United States Patent [19]

Garnett et al.

[11] **3,897,786**

[45] **Aug. 5, 1975**

[54] **DISPOSABLE MYRINGOTOMY APPARATUS**

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[73] Assignee: **Richards Manufacturing Company,** Memphis, Tenn.

[22] Filed: **Aug. 25, 1972**

[21] Appl. No.: **283,738**

Related U.S. Application Data

[62] Division of Ser. No. 112,933, Feb. 5, 1971, abandoned.

[52] **U.S. Cl.**..... **128/303 R;** 128/305; 128/260; 206/63.2 R

[51] **Int. Cl.**..... **A61b 17/34**

[58] **Field of Search**.... 128/305, 314, 303 R, 303 B, 128/350, 127, 130, 264, 329; 206/63.2 R, 72, 46 ST, 46 SG

[56] **References Cited**

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[57] **ABSTRACT**

Disposable apparatus for use in performing a single operation of the type in which a myringotomy tube is placed in an incision in the tympanic membrane of the ear. The apparatus includes a disposable inserter for inserting the myringotomy tube and various other disposable devices needed in the operation, which are sterilized and held as a unit in a package means for conveying the apparatus and maintaining it sterile until the performance of the operation.

2 Claims, 7 Drawing Figures

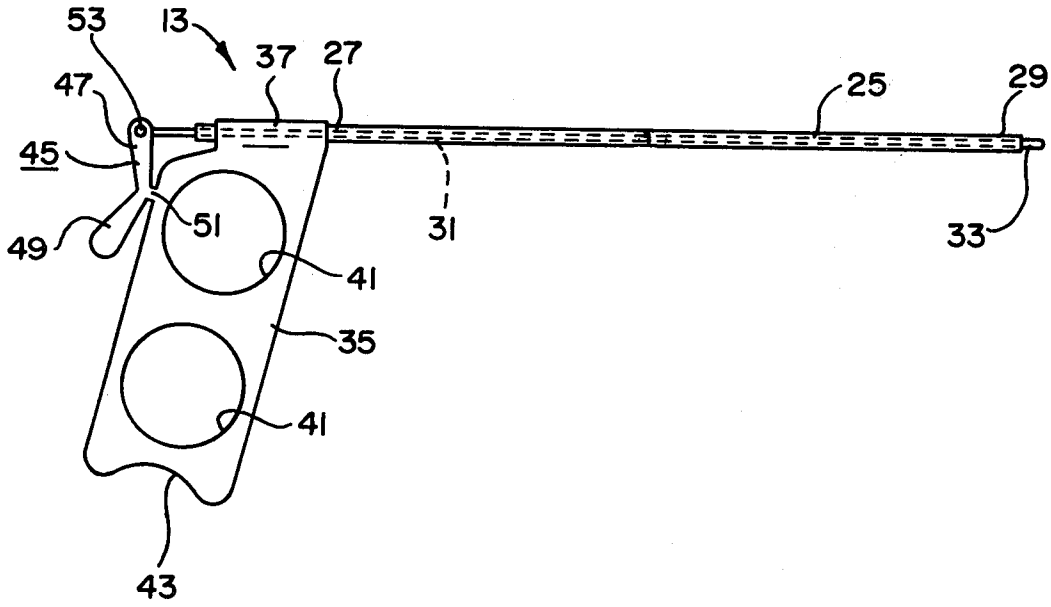


FIG. 1

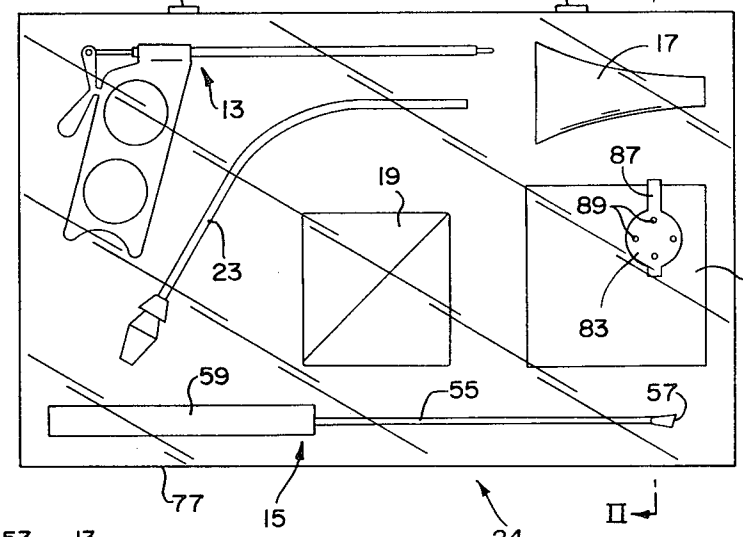


FIG. 2

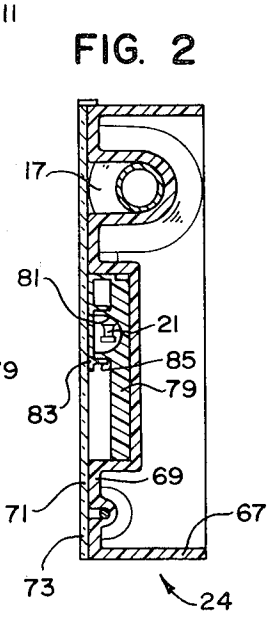


FIG. 3

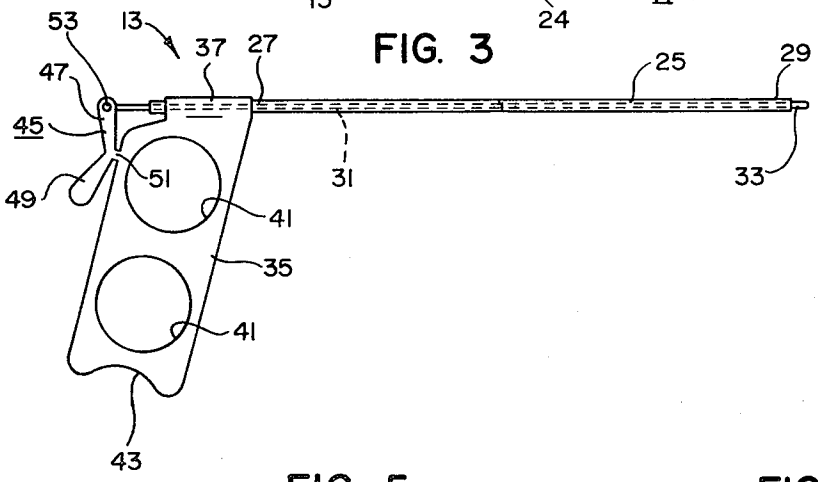


FIG. 4

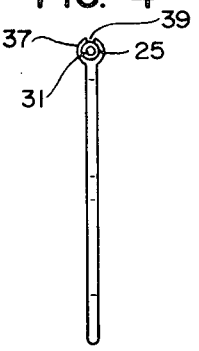


FIG. 5

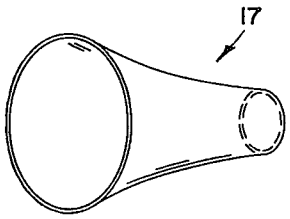


FIG. 6

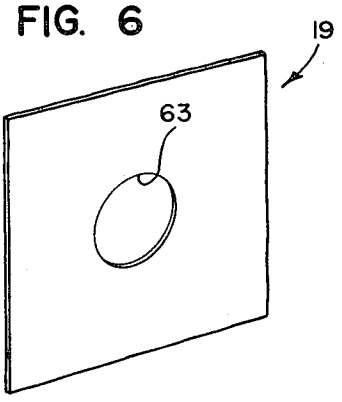
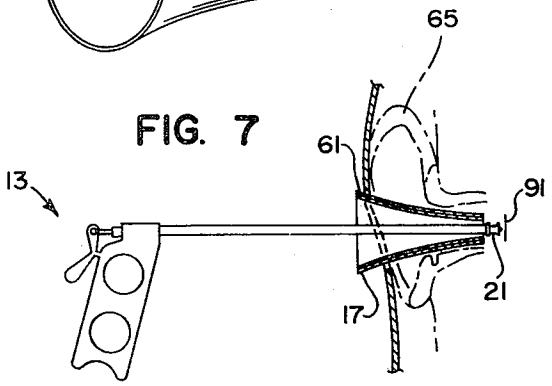


FIG. 7



DISPOSABLE MYRINGOTOMY APPARATUS

This is a division of application Ser. No. **112,933** filed Feb. **5, 1971** now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

This invention relates to disposable apparatus for use in performing an operation of the type in which a myringotomy tube is placed in an incidion in the tympanic membrane of the ear.

2. Description of the Prior Art:

The type of operation in which the apparatus of the present invention is adapted to be used is a well known one wherein an incision is made in the tympanic membrane of the ear and a myringotomy drain tube is inserted through the incision for drainage purposes. One means of performing the above mentioned insertion of the myringotomy tube is by a so-called Morgan Myringotomy Tube Inserter which is an instrument fabricated by Richards Manufacturing Co., the assignee of the present invention. This instrument and the use thereof is described in the publication ARCHIVES OF OTOLARYNGOLOGY, Vol **84**, No. **3**, Sept. **1966**, page **131.** The above described instrument has a barrel or sleeve with a protruding retractable pin. The diameter of the pin is slightly greater than the internal diameter of the lumen of the myringotomy tube. Due to this size difference, the plastic tube will hold a tight compressing fit when mounted on the pin. There are scissor-like handles for actuating the pin. Generally, a speculum and an operating microscope are used. The barrel of the myringotomy tube inserter with the myringotomy tube on the end thereof is inserted through the speculum and into the incision made in the tympanic membrane. Pressure on the rear scissors handle will retract the pin, completely freeing the myringotomy tube from the instrument as the pin retracts into the barrel. An alternate means of inserting the myringotomy tube is by means of grasping the tube with small alligator forceps.

The above described inserter instruments and other instruments used in the operation are of a semipermanent nature intended for long use. For example, The Morgan Myringotomy Tube Inserter is a stainless steel instrument which is used over and over in numerous operations. The cost of this instrument is approximately **$60,** and it must be sterilized before each operation by the operating personnel.

THE PRESENT INVENTION

It is a purpose and object of the present invention to provide a relatively inexpensive sterilized and disposable apparatus which is self-contained and has the necessary implements and devices for performing a single operation of the type in which a myringotomy tube is placed in an incision in the tympanic membrane of the ear. It is a further object to provide a convenient and time-saving means for performing such an operation. Thus, it is not necessary to take up the time of the operating personnel in sterilizing the instruments, but rather the instruments and devices are available in a compact package form already sterilized and which may be thrown away after the single operation has been performed.

The means by which the foregoing objects and concepts of the present invention are accomplished is by the structure of the apparatus of the present invention which includes, among other things, a disposable inserter for inserting the myringotomy tube in the incision in the tympanic membrane of the ear.

The disposable inserter of the present invention includes an elongated sleeve, a plunger slidably extending through the sleeve and being positionable in a forward position in which the plunger extends beyond the distal end of the sleeve to establish a protruding portion for receiving a myringotomy tube thereon, a plastic handle attached to the sleeve adjacent the proximal end of the sleeve and which handle is provided with a pair of finger holes therethrough and terminating in an arcuate portion for fitting the finger of the user, a plastic trigger, a narrow flexible plastic connecting portion integrally formed with the trigger and the handle, and the trigger is pivotally attached to the plunger at the distal end thereof with the trigger being initially in a first position to hold the plunger in the forward position and being movable by pressure on the lower portion to move the plunger and retract the protruding portion into the sleeve and push the myringotomy tube off the end of the plunger. In addition, the apparatus of the present invention includes a sterilized disposable liner for the speculum and a sheetlike drape having a hole therethrough adapted to receive the speculum. Also, there is provided a sterilized disposable knife for making the incision in the tympanic membrane and at least one myringotomy tube is provided. Additionally, if desired, a sterilized disposable ear suction needle may be provided.

It is a further object to provide package means holding the heretofore-mentioned instruments and devices as a unit preparatory to performing the operation and for maintaining the instruments and devices in a sterile condition.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of the apparatus of the present invention.

FIG. **2** is a sectional view taken as on the line II—II of FIG. **1.**

FIG. **3** is a side elevational view of the inserter of the present invention.

FIG. **4** is a front view thereof.

FIG. **5** is a perspective view of the disposable speculum liner of the present invention.

FIG. **6** is a perspective view of the disposable drape of the present invention.

FIG. **7** is a view showing certain instruments of the present invention in use ready to insert a myringotomy tube into the ear of the person.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The disposable myringotomy apparatus **11** of the present invention comprises in general a disposable myringotomy tube inserter **13,** a disposable knife **15,** a disposable speculum liner **17,** a disposable drape **19,** at least one myringotomy tube **21,** a disposable suction needle **23,** and a disposable package or container **24** for holding the inserter **13,** knife **15,** liner **17,** drape **19,** tube **21,** and suction needle **23** ready for use for the surgeon to perform a single operation, and to maintain the above mentioned devices in a sterilized condition until used by the surgeon.

Inserter **13** includes an elongated sleeve **25** preferably formed of metal and having a proximal end **27** and a distal end **29.** A pin or plunger **31,** also preferably

formed of metal, slidably extends through sleeve 25 and is positionable in a forward position, shown in FIG. 3, in which the plunger extends beyond the distal end of sleeve 25 to establish a protruding portion 33 for receiving the myringotomy tube 21 thereon. A handle 35 which is preferably formed of plastic or the like, as for example, polypropylene, has a barrel portion 37 formed along the upper edge of handle 35. The barrel portion 37 is preferably slit as at 39 along the length thereof and is of a size so as to closely and grippingly receive sleve 25 adjacent the proximal end 27 thereof. Thus, the proximal end 27 of sleeve 25 is forced into barrel portion 37 through slit 39 whereupon the resiliency of the plastic tightly holds the sleeve in place, and, if desired, cement or the like may be utilized to further fix the sleeve 25 to the barrel portion 37. Handle 35 has a pair of holes 41 therethrough adapted to receive the surgeon's first and second fingers. The lower end of handle 35 is provided with an arcuate portion 43 so as to provide a resting place for the third finger of the surgeon's hand. A trigger 45 which is preferably formed of plastic and integrally formed with handle 35 has an upper portion 47 and a lower portion 49. A narrow flexible connecting portion 51, preferably formed of the same plastic as handle 35 and trigger 45 is integrally formed with trigger 45 intermediate the upper and lower portions 47, 49 thereof and integrally formed with handle 35 on the upper rearward edge thereof, as best seen in FIG. 3. Upper portion 47 is pivotally attached to plunger 31 at the rearward end thereof by suitable means as by bending the end of plunger 31 at right angles to the main portion thereof and extending the bent end 53 through an aperture in upper portion 47. Trigger 45 is molded or formed in a first position as shown in FIG. 3 with lower portion 49 being spaced from handle 35 and with the trigger holding the plunger 31 in the heretofore-mentioned forward position so that tube 21 may be placed onto protruding portion 33, as seen in FIG. 4, when the surgeon is preparing to put the tube 21 in the opening in the tympanic membrane of the ear.

The knife 15 is preferably formed of an elongated malleable rod 55 of steel sharpened at one end as at 57 and having the other end embedded in a handle 59, preferably formed of a plastic, such as polypropylene.

Liner 17 is preferably formed of a thin piece of plastic, such as polyethylene, which is sleevelike and conical in form as shown in FIG. 5 so as to fit into the interior of a speculum, as speculum 61, shown in FIG. 7. In other words, the liner 17 being sterilized, when fitted into the interior of the speculum 61, prevents the relatively unsterile speculum from coming into contact with the other devices and instruments used in the operation so as not to contaminate them.

DRape 19 is preferably formed from a square sheet of flexible plastic, as polyethylene, and has a hole 63 therethrough of a size for receiving the speculum 61, as shown in FIG. 7. The drape 19 is placed over the ear 65 and the speculum 61 is extended therethrough so that the liner 17 protects the sterilized devices and parts from the unsterile ear 65 during the operation.

It will be understood that liner 17 and drape 19 may be omitted without departing from the spirit and scope of the present invention.

The suction needle 23 is of conventional construction and is used in a conventional manner, and therefore will not be described since it is well known to those skilled in the art.

Container 24 preferably includes a plastic base portion 67, formed, for example, from a polystyrene, having a shelf portion 69 which is formed with depressions to receive the inserter 13, knife 15, liner 17, drape 19, suction needle 23, and myringotomy tube 21 so that these devices and instruments will be depressed below the upper surface 71 of shelf portion 69. Container 24 also includes a covering 73 of rigid plastic or the like to cover shelf portion 69 and retain the instruments and devices in place and maintain them in the sterile condition. Covering 73 is preferably of clear rigid plastic and hinged along one edge as at 75 to bottom 69 and is preferably provided with a suitable snaplock, not shown, on the opposite edge 77 from the hinged edge. Alternately, if desired, covering 73 may be formed from a thin flexible sheet of polyethylene plastic which covers the entire surface 71 and base portion 67, in which case the instruments and devices are preferably sterilized by ethylene oxide gas which penetrates through the plastic.

Preferably the myringotomy tube 21, or tubes, are placed in an inner package 79 and then the inner package placed in a depression in the base portion 67, as best seen in FIGS. 1 and 2. Inner package 79 is preferably of a conventional type formed of plastic, having a cavity 81 therein for receiving the myringotomy tube 21, and having a removable top 83 tightly fitted over the rim 85 of the cavity 81 and flexibly attached to the main body of the inner package 79 by the flexible strap 87. Top 83 preferably has holes 89 therethrough so that the myringotomy tube 21 in the cavity 81 can be sterilized while therein, either by autoclaving or by ethylene oxide gas.

When it is desired to perform the operation, the covering 73 is removed, and the myringotomy tube 21 is removed from the package 79 and placed on the protruding portion 33 of inserter 13, as heretofore described. Also, as heretofore described, the liner 17 is placed in the speculum 61 and the two are then inserted through the hole 63 of drape 19, which drape is placed over the ear 65, as shown in FIG. 7. Then, the surgeon, with the use of the knife 15, makes the incision, not shown, in the tympanic membrane 91 of the ear. The surgeon then places the myringotomy tube 21 in the above-mentioned incision and pushes trigger portion 49 towards handle 35 to cause retraction of protruding portion 33 to withdraw it from the myringotomy tube 21 and leave it in the incision in the tympanic membrane. Also, if desired, the suction needle 23 may be utilized in the conventional manner. Then, after the operation, the surgeon disposes of the apparatus 11 and all the parts thereof.

Although the invention has been described and illustrated with respect to a preferred embodiment, it will be understood that it is not to be so limited since changes and modifications may be made therein which are within the full intended scope of this invention.

I claim:

1. Disposable myringotomy apparatus for performing an operation which includes placing a myringotomy tube in the tympanic membrane of the ear, said apparatus comprising a disposable inserter including an elongated sleeve having a proximal end and a distal end, a plunger slidably extending through said sleeve and being positionable in a forward position in which said

plunger extends beyond the distal end of said sleeve to establish a protruding portion for receiving a myringotomy tube thereon for placement into a myringotomy opening in the tympanic membrane of the ear, a handle attached to said sleeve adjacent the proximal end thereof, a trigger having an upper portion and a lower portion, a flexible connecting portion integrally formed with said trigger intermediate the upper and lower portions thereof and integrally formed with said handle, said trigger at said upper portion thereof being pivotally attached to said plunger at the distal end thereof, said trigger being initially in a first position to hold said plunger in said forward position and being movable by pressure on said lower portion to move said plunger and retract said protruding portion into said sleeve to push the myringotomy tube off the end of said plunger for retention in the myringotomy opening.

2. Disposable myringotomy apparatus for performing an operation which includes placing a myringotomy tube in the tympanic membrane of the ear, said apparatus comprising a disposable inserter including an elongated sleeve having a proximal end and a distal end, a plunger slidably extending through said sleeve and being positionable in a forward position in which said plunger extends beyond the distal end of said sleeve to establish a protruding portion for receiving a myringotomy tube thereon for placement into a myringotomy opening in the tympanic membrane of the ear, a plastic handle attached to said sleeve adjacent the proximal end thereof and being provided with a pair of finger holes therethrough and terminating at the end remote from said sleeve in an arcuate portion for fitting a finger, a plastic trigger having an upper portion and a lower portion, a narrow flexible plastic connecting portion integrally formed with said trigger intermediate the upper and lower portions thereof and integrally formed with said handle, said trigger at said upper portion thereof being pivotally attached to said plunger at the distal end thereof, said trigger being initially in a first position to hold said plunger in said forward position and being movable by pressure on said lower portion to move said plunger and retract said protruding portion into said sleeve to push the myringotomy tube off the end of said plunger for retention in the myringotomy opening.

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