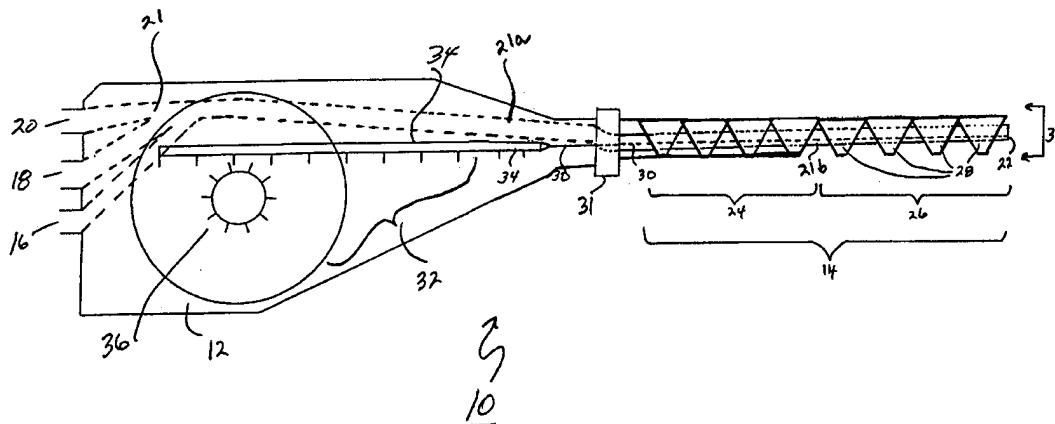


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(54) Title: LAPAROSCOPIC SEALANT APPLICATOR



(57) Abstract

A laparoscopic applicator device (10) for the selective directional application of one or more liquids to a surgical site is disclosed. The device (10) comprises a handle (12) with liquid inlets (16, 18, 20) at one end, discrete channels within one or more tubes (21) connecting with said inlets (16, 18, 20) extending through said handle (12) to a nozzle (22), and a dual injection shaft (14) at the nozzle end for inserting the shaft (14) and nozzle (22) through a surgical trocar. The dual shaft (14) comprises a rigid portion immediately adjacent the handle (12) and a flexible portion near the nozzle tip. Means are provided preferably within the handle (12), for the controlled articulation of the flexible shaft (14)/nozzle (22) assembly, thereby providing application of the liquids in a desired direction. The present invention is particularly useful in the application of surgical sealants, e.g., fibrin sealants. Methods of applying such components are also a part of the invention.

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Laparoscopic Sealant Applicator

Field of the Invention

This invention relates to a laparoscopic sealant applicator wherein a multi-lumen tubing, in fluid communication with a source of sealant, extends a suitable distance beyond a handle so that the tubing can be laparoscopically inserted and articulated in a desired direction to a desired site.

PCT/US96/19505, entitled *A Method of Applying a Mixture of Two Liquid Components as well as a Device for Carrying Out the Method*, filed December 6, 1996, discloses an applicator device for applying a surgical sealant, e.g., a fibrin sealant, to a desired site. The applicator consists of a relatively thin multi-lumen tubing which is in fluid communication with sources of sealant components at one end and forms, or is connected to, a spray tip at the other end. In a preferred embodiment, the tubing runs through a handle at or near the spray tip end. The handle is the part of the instrument held by the surgeon to apply the sealant and it may include activating means for actuating the spray from the component sources.

Sealants would also be useful in laparoscopic procedures.

Brief Description of the Figures

Figure 1 shows a lateral partial cross sectional view of the laparoscopic applicator device of the present invention.

Figures 2a and 2b illustrate the inarticulated and fully articulated arrangement of wedges incorporated into the shaft.

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SUMMARY OF THE INVENTION

In accordance with the present invention a laparoscopic applicator device for the selective directional application of one or more liquids to a surgical site is disclosed. The device comprises a handle with liquid inlets at one end, discrete channels within one or more tubes connecting with said inlets and extending through said handle to a nozzle, and a dual insertion shaft at the nozzle end for inserting the shaft and nozzle through a surgical trocar. The dual shaft comprises a rigid portion immediately adjacent the handle and a flexible portion near the nozzle tip. Means are provided, preferably within the handle, for the controlled articulation of the flexible shaft/nozzle assembly, thereby providing application of the liquids in a desired direction. The present invention is particularly useful in the application of surgical sealants, e.g., fibrin sealants. Methods of applying such components are also a part of the invention.

Detailed Description of the Preferred Embodiment

The present invention provides a useful device for the laparoscopic application of one or more liquid components to a surgical site. Preferably, the components form a surgical sealant, e.g., a fibrin sealant and the present invention will be further disclosed with regard to fibrin sealants. The device is designed to be utilized through a surgical trocar and facilitates the selective directional application of fibrin sealants via the controlled articulation of a flexible portion of an insertion shaft, including a dispensing tip or spray nozzle.

Figure 1 shows a device 10 of the present invention which

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includes a handle 12 and an insertion shaft 14 adapted to be insertable through a surgical trocar. At a first end of the handle 12 are inlets 16, 18, 20 for the one or more liquid or sealant components and optional gas component where spray application is desired. Any number of inlets may be provided. The inlets 16, 18, 20 are adapted to receive the liquid/gas components, and sources (not shown) of the components may be directly adjacent to inlets or may be remote from said inlets but in fluid communication with the inlets via supply tubing. A tubing means 21 extends from the inlets through the handle 12 and insertion shaft 14 to a nozzle or applicator tip 22. This provides for the liquid/gas components to be delivered from the sources to, and out of, the nozzle 22 preferably activated by a separate means controlling the actual flow of liquid and gas. Preferably, the insertion shaft 14 is enclosed with a cladding (not shown) suitable for endoscopic and laparoscopic use. Figure 1 further illustrates that the invention shaft 14 is a two-part assembly comprising a rigid shaft 24 integral with a second end of the handle 12 and a flexible shaft 26 integral with the rigid shaft 24 and preferably coextending and continuous with the tubing means 21 and nozzle 22. The flexible shaft 26 includes a series of hinges 28 which are interconnected so as to enable the bending of the flexible shaft 26 in one direction and straightening of the flexible shaft 26 to its original position. Preferably, the hinges 28 are wedges pivotally interlocked at their tops and disposed laterally along one or both sides of the portion of the tubing means which is included within the flexible shaft 26. The present device further comprises a means for articulating the hinges 28 and flexible shaft through its bent and straightened positions which preferably includes a control

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or push/pull wire 30 connected at a first end at or in the nozzle 22 of the tubing means 21 and running through or along the tubing means to a control means 32 within said handle 12 for controlling the articulation of the nozzle 22. If the wire 20 runs through the tubing means 21, then the wire 30 and tubing means intersect at a manifold 31. This provides a juncture at which the wire 30 exits the tubing means 21 to engage the control means 32. Thus, the tubing means would comprise a wireless portion 21a and a wire containing portion 21b in fluid communication with each other via manifold 31. Optionally, the control means can be a remote manually operated or foot pedal-operated system. The control means 32 preferably comprises a rack and pinion assembly comprising a rack 34 (or tooth-containing element) engaged with a rotatable pinion or knob 36, such that rotation of the knob 36 extends or retracts the wire 30 which in turn articulates or straightens the flexible shaft 26. This articulation is illustrated in Figure 2a and 2b. Figure 2a illustrates the relative position of the hinges or wedges 28 when the wire 30 is retracted or withdrawn by the control knob (not shown). Figure 2b illustrates the relative position of the hinges or wedges 28 when the wire (not shown) is extended by the control knob and the wedges and tubing (not shown) are allowed to fold down upon themselves. The degree of extension/retraction dictates the degree of articulation.

Figure 3 shows an end view of the nozzle 22 of the device of the present invention. The nozzle 22 includes outlets 38 corresponding by fluid communication via discrete channels in the tubing means to inlets 16, 18 and 20. The outlets 38 for liquids and optionally a gas for spray are shown arranged within the end wedge 28 which preferably comprises wedges 28a

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and 28b on either side of the so-arranged outlets 38 and further includes a bridging portion 28c. Preferably, the outlets 38 and attached end 40 of the wire 30 are incorporated within the preferred single tubing means 21b, although individual tubes can be employed. As can be seen the preferred tubing means 21 comprises the tubing means and having integral channels therein which terminate in the outlets 38 on the nozzle 22. The tube can be of any flexible material, e.g., plastic material, suitable for such medical purposes. The nozzle 22 can be a separate component or can just be the open end of the tube 21b. A cladding 42 can be placed around the entire nozzle/tubing assembly as shown and preferably extends the length of the insertion shaft 14, i.e., the rigid shaft 24 and the flexible shaft 26. The cladding can be of any convenient material utilized in endoscopic and laparoscopic devices.

Preferably, this is a single patient use, disposable device. It is intended that the flexible shaft and the rigid shaft (typically, a total of about 12 cm in length) are the parts of the device which are to be passed into and through the trocar. It is intended that the maximum cross sectional measurement of any part of the rigid or flexible shaft shall be chosen, so that the device can be used with commercially available trocars.

Although any liquid components can be used, the present invention is particularly well-suited for surgical sealant, e.g., fibrin sealant application. A preferred sealant is disclosed by Edwardson et al. In EP 592242 which employs a low pH4 fibrin monomer composition co-applied with a pH10 acetate buffer.

Claims

1. An applicator device for the directional laparoscopic delivery of one or more liquid components to a surgical site comprising

a handle having at a first end inlets for fluid communication with sources of said one or more liquid components;

discrete channels corresponding to each of said inlets for each of said liquid components, said channels incorporated into a tubing means extending from said first end and through said handle to a second end of said handle where said channels form, or are integral with, a nozzle for dispensing said one or more liquid components to said surgical site;

a two-part insertion shaft at said second end of said handle adapted to be insertable into a trocar, said insertion shaft comprising a rigid shaft integral with said handle and a flexible shaft integral with said rigid shaft, said flexible shaft being coextensive and coterminating with said nozzle and tubing means, means within said handle for the controlled articulation of said flexible shaft, and thereby said nozzle, to provide for the dispensing of said one or more liquids in a desired direction at a surgical site.
2. The laparoscopic applicator device of claim 1 wherein said means for articulation comprises
 - (a) a series of interconnected hinge means laterally disposed along the length of said tubing means and nozzle within said flexible shaft;

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(b) a push/pull wire connected to and extending from said nozzle end of said tubing means, through or along said tubing means and into the handle; and

(c) control means within said handle connected to a second part of said push/pull wire such that actuation of said control means provides for the desired degree of articulation in said flexible shaft to apply said one or more liquids in a desired direction.

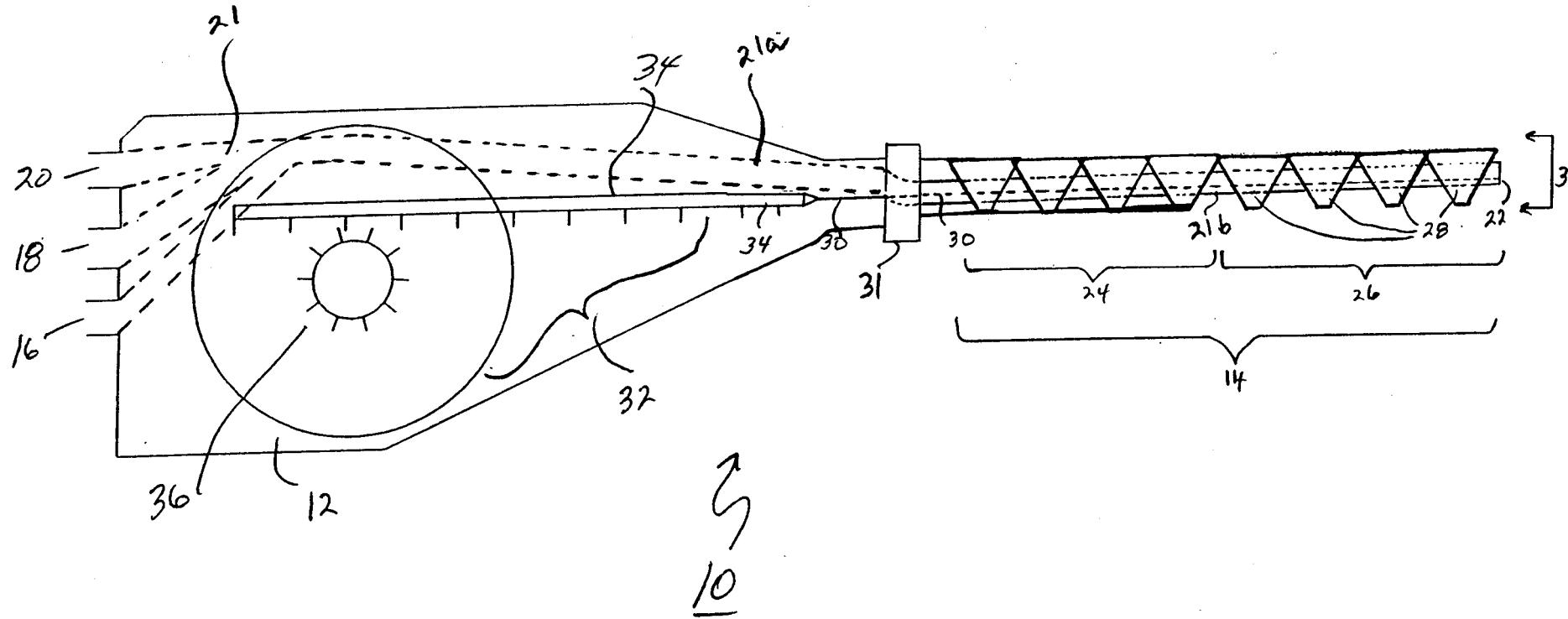
3. The laparoscopic applicator of claim 2 wherein said hinge means comprise wedges of a rigid material disposed along the length of said tubing means comprising said flexible shaft.
4. The laparoscopic applicator of claim 2 wherein said control means comprises a rack and pinion assembly integral with said second end of said push/pull wire and a control knob or activator.
5. The laparoscopic applicator of claim 1 wherein sources of said one or more liquids can be located directly adjacent said inlets or can be remote from said inlets and in fluid communication with said inlets via a supply tubing.
6. The laparoscopic applicator of claim 1 wherein said one or more liquids are components to form a surgical sealant.
7. The laparoscopic applicator of claim 6 wherein said sealant is a fibrin sealant.
8. The laparoscopic applicator of claim 7 wherein said components comprise a fibrinogen component and a component capable of catalyzing the cleavage of fibrinopeptides A and/or B from fibrinogen.
9. The laparoscopic applicator of claim 7 wherein said components comprise a fibrin component and a component

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capable of polymerizing said fibrin monomer.

10. The laparoscopic applicator of claim 6 further incorporating a gas to spray said sealant.

FIGURE 1



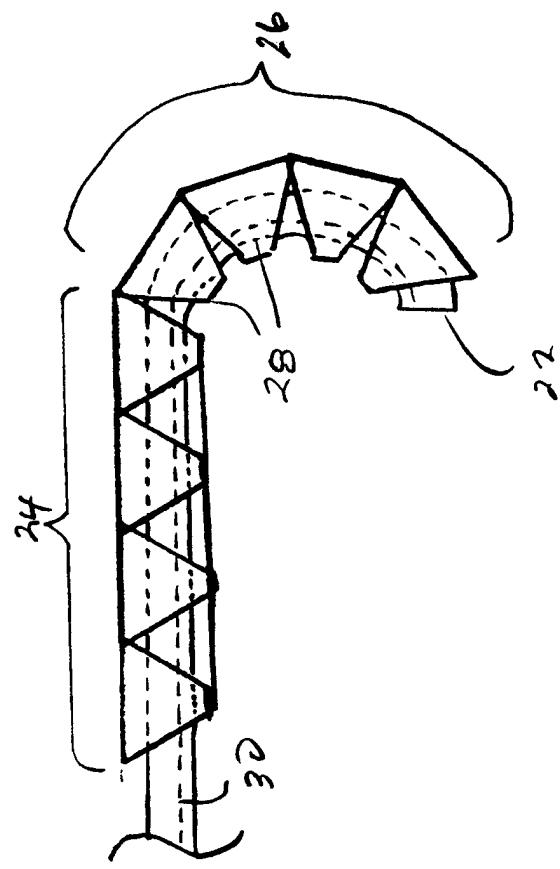
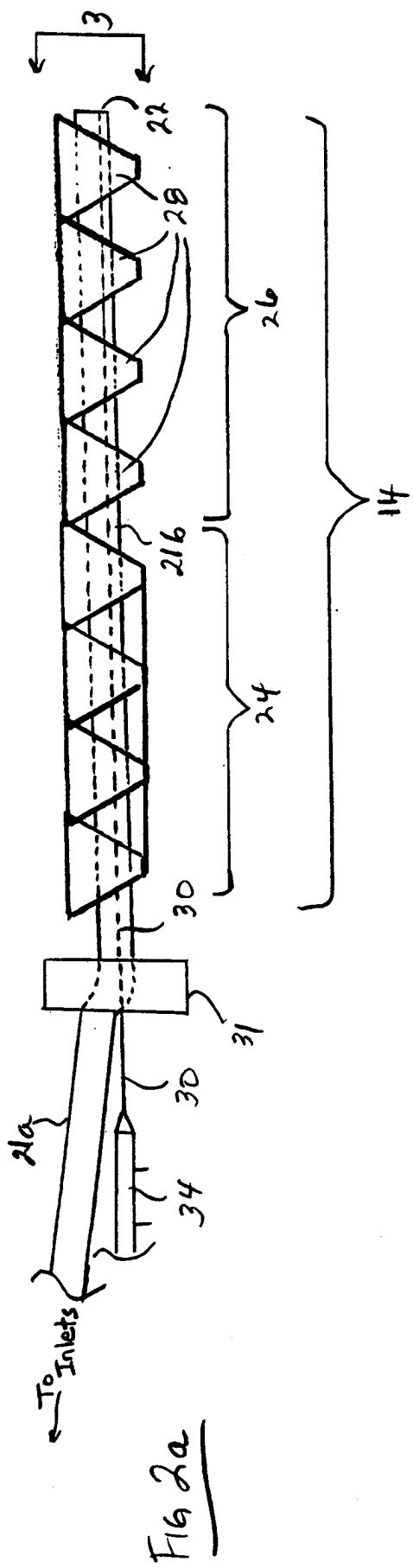
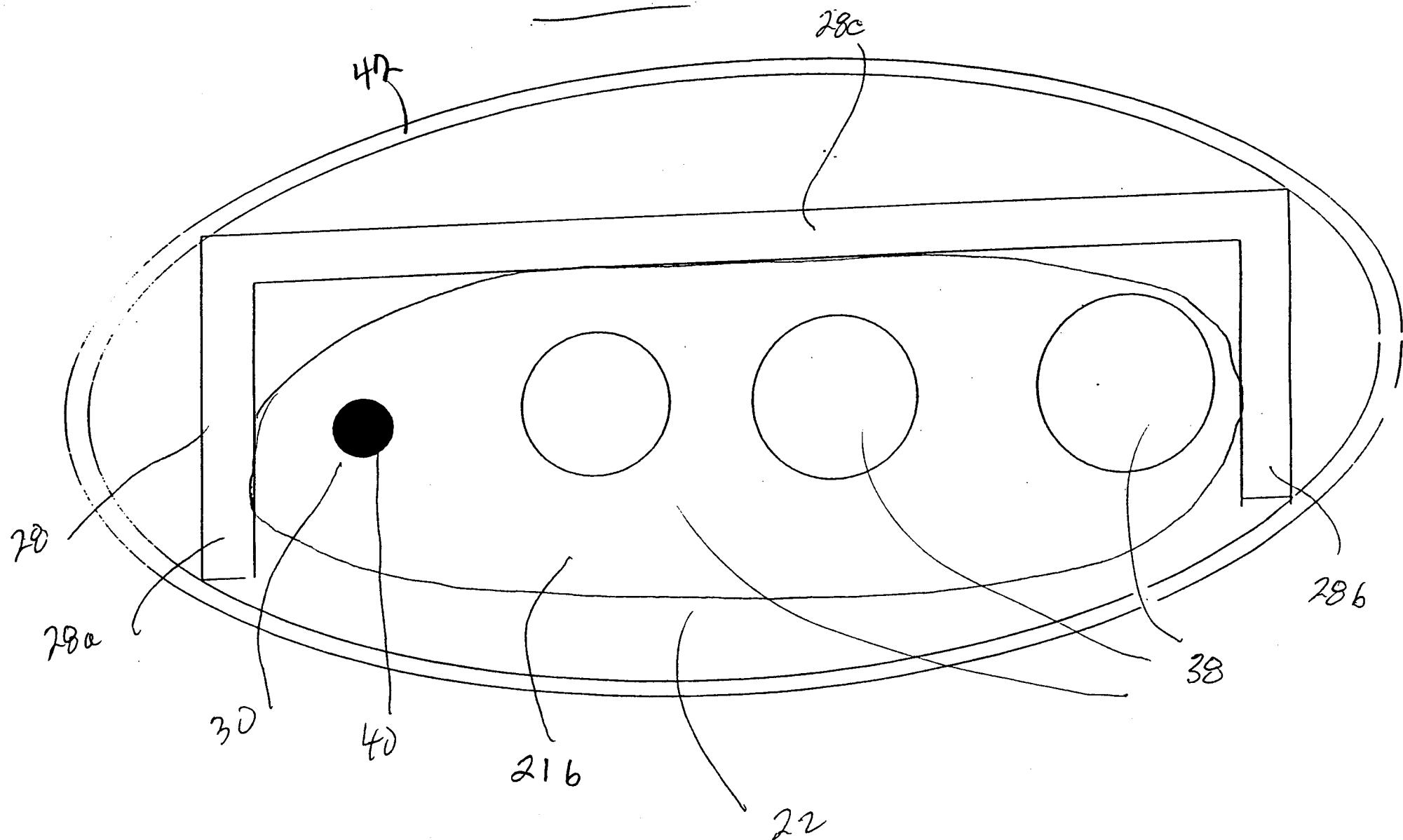


Fig. 2b

FIGURE 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/06100

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A 61B 17/00

US CL :606/214

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)

U.S. : 606/214

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,383,899 A (HAMMERSLAG) 24 JANUARY 1995, FIG. 1.	1-5
Y	US 5,318,524 A (MORSE ET AL) 07 JUNE 1994, ABSTRACT.	6-10

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"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
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