulated appendix.
10. A method of manufacturing a simulated tissue structure comprising the steps of:
 - providing a mandrel;
 - applying a first layer of wet silicone to the mandrel;
 - curing the first layer of wet silicone to create a first tubular structure defining a central lumen;
 - providing a narrow strip of silicone;
 - applying the narrow strip longitudinally along the first tubular structure;
 - applying a second layer of wet silicone over the first tubular structure and narrow strip of silicone;
 - curing the second layer of wet silicone; and
 - removing the first layer, second layer and narrow strip from the mandrel.
11. The method of claim 10 further including the step of adhering the narrow strip to the first tubular structure.
12. The method of claim 10 further including the steps of:

making a hole in the central lumen;
providing a second tubular structure sized and configured for insertion in the hole;
inserting the second tubular structure into the hole; and
attaching the second tubular structure to the first tubular structure;

13. The method of claim 10 wherein the step of providing a narrow strip of silicone includes providing a narrow strip of silicone that is white in color and the first layer and the second layer are white in color.

14. The method of claim 10 wherein the step of providing a narrow strip of silicone includes providing a narrow strip that has one or more wider lateral portions interspersed with relatively narrower lateral portions along a longitudinal length of the narrow strip; and the step of providing an elongate mandrel includes providing an elongate mandrel that has portions of reduced diameter along a longitudinal axis; and wherein the step of applying a narrow strip includes aligning the one or more wider lateral portion with the portions of reduced diameter.

15. The method of claim 10 wherein the step of providing a mandrel includes providing a mandrel having a proximal portion and a distal portion; the proximal portion of the mandrel defining a longitudinal axis and a substantially cylindrical shape and having a first diameter and the distal portion of the mandrel being angled with respect to the first portion and having a second diameter that is smaller than the first diameter.

16. A simulated tissue structure for surgical training comprising:
an appendectomy model including:
a first layer of silicone having an inner surface defining a central lumen having a diameter;
a second layer of silicone;
a strip of silicone having an inner surface, an outer surface, a length defined between a top edge and a bottom edge, and a width defined between a

first side edge and a second side edge; the strip being embedded between the first layer and the second layer.

17. The simulated tissue structure of claim 16 wherein the inner surface of the strip is adhered to the outer surface of the first layer.

18. The simulated tissue structure of claim 16 wherein the second layer is molded over the first layer and the strip.

19. The simulated tissue structure of claim 16 wherein the width of the strip includes wider portions defined between the first side edge and the second side edge interspersed with relatively narrower portions and the central lumen includes corresponding areas of smaller and relatively larger diameter; wherein the wider portions are aligned with the areas of smaller diameter.

20. The simulated tissue structure of claim 16 further including a second lumen angled and interconnected with the central lumen.

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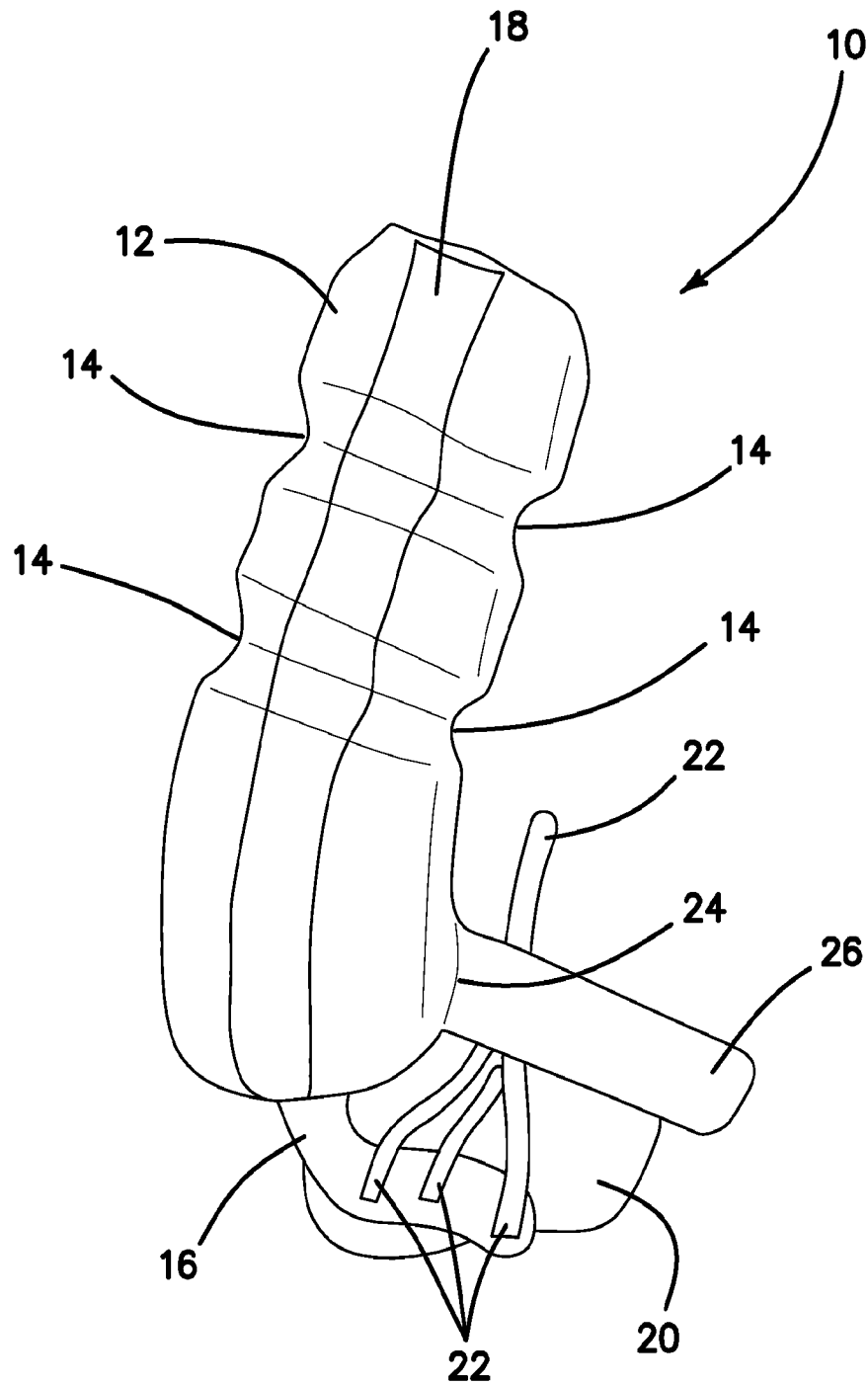


FIG. 1

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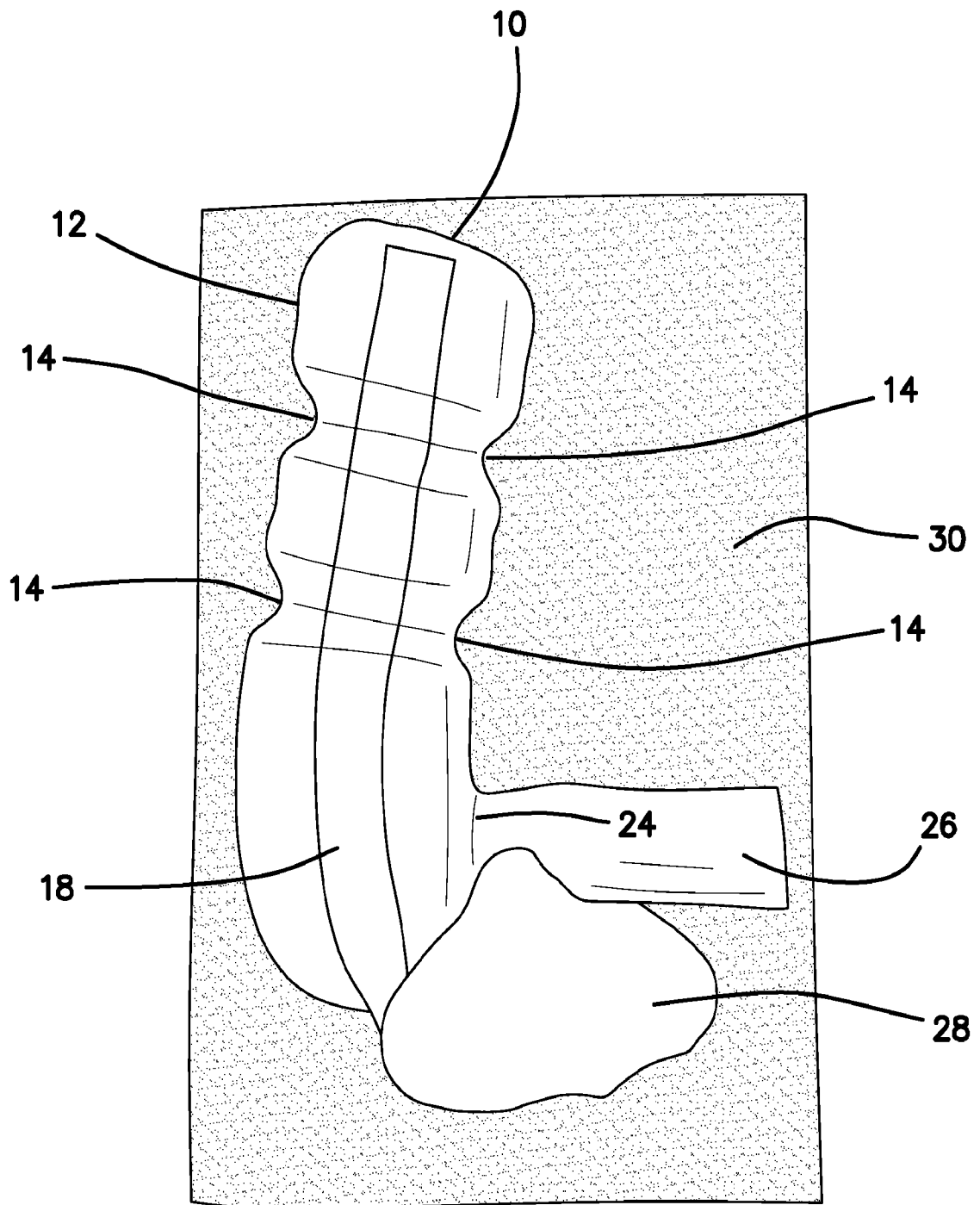


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/043277

A. CLASSIFICATION OF SUBJECT MATTER
 INV. G09B23/28 A61B17/00
 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)

G09B 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 practicable, search terms used)

EPO-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.
X	WO 2004/082486 A1 (GASCHE ANKE [AT]) 30 September 2004 (2004-09-30) the whole document	1-20
A	US 5 403 191 A (TUASON LEO B [US]) 4 April 1995 (1995-04-04) the whole document	1-20
A	CN 101 313 842 A (YONGDONG GAO [CN]) 3 December 2008 (2008-12-03) the whole document	1-20
A	US 2007/225734 A1 (BELL STEPHEN GRAHAM [IT] ET AL) 27 September 2007 (2007-09-27) paragraph [0051] paragraph [0052] paragraph [0059] paragraph [0061] figures 1-4,14,15	1-20



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

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

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"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

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04/10/2016

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/043277

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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