March 19, 1968 J. M. FIORE ETAL 3,373,736

SIGMOIDOSCOPE AND ILLUMINATING MEANS THEREFOR

Filed March 22, 1965 2 Sheets-Sheet 1

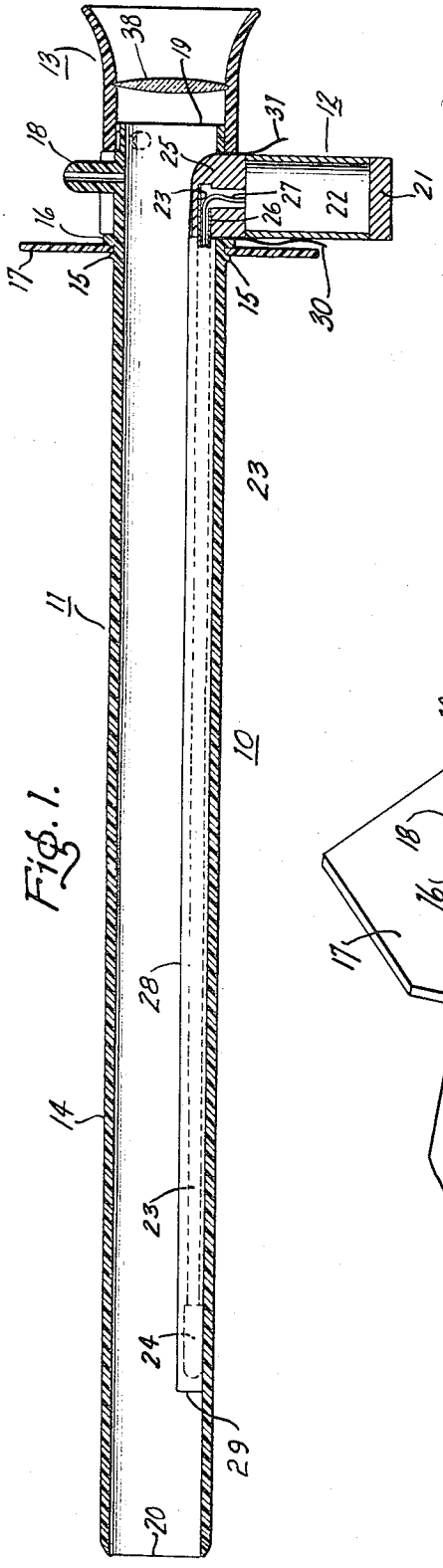

Fig. 1.

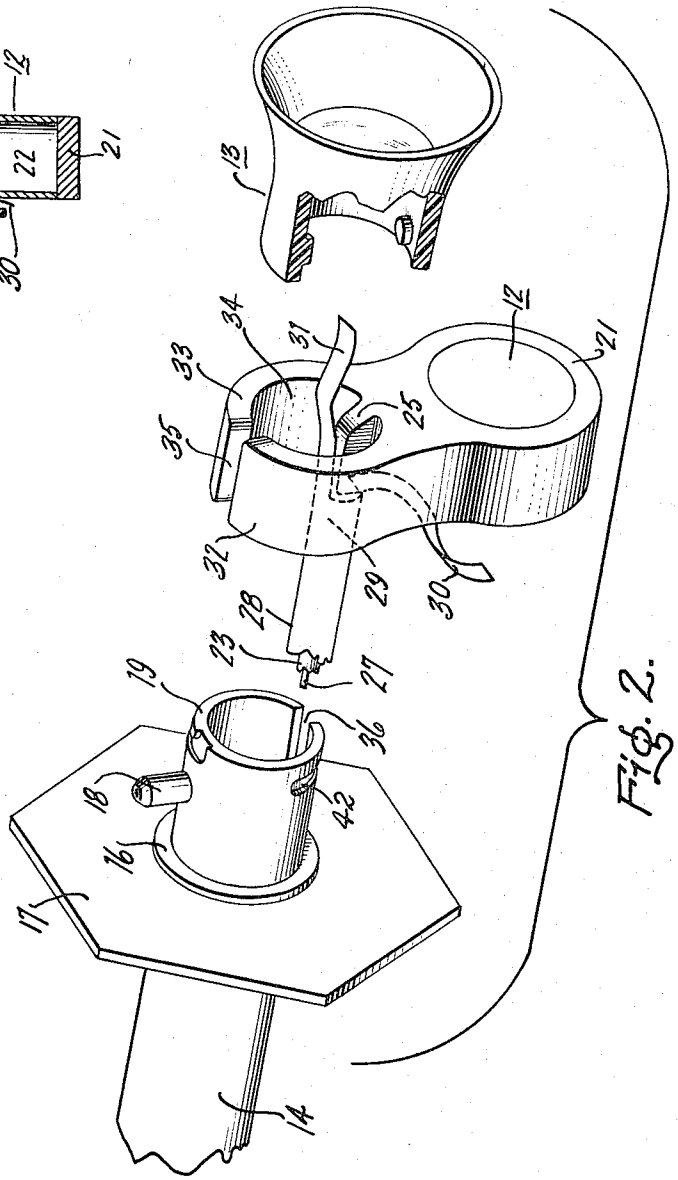

Fig. 2.

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SIGMOIDOSCOPE AND ILLUMINATING MEANS THEREFOR

Filed March 22, 1965 2 Sheets-Sheet 2

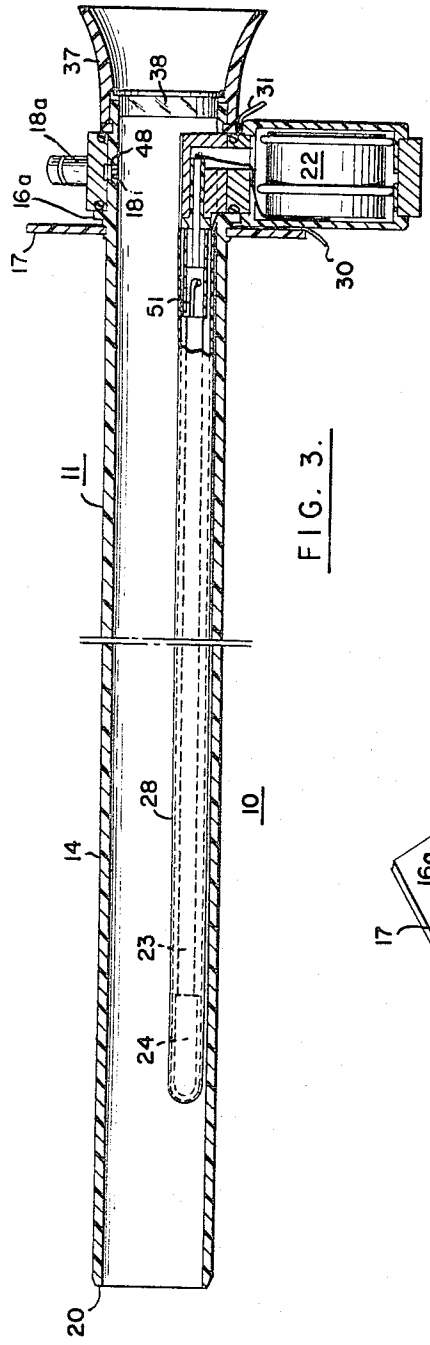

FIG. 3.

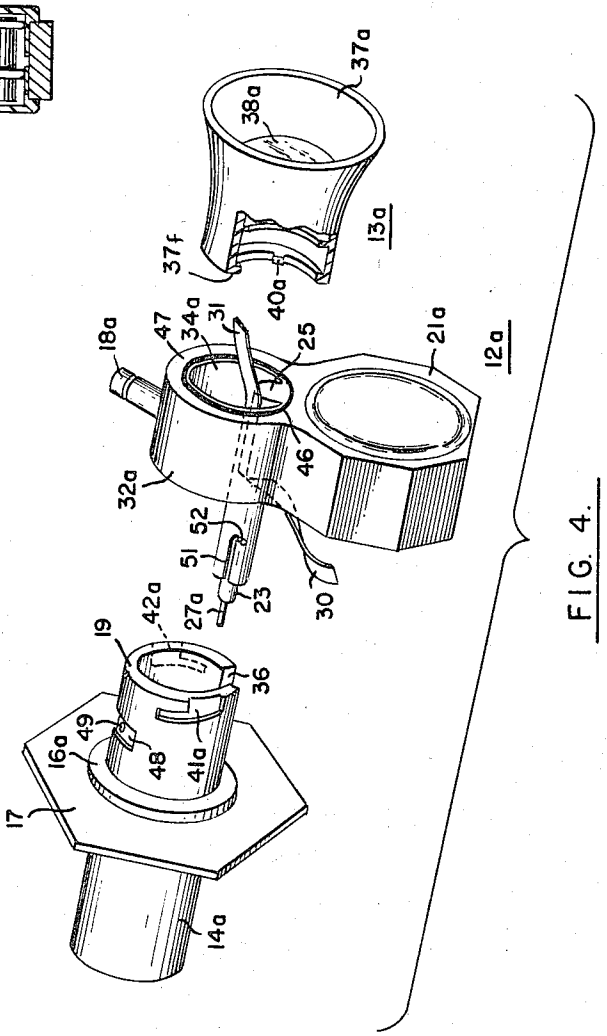

FIG. 4.

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SIGMOIDOSCOPE AND ILLUMINATING MEANS THEREFOR

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Continuation-in-part of application Ser. No. 339,479, Jan. 22, 1964. This application Mar. 22, 1965, Ser. No. 441,813

5 Claims. (Cl. 128—6)

ABSTRACT OF THE DISCLOSURE

An illumination unit for use with a speculum device consisting of a housing means, releasably secured to the proximable end of the speculum, elongated support means releasably secured to the housing means, illuminable means secured to the free end of the support means, and disposable contamination means surrounding both the support and illuminable means.

This application is a continuation in part of our copending application Ser. No. 339,479, filed Jan. 22, 1964, now abandoned.

This invention relates to a single use disposable sigmoidoscope and illumination means therefor, and more particularly to a contamination protected non-disposable light source means positioned internally and at the distal end of a disposable sigmoidoscope.

In the use of medical speculum devices generally a light source is desirable to increase the accuracy of more precise types of diagnostic examinations, and also to facilitate various treatment processes carried on through the device. Ordinarily such a light source may be one which is ordinarily separate from the instrument, or one which is attached thereto, and arranged in either instance to have light directed into or through the speculum. These and other similar arrangements suffice for short-length speculum devices where relatively low lighting power of the light source is sufficient. However, in the longer speculum instruments such as a sigmoidoscope, where the effective length may be on the order of 25 centimeters or more, and where the instrument is of necessity an enclosing cylinder, more lighting power is necessary because of distance involved and the area to be examined. Because of these notable requirements, it is usual practice in sigmoidoscopes for the light source to be placed inside the instrument and at the distal end thereof. In this position, however, the light source is subject to contamination from contact with the patient directly or indirectly so that without means for maintaining the light source in a sterile or sanitary condition immediate reuse for other patients is prohibited. The high desirable disposability of the sigmoidoscope is therefore limited by being combined and employed with a lighting means which is not disposable.

Accordingly, it is an object of this invention to provide an improved disposable speculum and illumination means.

It is another object of this invention to provide an improved disposable sigmoidoscope with self-contained internal illumination means externally releasably secured thereto.

It is a further object of this invention to provide means for continuously maintaining internal illumination means in a disposable sigmoidoscope in a sanitary or sterile condition.

It is another object of this invention to provide an externally attached, internally positioned, illumination means in the form of an electrical lamp adjacent the distal end of a disposable sigmoidoscope and prevented from direct or indirect contact with the patient.

It is still another object of this invention to provide

lighting means for disposable sigmoidoscope having the lighted portion enclosed in a sanitary casing and positioned internally of the sigmoidoscope at the distal end thereof.

Briefly described, this invention includes, in one preferred form, the combination of a readily and economically disposable sigmoidoscope, together with an internal light source which is protected from contamination. A rechargeable battery unit is releasably secured externally at the proximal end of the sigmoidoscope, and a support rod projects into the sigmoidoscope terminating adjacent the distal end thereof. An electrical lamp is positioned at the end of the support rod to provide a light source closely adjacent the area to be examined. A removable transparent sleeve or cover about the support rod maintains the support rod and lamp assembly free from contamination during the use of the sigmoidoscope.

In another embodiment, all of the materials of construction and physical features are the same, excepting the effective length of the light support rod, which is substantially shortened to about 15 cm. to adapt the instrument to examination of the middle portion of the sigmoid colon, referred to in the medical art as a proctoscopic examination.

In a third embodiment, the effective length of the rod support of the rectal speculum of this invention is reduced to about 8 cm., for what is termed an anoscopic examination. Thus, variation of the effective length of this instrument is within the scope of the invention to accomplish the particular species of rectal examination intended by the practitioner.

It is also contemplated as within the scope of this invention to mate speculums and support rod of dissimilar lengths. For example, a support rod of about 7 cm. may be employed with a sigmoidoscope of about 25 cm. in effective length. This is to accommodate those medical practitioners who prefer a proximal light source rather than a distal one when conducting a sigmoidoscopic examination.

This invention will be better understood when taken in connection with the following description and the drawings in which:

FIG. 1 is a cross-sectional assembly view of one preferred embodiment of this invention.

FIG. 2 is an exploded view of the assembly of FIG. 1 denoting the interfitting relationship of the illustrated parts.

FIG. 3 is a cross-sectional assembly view of another preferred embodiment of the lamp unit of this invention; and

FIG. 4 is an exploded view of the major parts of the embodiment of FIG. 3.

Referring now to the drawing, wherein like parts have been designated with like reference numerals, and to FIG. 1, in particular, there is illustrated one preferred configuration of a sigmoidoscope assembly **10** in accordance with the teachings of the invention. Sigmoidoscope assembly **10** comprises a three part arrangement including a sigmoidoscope **11**, a light unit **12** and an eye piece **13**. Sigmoidoscope **11** in one preferred form of this invention is a single use disposable sigmoidoscope similar to the sigmoidoscope disclosed in copending application Ser. No. 322,597, Fiore et al., filed Nov. 12, 1963, now abandoned. In the mentioned copending application a similar sigmoidoscope is described which is manufactured or produced by a molding process from a readily and economically disposable material including such materials as produced from fibers, thermo-plastics, etc. Accordingly, scope assembly **10** may be fabricated from plastics having the aforementioned features, such as economy of material, durability, sterilizability, and sufficient rigidity without brittleness. We have found that the thermoplastics known

as the linear polyolefins, which can be readily injection molded, give disposable instrument components having the right combination of physical properties.

Thermoplastic resins, particularly the polyolefins, possess most of the properties desired in the material for the speculum of this invention, because of their moldability, flexibility, lack of toxicity, and general good resistance to deterioration by environment conditions and aging. While we can use any solid linear polyolefin successfully for the practice of this invention, we prefer to use those linear polyolefins, and particularly linear polyethylene, having a density of 0.940 to 0.980, which in the molded product contributes to a lack of sharp edges, a feature which is important to the present invention. Linear polyolefins particularly suitable for injection and/or extrusion molding in accordance with this invention are the high density polyolefins made, for example, in accordance with the Hogan and Banks U.S. Patent No. 2,825,712, issued Mar. 4, 1958. This family of polyolefins are of higher density than the original high pressure polyolefins. To illustrate, polyethylene of this type has a density of 0.960 to 0.980, as compared to higher pressure polyethylenes of about 0.920. Even when copolymerized with minor amounts of other olefins, such as 1-butene, the density of the copolymer is above 0.940. ALATHON 7050, a linear polyethylene having dielectric properties, is a typically suitable linear polyethylene for the practice of this invention. The aforementioned application also describes a "single use" device wherein the sigmoidoscope is completely disposable, i.e. not intended for any further use, after a single use. The disclosure and teachings of the mentioned copending application is included by reference herein.

In the present invention, the disposable sigmoidoscope **11** includes, for example, linear polyolefins, such as linear polyethylene or polypropylene barrel or hollow cylinder portion **14** which is provided during the forming or molding process with a pair of ridges or shoulders **15** and **16**. Ridges **15** and **16** are adapted to position and retain therebetween a suitable hand guard **17**. Hand guard **17**, which may be of the same material as cylinder **14**, is assembled on cylinder **14** in the position illustrated by being forced over ridge **15**. Because of the pliable nature of the linear polyolefin material of guard **17** and cylinder **14**, the described force fitting is not detrimental to the device, and hand guard **17** is releasably retained in the illustrated position. Cylinder **14** is also provided with a nipple outlet **18** between the hand guard **17** and the proximal open end **19** to introduce or withdraw air from the interior of cylinder **14** during operative practice of this invention. Cylinder **14** is also fitted with a slidably removable obturator assembly (not shown) which projects from open distal end **20** as is the usual practice in the art. The obturator assembly facilitates insertion of the cylinder **14** into a body orifice and is withdrawn prior to the insertion of light assembly **12** into cylinder **14**.

Light unit **12** as illustrated in its operative position in FIG. 1 includes a housing **21** adapted to contain an electrical power source, such as a battery or rechargeable element **22**. Battery element **22** in one preferred form of this invention is a rechargeable nickel cadmium cell as is well known in the art. Attached to housing **21** is an elongated rod-like support **23** which extends into cylinder **14** along and adjacent the wall thereof terminating near the distal end **20**. At the end of rod **23** there is positioned a very small prefocused electrical lamp means **24** as the light source for the sigmoidoscope **10**. A suitable miniature lamp is one rated at 2.5 volts, and 300 milliamperes, such as the General Electric 1861D. Lamp means **24** is suitably electrically connected to battery element **22** by one of several means, for example, by having suitable conductors extending through rod **23** or in a preferred form of this invention, by a single electrical conductor extending through and insulated from rod **23**, where a metal rod **23** is employed as an additional electrical conductor. Numerous other well known electrical connections may be suitably employed without departing from the scope of this invention. Rod **23** may be of a telescopic or otherwise adjustable nature, or manufactured in various lengths, so that the distal position of lamp means **23** in cylinder **14** may be varied, or so that light unit **12** may be suitably employed with various other similar devices having shorter or longer similar cylinders such as cylinder **14**.

In one embodiment of this invention rod unit **23** is releasably secured to projection **25** of housing **21**, with rod **23** fitting within an aperture **26** in projection **25**. The insertion of rod **23** into projection **25** also serves to provide the proper electrical connection from electrical conducting means in rod **23** to a suitable electrical conductor **27** leading to battery **22**. While the insertion of rod **23** into aperture **24** may be provided through various suitable known bayonet or prong means which close a defined electric circuit and effectively securely lock the elements in place, it is contemplated that other electrical switching means such as on off switches may be employed which are operable by the practitioner as desired, and which do not involve assembling of parts.

The rod **23**, together with lamp means **24** in the position as illustrated, is exposed during use to considerable contamination by the patient, and would accordingly need to be sanitized or sterilized before each succeeding use. Otherwise transmission of various bacterial or virus infections may take place from one patient to another or from the patient to the medical practitioner or to associated coworkers. It is necessary that the exposed rod **23** and lamp means **24** be maintained in a sterile or sanitized condition such that it may be reused without necessity of undesirable expensive and time consuming cleansing procedures. Otherwise the numerous and highly desirable advantages which flow from the use of a disposable sigmoidoscope are limited by a light source, when so employed, which is either not disposable in the same sense as the scope is disposable, or requires special cleansing which would delay immediate reuse for the same type of examination or with other instruments or devices as mentioned.

Accordingly an important feature of this invention is the use of a disposable closed end sleeve element **28** which is positioned to contain rod **23** therein and to prevent any contamination of rod **23** or light unit **12**. Sleeve **28** may be produced from various materials and combinations of materials, which may be rigid, semirigid, or flexibly soft. The only critical requirements of sleeve **28** is that the material be relatively impervious to fluids for a reasonable time or otherwise prevent transmittal of virus or bacteria therethrough. It is also necessary that the closed end **29** be transparent or translucent to transmit light from lamp **24** therethrough without substantial diminishing of intensity. Most clear plastics meet these requirements and are suitable sleeve **28** materials. By way of example, such materials may include pliofilm, polyethylene, cellophane, etc. In one preferred form of this invention sleeves **28** are of a clear thin polyethylene film and from about ⅛ to ¼ inch inside diameter.

The open end of cylindrical sleeve **28** is provided with an axial slit to form a pair of extending flaps **30** and **31**. In the operative position illustrated in FIG. 1, one of these flaps **30** from the underside of rod **23** extends into the space between hand guard **17** and housing **21**, and the other flap **31** extends over projection **25** and between housing **21** and eye piece **13** externally of the instrument. These flaps serve a two-fold purpose. They provide ready means for the practitioner to grasp to remove sleeve **28** from rod **23**, and they provide further protection to projection **25** and casing **21**. One method employed to produce a satisfactory sleeve **28** includes providing a long narrow rectangular strip of clear thin plastic and folding it in half transversely. The longitudinal edges are

then heat sealed leaving a sufficient length at the open end unsealed to provide flaps **30** and **31**.

A further important feature of this invention is the light unit **12** in combination with the sleeve **28** and together in combination with sigmoidoscope **10**. Light unit **12** is releasably secured externally of the sigmoidoscope **11** while rod **23** extends internally therein. The releasably securing means thus requires cooperative relationship of specifically provided means on the sigmoidoscope **11** and on the housing **21**.

Referring now to FIG. 2, the securing means associated with housing **21** includes a pair of encircling arm members **32** and **33**, extending from or being a part of housing **21**, which define a central opening **34** of sufficient size to slide over the proximal end **19** of sigmoidoscope **10**. At the same time the ends of arm members **32** and **33** are spaced apart to define an open slot **35** which is adapted to slide by and contain nipple **18** on sigmoidoscope **11**. In order to provide the positioning of housing **21** adjacent hand guard **17**, a longitudinal slot **36** is provided in the wall of the distal end **19** of sigmoidoscope **11**. This slot **36** is dimensioned to slidably receive projection **25** on housing **21**. The combination of slot **36** containing projection **25** secures and positions lighting unit **12** and prevents relative rotation between the unit **12** and sigmoidoscope **11**. At the same time the fitting of nipple **18** in slot **35** adds stiffness to this feature and permits ready rotation of the sigmoidoscope by means of housing **21**.

Where necessary or where desirable, an eye piece **13** may be fitted to the open proximal end **19** of sigmoidoscope **11**. An eye piece is generally necessary when air is to be introduced into cylinder **14** through nipple **18**, or where object magnification is desired. Such an eye piece may be economically produced from various plastics as those mentioned and accordingly be of a single use disposable variety.

In FIGS. 3 and 4, in one preferred form of this invention, eye piece **13** includes a one piece molded plastic flared housing **37** containing an integral lens **38**. Lens **38** is not required to have a high degree of magnification, if indeed any magnification, and therefore need not be optically perfect. Such plastics as Plexiglass or Lucite acrylic resins may be gainfully employed for eye piece **13**. In addition, since only a transparent lens is basically required, no criticality attaches to the material or structure of housing **37**. Thus, housing **37** may be of one material as a metal, non-metal, organic or inorganic, and the lens of a different transparent material sealed in place.

In order to secure eye piece **13** to sigmoidoscope **11**, eye piece **13** is provided with a pair of diametrically opposed inner projections **39** and **40** which may be of plastic molded integrally with housing **37** or of a metal inserted in the plastic. Suitable J slots **41** and **42** are provided in the distal end **19** of sigmoidoscope **11** so that eye piece **13** may be fitted on the end **19** of sigmoidoscope **11** with projections **39** and **40** fitting into J slots **41** and **42**. By moving eye piece **13** axially on distal end **19** for a short distance and then rotating eye piece **13** clockwise, eye piece **13** is secured to sigmoidoscope **10** through the interfitting relationship of projections **39** and **40** and slots **41** and **42**.

In another embodiment, the physical features are substantially the same. The principal differences in this embodiment are changes in the position of outlet **18***a*, the form of housing **21***a* which is the air introduction means, and the manner of releasable attachment of cylinder **14***a*, lamp unit **12***a*, and eyepiece **13***a* as shown in FIGS. 3 and 4.

Firstly, the arm members **32** and **33** of the first embodiment have been made continuous, as now shown as hollow cylindrical member **32***a*. The nipple **18***a* is secured to member **32***a* and communicates with the central opening or chamber **34** therein. A circular channel **46** is provided in the proximal face of **32***a* to accommodate a resilient O-ring **47**. A similar channel and O-ring (not seen) are provided in the hidden distal face of member **32***a*. In this manner, a hermetic seal can be maintained within chamber **34***a* when supplied with air through pipe **18***a* by the sealing of the O-rings against abutting ends **16***a* and **37***f*.

Other locations for the O-ring seals are within the scope of this invention. For example, a circular channel (not shown) may be provided in each of the abutting ends, **19** of tube **14***a*, and in face **37***f* of eye piece **13**, with resilient O-rings being disposed respectively therein, to provide the desired sealing of chamber **34**.

The proximal end of cylinder **14***a* has been modified as shown, to accommodate the modified structure of member **32***a*. A J-shaped recess **41***a* is seen in the viewable face of cylinder **14***a*, and a diametrically opposing recess **42***a* is provided in the hidden face of **14***a*. A transverse recess **48** is provided in the outer and upper face of tube **14**, near its proximal end. Within recess **48**, is perforation **49**, which permits communication to the inside of tube **14** for the introduction of air pressure. Longitudinal slot **36** is retained to slidably key on projection **25**. Eye piece **13***a* has been modified as to its threading and the inclusion of internal projection **40***a* to detachably engage the slot **42***a* on tube **14**. Another projection (not shown) engages slot **41***a*.

When the scope has been positioned within the body cavity, as will be described, the components will then be cooperatively attached, as shown in FIG. 3, to conduct the examination. At its distal end, projection **25** is provided with a J-slot **51** that detachably secures pin **52** of rod **23** in fixed relation.

It will be observed that slot **48** has been carefully positioned so as to overlap the inlet end **18***i* of pipe **18***a*. In this manner, the introduction of air through the pipe will be directed only through the matched passages to the inside of tube **14**, as desired. Where dilation of the body cavity is indicated, an ancillary source of air pressure (not shown), perhaps only a squeeze bulb, is detachably secured to pipe **18**. Slots **41***a* and **42***a* may be tapered to provide a camming action to insure tightness of seal of eye piece.

The embodiment of this invention as illustrated in FIG. 1 is shown in its operative completeness, for example, as inserted in a body orifice. As a practical matter the practitioner may have on hand a large number of the disposable sigmoidoscopes **10** and perhaps only one lighting unit **12**. At the same time the practitioner may have a large number of closed end sleeves **28** available. It is not required that the sleeve **28** be physically included with the sigmoidoscope **11** in the same package, for example. However, it is contemplated that one or more sleeves **28** be packed in the same package as contains the sigmoidoscope **11**. Sigmoidoscope **11** is placed in a suitable wrapper, for example, a sealed plastic bag to maintain its sterility. Sigmoidoscope **11** may be sterilized previous to packaging as in one operative practice of this invention, or may be placed in a plastic bag and thereafter subjected to ethylene oxide gas treatment for sterilization.

Upon use of this invention the sigmoidoscope **11** complete with a removable obturator is removed from its sterile or sanitary wrapper, and according to standard practices inserted into the proper body opening. The practitioner then procures lighting unit **12** and places a sleeve **28** over rod **23** with flaps **30** and **31** positioned to take up their position as shown in FIG. 1. Then, light unit **12** is inserted into sigmoidoscope **11** and securely attached thereto as heretofore described. Finally, if to be used, eye piece **13** is also fitted to sigmoidoscope **11** as heretofore described. At the completion of the examination the sigmoidoscope assembly **10** is removed from the body cavity by parts in the reverse order mentioned, or the assembly **10** may be removed as a unit. In either event, the sigmoidoscope **11** is permanently discarded, and the sleeve **28** stripped from rod unit **23** and also permanently discarded. At this point rod **23** may be removed from projection **25**

if that feature is relied upon to remove lamp **24** from the power circuit. In one preferred embodiment of this invention a recharging unit is provided (not shown) so that housing **21** fits therein for recharging and storage purposes. Such recharging units are well known in the art.

Releasably secured or releasably attached denotes ordinary and usual detaching means, for example, after each use rather than an assembly connection as a structural feature. Single use disposable indicates permanent discarding after a sole use.

The speculum of this invention may be suitably optically darkened to prevent unwanted or undesirable light reflection. In this respect, linear polyolefins are ordinarily opaque with minimal light reflection. One preferred procedure is to reduce the light reflection along the inner surface of tubes **14** and **14***a* by abrading the surface with a wire brush means or the like. It is also possible to reduce glare by tinting the transparent lens **53** of eye piece **13**.

While other modifications of this invention and variations of apparatus may be employed within the scope of this invention and have not been described or illustrated, the invention is intended to include all such modifications as may ordinarily be embraced within the following claims.

What is claimed is:

1. A lighting unit for use with a speculum device including a cylindrical barrel for insertion into a proper body cavity, said lighting unit comprising,

(a) a housing assembly adapted to contain a portable source of electrical power,

(b) means on said assembly to at least partly encircle the exterior of said barrel for releasable attachment thereto,

(c) support means releasably attached at one end thereof to said housing assembly and extending into said barrel to lie adjacent the wall therein,

(d) lamp means secured to the free end of said support means for providing illumination within said speculum, and

(e) conducting means connecting said lamp means to said source of power, and

(f) separate disposable contamination prevention cover surrounding both said support and lamp means to prevent contamination thereof, said cover comprising an at least partially translucent end thereabout adapted to transmit light through one end thereof and being suitable for a single use and discarding thereafter.

2. The invention according to claim **1** wherein the sleeve includes at least one flap extension at the open end thereof of sufficient length so as to be manually graspable while said light unit is being positioned within said barrel.

3. A light unit for use with a speculum device consisting of a hollow barrel for insertion into a body cavity, a guard secured about said barrel spaced from its proximal end to limit said insertion defining an elongated distal end from said guard, and an eye piece adapted to be detachably secured to said proximal end by means of lugs provided on the internal periphery of said eye piece, said light unit comprising,

(a) a housing assembly adapted to contain a portable electrical power source and to lie adjacent the proximal end of said barrel,

(b) arm means on said housing at least partly encircling said proximal end for releasable attachment to said barrel,

(c) fluid conduit means secured to the outer surface of said arm means communicating between the environment and the inner surface of said arm means,

(d) an axial projection disposed internally of said arm means and adapted to slidably engage an axial slot in the proximal end of said barrel,

(e) hollow rod means detachably secured at one end thereof to said axial projection so as to lie axially within said barrel adjacent the wall thereof,

(f) lamp means capable of providing illumination within said barrel secured to the free end of said rod means, and

(g) conducting means disposed within said rod means connecting said lamp means with said source of power for energization thereof.

4. A light unit for use with a speculum device consisting of:

a hollow barrel for insertion into a body cavity, a guard secured about said barrel and spaced from its proximal end to limit the degree of insertion thereof, an eye piece adapted to be detachably secured to said proximal end by means of lugs provided on the internal periphery of said eye piece, said light unit comprising:

(a) a housing assembly adapted to contain a portable electric power source to be attached about the proximal end of said barrel,

(b) hollow cylindrical means on said assembly encircling at least a portion of the exterior of said proximal end, and adapted for releasable attachment thereto,

(c) fluid conduit means secured to the outer surface of said hollow cylindrical means communicating between the environment and an annular chamber defined by the inner surface of said cylindrical means and the outer surface of said barrel,

(d) an axial projection disposed internally of said hollow cylindrical means and adapted to slidably engage an axial slot, provided in the proximal end of said barrel,

(e) means disposed between the abutting portions of said barrel, hollow means and eye piece, when assembled, to hermetically seal annular chamber,

(f) hollow rod means detachably secured at one end thereof to said axial projection so as to lie axially within said barrel adjacent the wall thereof,

(g) lamp means capable of providing illumination within said barrel secured to the free end of said rod means, and

(h) conducting means disposed within said rod means connecting lamp means with said source of power for energization thereof.

5. The invention as recited in claim **4** wherein a separate disposable contamination prevention means surrounds both said rod and illumination means to prevent contamination thereof, said contamination prevention means being suitable for a single use and discarding thereafter.

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