United States Patent [19]

Poirier

[11] **3,745,992**

[45] **July 17, 1973**

[54] **SPECULUM**

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[73] Assignee: **Medspecs, Inc.,** Frederick, Md.

[22] Filed: **Aug. 12, 1971**

[21] Appl. No.: **171,187**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 46,725, June 16, 1970, abandoned.

[52] **U.S. Cl.** **128/17**

[51] **Int. Cl.** **A61b 1/30,** A61b 1/32

[58] **Field of Search** 128/3, 17, 18, 19, 128/242, 345

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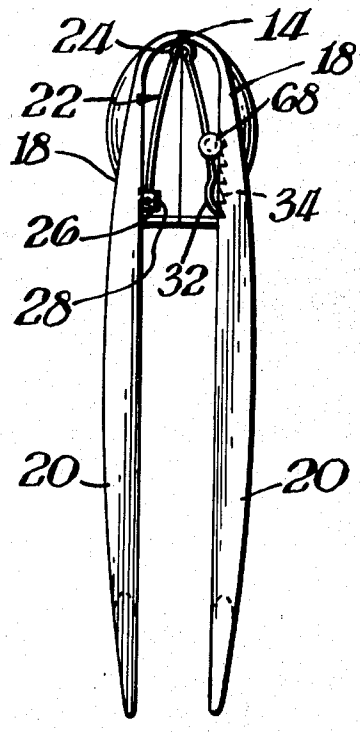
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[57] **ABSTRACT**

A speculum is formed of a stiffly flexible plastic material whereby two blade-like members are joined along one edge by a hinge which integrally connects the two blades together for pivotable movement. The hinge means permits the blades to be manipulated between open and closed positions. A locking member formed between the blades permits the opening angle between the blades to be adjusted as desired. The blade-like members, when in a closed position, appear generally triangular in cross-section with the hinge means forming one of the vertices of the triangle. Additional design configurations facilitate the speculum's usage.

9 Claims, 13 Drawing Figures



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SHEET 1 OF 2

Fig. 2.

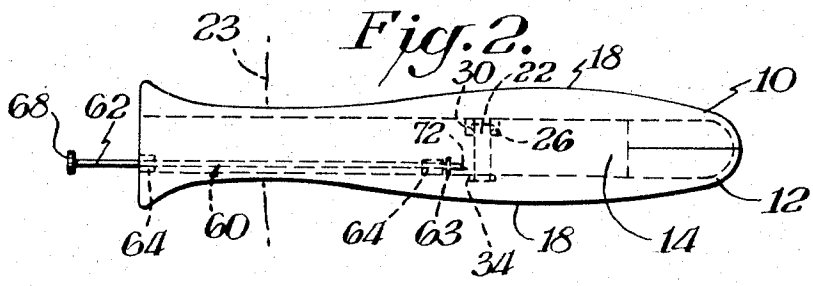


Fig. 3.

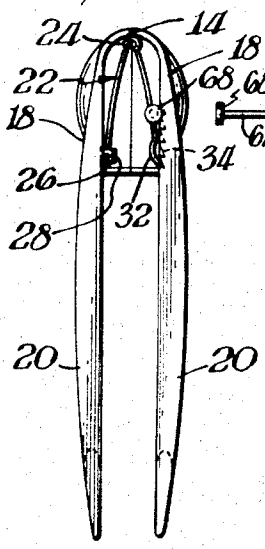


Fig. 1.

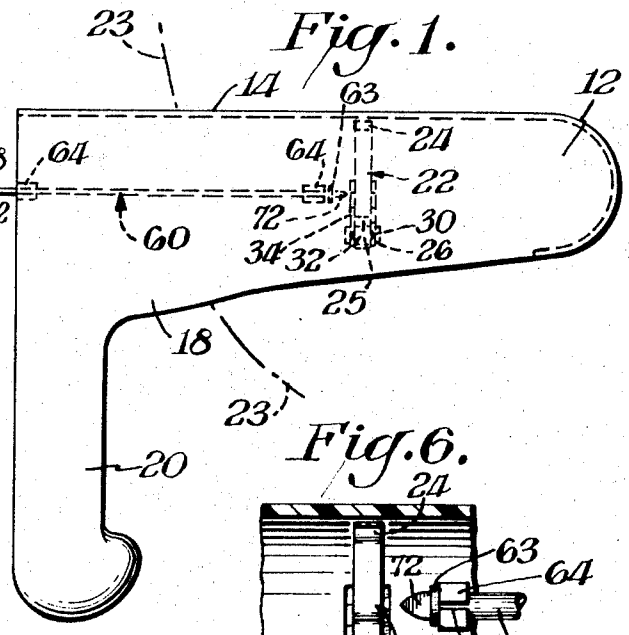


Fig. 4.

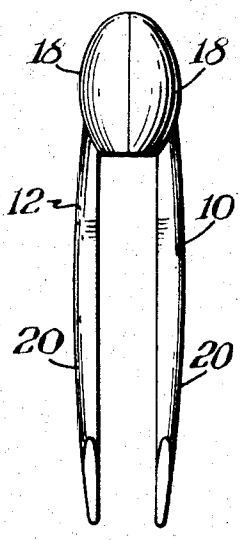


Fig. 6.

Fig. 5.

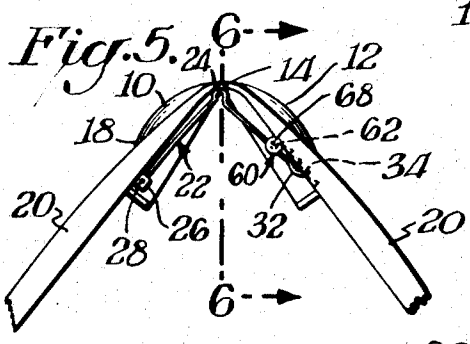


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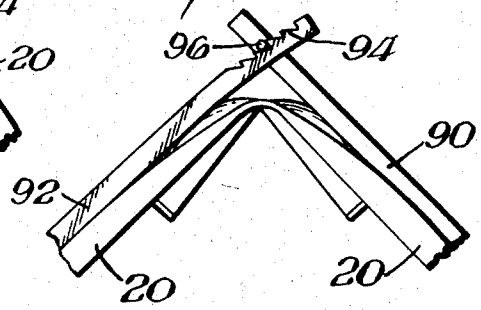
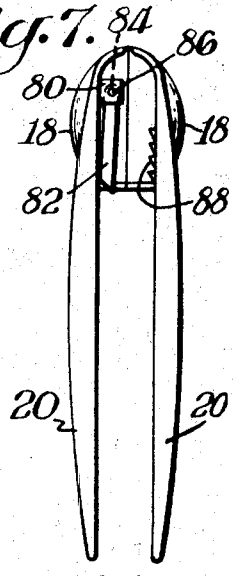


Fig. 7.



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Fig. 10.

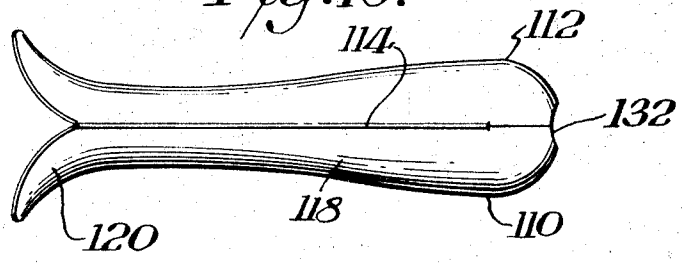


Fig. 11.

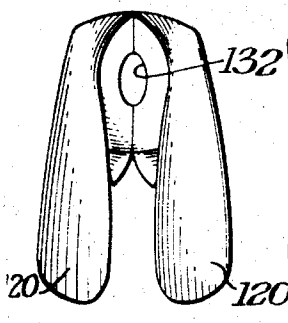


Fig. 9.

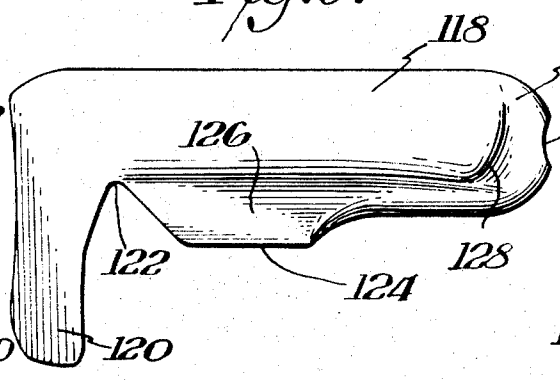


Fig. 12.

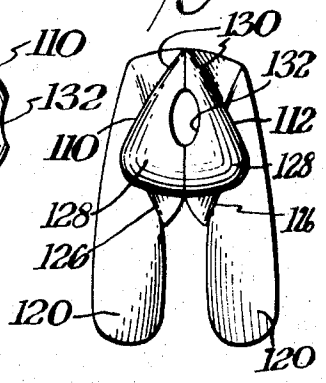
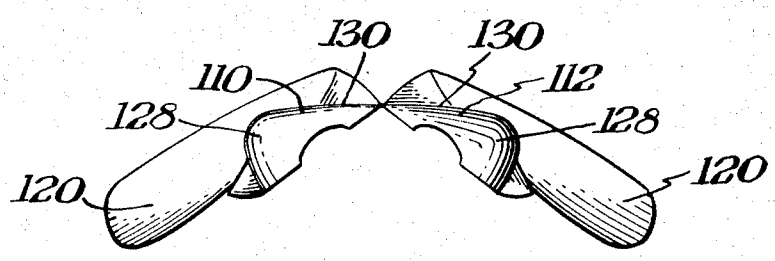


Fig. 13.



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SPECULUM

BACKGROUND OF THE INVENTION

This invention is a continuation-in-part of an application Ser. No. 46,725 entitled "Speculum" filed June 16, 1970 by Jean R. Poirier now abandoned.

This invention relates to a speculum which facilitates the examination of certain body passages, and in one embodiment, to a speculum the major portion of which is formed of an integral piece of plastic material.

In the field of gynecology, and for that matter, in the general practice of medicine, it is often desirable and necessary for the doctor to examine both visually and with instruments, the interior of certain body passages. In the case of cancer of the reproductive organs, for example, 95 percent of all cancer occurs at the cervix. One of the tests used for the early detection of such cancer is the so-called "Pap Test" which requires that a vaginal smear be made. To effect this test the physician must open the vaginal passage or vault in order to obtain visual access to the cervix. For this purpose, the physician typically uses one of the many vaginal speculums that are available today. Most of these speculums are made of metal and must be washed and sterilized after each use. Due to excessive vaginal discharge, particularly in women suffering from an infection, these existing instruments are difficult if not impossible to thoroughly clean. Particles often remain attached to the instrument even after washing, cleaning and sterilization, this tends to leave a doubt in the mind of the doctor and his staff as to whether or not they are, in fact, reinfecting the women under examination.

Furthermore, the cleaning problem is no small task. Even in the typical general practitioners office it is often necessary to make some 30 or more vaginal smears daily. This requires the stocking of at least 30 vaginal speculums. After each smear is made, the speculum must be disassembled, washed and sterilized. This creates an excessive labor problem not to mention the difficulties encountered in thoroughly washing the speculums.

It is, accordingly, an object of this invention to provide an improved relatively simple, disposable speculum, thereby obviating the washing and sterilizing problems.

Many of the presently available vaginal speculums are constructed such that their blades open and close in a vertical plane. This is unfortunate inasmuch as when taking vaginal smears, it is the posterior fornix which collects most of the discharge and which is in the most productive area for discharge collection for the detection of cancer cells. With the blades of the existing instruments opening in a vertical plane, the blade itself tends to obscure this area of the vaginal vault. Accordingly to permit a sample to be collected from this area, the speculum must be partially withdrawn from the vaginal vault and tilted to permit such access. The tilting operation sometimes pinches the cervix and causes discomfort to the patient.

Accordingly, it is another object of this invention to provide an improved vaginal speculum which facilitates visual access to certain body passages.

In the performing of episiotomies to assist in the birth of a child, it becomes necessary in the post partum phase to stitch up the surgical incisions made. Such surgery is extremely difficult due to the flaccid nature of the surrounding tissue which exists immediately after

birth. Existing speculums do not permit access to the area in which the stitching is required and furthermore tend to interfere with the surgeons ability to make the stitches in the first place.

Accordingly, it is another object of this invention to provide an improved vaginal speculum which facilitates the repair of surgical incisions.

Also, this speculum provides marked improvement of exposure in doing surgical operations such as "D & C" and posterior vaginal repair.

BRIEF DESCRIPTION OF THE INVENTION

The speculum of a preferred embodiment of this invention includes first and second members integrally joined together by a hinge means. The members each include an elongated blade with a convex outer surface and a handle. The blade portions are integrally connected along one edge for pivotable movement. Preferably, the members themselves are formed of a stiffly flexible plastic and the hinge means is formed by providing a relatively thin thickness dimension in the plastic material, i.e., the material is grooved, so that the two blades may flex along this thin dimension or groove. In one embodiment, a ratchet-like supporting brace cooperates with the interior portion of the two blades to permit the blades to be separated to the degree desired. Such brace is particularly useful for surgical applications where both hands of the surgeon are needed.

The blades when in a closed position form a bulbous tip that has a generally triangular silhouette when viewed from the front end. The handles are flared outwardly relative to the axis of the hinge means to improve visual access to body passages and there are deep recesses formed between the handles and the blades to accommodate surgical repair. Finally, an opening in the front end of the blades further enhances visual access to body passages.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features that are considered characteristic of this invention are set forth with particularity in the appended claims. The invention itself, however, both as to its organization and method of operation, as well as additional objects and advantages thereof will be best understood from the following description when read in connection with the accompanying drawings, in which:

FIG. 1 is a side elevation view of a speculum constructed in accordance with this invention illustrating by dotted lines the interior ratchet-type brace in a flexed position;

FIG. 2 is a top plan view of the speculum illustrated in FIG. 1 again illustrating the ratchet-type support in its flexed or closed position;

FIG. 3 is a back end view illustrating the speculum shown in FIG. 1 which clearly depicts the removable ratchet-like support in its closed position;

FIG. 4 is a front end view of the speculum illustrated in FIG. 1;

FIG. 5 is a partial back end view of the speculum illustrated in FIG. 1 shown in an open position with the ratchet-like brace unflexed to an open position;

FIG. 6 is a partial cut-away view taken in elevation of the ratchet-like brace in the open position as occurs in the illustration of FIG. 5;

FIG. 7 is a back end view showing the speculum illustrated in FIG. 1 but with an alternative embodiment of the ratchet-like support brace;

FIG. 8 is a back end view of the speculum illustrated in FIG. 1 but with still another alternative ratchet-like support brace;

FIG. 9 is a side elevation view of a speculum constructed in accordance with an alternative embodiment of this invention in which the locking member is omitted for the sake of clarity;

FIG. 10 is a top plan view of the speculum illustrated in FIG. 9 in its closed position;

FIG. 11 is a back end view illustrating the speculum shown in FIG. 9 in its closed position;

FIG. 12 is a front end view of the speculum illustrated in FIG. 9 is a closed position; and

FIG. 13 is a front end view of the speculum illustrated in FIG. 9 in an open position.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The major portion of the speculum of this invention is preferably formed of the unitary piece of material as is seen most clearly in FIGS. 1 through 4, inclusive. The speculum is made up of two side members 10 and 12 which are integrally connected together by a hinge means 14 at one edge. Each of the members 10 and 12 is generally hollow and shell-like to provide a convex exterior of the required shape for the purpose intended. The primary usage or purpose intended, although certainly not the only one, is that of a vaginal speculum for use in visually inspecting the interior of the vaginal vault as well as inserting instruments thereinto.

Each of the side members 10 and 12 is formed of two integrally connected parts — a blade portion 18 and a handle portion 20. The hollow interior of the blade portion may be most clearly seen in the illustration of FIG. 3. The two side members 10 and 12 preferably are formed of a single piece of stiffly flexible plastic material such as polyamid sold under the trade name "NYLON," polytetrafluoroethylene sold under the trademark "TEFLON" or perhaps most preferably, a polypropylene plastic may be used.

The hinge means is of the same materials of which the two side members 10 and 12 are formed. To form the hinge means, the material joining the two side members 10 and 12 along their upper longitudinal edge is merely molded or fabricated to have a relatively thin wall thickness dimension or groove as seen at 14 (FIG. 3) such that the plastic which is stiffly flexible to begin with can more easily flex at this point. A hinge of this type is capable of many flexures over an extended period of time without the plastic material fatiguing or breaking. The hinge 14 extends only along that portion of the adjoining edges of the side members 10 and 12 which lie along a straight line. Otherwise the flexure of the two pieces would be inhibited. It is thus seen that the hinge 14 permits the two side members 10 and 12 to flex or pivot about the common longitudinal edge of the blade portions 18 such that the lower longitudinal blade edges of the speculum may be pivoted open, as may be seen most clearly in FIG. 5, to permit visual access to the interior of body passages.

A supporting ratchet-like brace means may be provided for those speculums designed for surgical usage, i.e., episiotomies and the like. For general usage, such as taking vaginal smears, the brace means is not normally required. In any event, such brace means 22 when used is in the general form of an arc. The apex of the brace has a small inverted "U-shaped" flexure point 24 normally urging the arc into an open position. The brace is positioned preferably mid-way along the longitudinal blade portion that is normally inserted into the body cavity, the interior of such cavity being generally depicted by the dash-dot line 23. This prevents unequal pressures from acting on the brace. One end of the brace means 22 has a rectangular stud 25 adapted to be inserted into a hollow receptacle 26 which is attached to or, more preferably, is formed integrally with one of the blades 18 at the mid-longitudinal points described as is seen most clearly in FIG. 3. The receptacle 26 is formed in this illustration to be integral with one of the blades, in this case illustrated as the lefthand (in the drawing) blade 18. The stud 24 has a small protuberance or locking nipple 28 adapted to engage a complementary dimple 30 formed in the inner side wall of the receptacle 26 so that it may be inserted and in effect "locked" or snapped in place after the molding is accomplished. In alternative embodiments, this brace means may, if desired, be molded integrally with the entire assembly. The opposite end 32 of the brace means has a slight reverse curvature such that it can easily engage a row of rack-like notches or recesses 34 formed along the inner side wall of the righthand blade 18. This sequence of recesses performs the function of a rack with the free end 32 of the brace means acting as the pawl.

Thus, with the free end 32 of the brace 22 flexed or folded as illustrated in FIGS. 1, 2 and 3 and the stiffly flexible plastic forming the blade sufficiently thin to permit easy flexure, an outward force is exerted at all times on the two blades 18 to facilitate their opening about the pivot edge 14. As the handles 20 and hence the blades 18 are opened, the free end 32 of the brace 22 is permitted to snap or click from notch to notch until the brace is open, as seen most clearly in FIG. 6, with the free end 32 extending into one of the notches 34 in the conventional pawl and rack manner. The blades are now locked open.

With the blades open, the physician has immediate access to an extensive region of the vaginal chamber and may very quickly and easily obtain the sample necessary for the vaginal smear or may, if desired, quickly perform the stitching required in post partum procedures. When it becomes necessary to remove the speculum, this removal is accomplished by depressing plunger 60. The plunger 60 has a shaft 62 adapted to slide longitudinally through a pair of slotted guide members 64 formed integrally with and on the inner wall of the righthand blade 12. The shaft 62 has a stop ring or screw 63 adjacent one end and a thumb plate 68 on the other. The guide members 64 each have a bore to loosely accommodate the shaft 62 and a slot 70 of width less than that of the shaft communicating with the bore. In this manner the plunger shaft may simply be snapped into position in the bore through the slots 70. The end of the shaft contiguous the stop screw is tapered to form a wedge 72 such that when the plunger 60 is depressed, the wedge forces the free end of the brace out of the notches 34 and permits the closure of the speculum blades.

An alternative embodiment of the supporting brace means is shown in FIG. 7. In this instance a protuberance 80 is integrally formed with one of the side walls

of one of the blades **18**. A pivotable brace or pawl **82** having a pivoting stud **84** is adapted to be freely pivotable in the plane in which the pivoting of the blades occurs by inserting the stud **84** into a hole **86** formed in the protuberance **80**. A corresponding number of tooth-like protuberances (or alternatively recessed notches) **88** are formed on the inner wall of the opposite blade **18** such that the end of the brace **82** may coact therewith in a conventional pawl and ratchet manner. Thus when the blades **18** are open and the brace **82** inserted into one of the notches formed by the protuberances **88**, the blades open position is maintained until such time as the brace **82** is again removed from its position. Such removal is easily accomplished either by spreading the blades and allowing the brace to fall away from the notches or by disengaging it with the finger.

In still another embodiment, the supporting brace is formed by securing additional members **90** and **92**, respectively, to the side or back of the handles **20** (FIG. **8**). Alternatively, these members **90** and **92** may be integrally formed with the handle **20**. The end of one of the arms **92** is curved along an arc corresponding to the arc that will be described by the end of the remaining arm **90**. Furthermore, the first arm **92** is formed to provide a rack-type action by forming notches **94** therein. A corresponding stud or pawl **96** formed in the second support arm **90** is adapted to engage the notches **94** such that a pawl and rack-type action is provided. Thus, as the speculum blades are pivoted open, the stud **96** will engage the appropriate notch and the blades will remain open in such pivoted position until the pawl **96** is released as by the surgeon's finger depressing the member **92** and the blades permitted to close.

In the alternative embodiment illustrated in FIG. **9** the means for holding the speculum blades in an open position is omitted for the sake of clarity. In this embodiment, the speculum has a somewhat modified blade and handle structure but is otherwise constructed in the same manner and of the same materials as those hereinbefore described. Thus the speculum illustrated has a pair of side members **110** and **112**. Each of the members includes a blade portion **118** and a handle portion **120**. The blade portions **118** are joined together along one edge by the so-called "living" hinge **114**. If desired, a conventional hinge may be employed to join the two blade portions.

The handles **120** are both flared outwardly relative the axis of the hinge **114** at the rear portion of the speculum to improve the visual access to the interior of the speculum and to provide more working room for the surgeon in doing surgical repair work and the like. Immediately contiguous to the handle, the blades are recessed or formed to have a reduced radial dimension as seen at **122**. This is a portion of the speculum that when in use is normally in the region of the lip of the vagina or other body passage. This recess **122** decreases the strain on the lip portion and facilitates such surgical stitching as may be required. Further out along the blade portion **118**, the radial dimensions of the two blades are increased as seen at **124**, although the region **126** is relatively planar, for the purpose of providing greater arcuate movement to the lever arms for a given arcuate pivot action of the speculum blades. This provides a wider speculum opening and better access to the interior of the body passage. The end portion of the blades is somewhat bulbous when they are in the closed position, i.e., the convexity of the blades increases as a function of the distance from the handles. This facilitates the speculum remaining in position within the vagina without the normal tendency for it to be expelled by the normal contractions of the vaginal muscles.

The blades are generally planar in the vicinity of the hinge means but are rounded back inwardly as the radial distance from the hinge **114** as seen at **128** such that the speculum blades when viewed from the front end position form a generally triangular silhouette. This has the advantage that when the speculum is opened the upper wall of the speculum blades, as seen at **130** (FIG. **13**) is relatively planar and permits the greatest access to the body cavity possible. Finally, the very tip end of the speculum has an oval orifice as seen most clearly at **132** (FIG. **12**). This further improves visual access to the rear portion of the body passage under examination.

In all of the embodiments described, the brace mechanism and plunger preferably are molded of the same material as the speculum. It is to be understood, however, that any other suitable material such as stainless steel may be substituted as desired.

There has thus been described a relatively simple disposable speculum which provides greatly improved visual as well as manual access to certain body passages. In a preferred form the speculum is formed substantially of one integral piece of stiffly flexible plastic and as such may be discarded after each use.

What is claimed is:

1. A speculum which facilitates the examination of certain body passages comprising:

first and second members each having an elongated blade with a convex outer surface, an elongated edge, and a handle,

hinge means connecting said blades together on an axis substantially coaxial and coextensive with at least a portion of said elongated edge for pivotal movement of said members at said hinge means between closed and open positions, thereby to open said body passage to viewing and examination.

2. A speculum according to claim **1** wherein said speculum is plastic and said hinge means and said members are integral.

3. A speculum according to claim **2** which includes first means for maintaining said member in said open position.

4. A speculum according to claim **2** wherein said speculum is formed of a stiffly flexible material.

5. A speculum according to claim **1** wherein said blades when in closed position each have a portion which defines an exterior surface which has a generally triangular end view silhouette with the vertex of the triangle coinciding with the axis of said hinge means, thereby to improve the ability of said speculum to open said body passages.

6. A speculum according to claim **1** wherein each of said blades defines a generally V-shaped cutaway portion contiguous said handle, thereby to engage the lip of said body passages.

7. A speculum according to claim **1** wherein each of said handles is flared outwardly relative to a plane including the axis of said hinge means with the blades in a closed position, each said handle having a longitudinal axis transverse to the axis of said blades.

8. A speculum according to claim 1 which includes first means for maintaining said members in said open position.

9. A speculum according to claim 1:

which includes first means for maintaining said members in said open position,

and wherein said blades when in closed position each have a portion which defines an exterior surface which has a generally triangular end view silhouette with the vertex of the triangle coinciding with said hinge means, thereby to improve the ability of said speculum to open said body passages

said speculum has a bulbous front end portion with said blades in said closed position, whereby said speculum is more easily self-retained in said body passages; and

each of said blades defines a cutaway portion contiguous said handle.

* * * * *