

[54] SPECULUM

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 [51] Int. Cl. **A61b 1/32**
 [58] Field of Search 128/17, 20

[56] **References Cited**

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[57] **ABSTRACT**

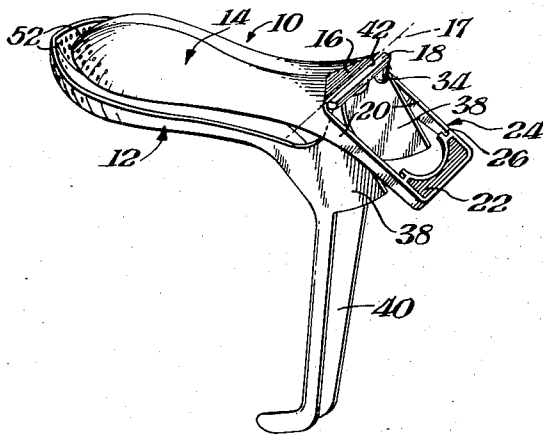
A speculum is formed of a stiffly flexible plastic material and comprises two members. Each member has an

elongated blade with a convex outer surface. In one embodiment, the top member is in the form of an integral hinge with the blade-like portion forming the front leaf. A pair of assembly pins are attached to the rear leaf and are adapted to fit into sockets formed in the rear portion of the lower member. Laterally spaced, arcuate web-like portions on the bottom member are adapted to engage slots formed in laterally spaced arms extending rearwardly from the blade portion of the top member. A handle may be formed on the lower member to facilitate the use of the device. The two blade-like portions are disposed by the hinge in side-by-side relationship for pivotal movement of the two blades about the hinge axis.

In another form of the speculum, the top member has a pair of sockets formed therein adapted to receive a pair of assembly pins which are integral with the bottom member of the speculum. A constricted portion is formed in each pin to form a "living" hinge which permits the operation of the speculum.

In still another embodiment, both blades and the interconnecting pins are integrally formed of a material having sufficient flexure to function as a "living" hinge.

17 Claims, 12 Drawing Figures



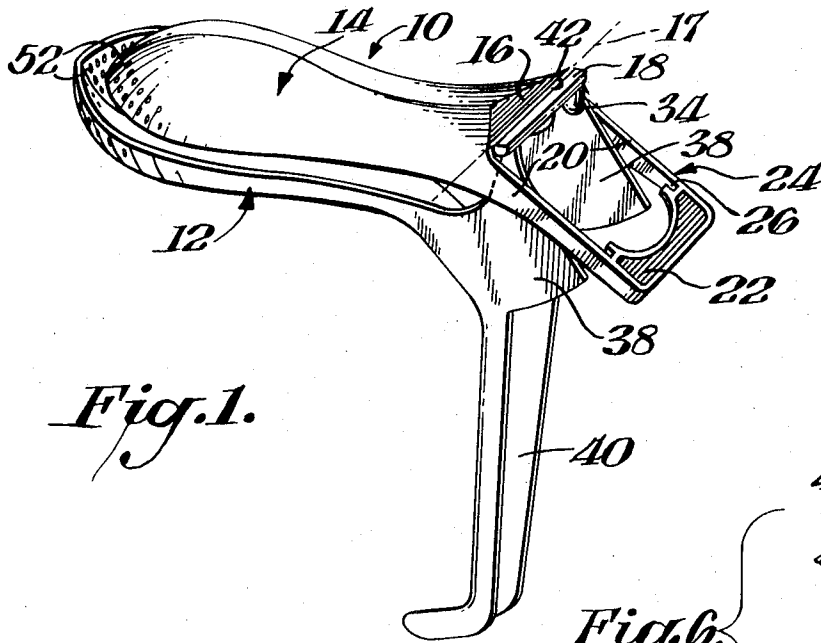


Fig. 1.

Fig. 6.

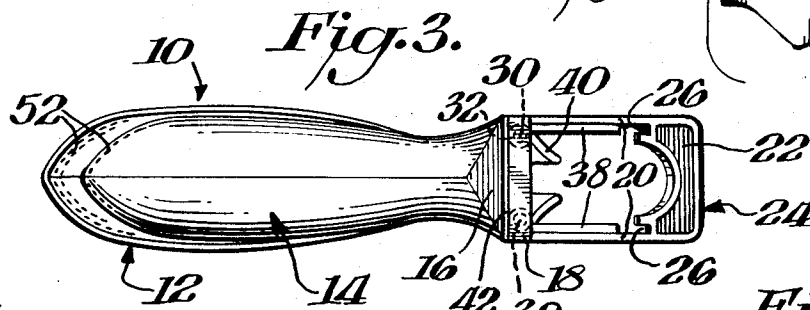


Fig. 3.

Fig. 4.

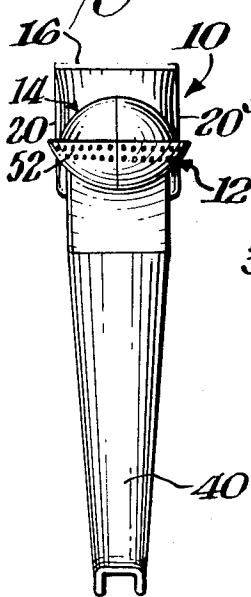


Fig. 5.

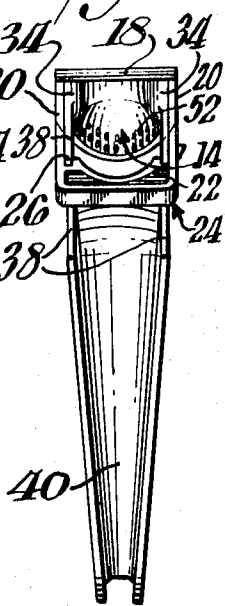
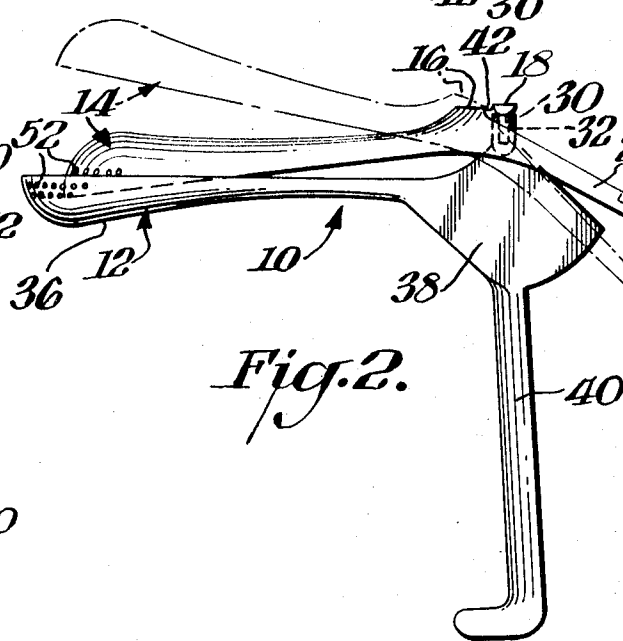


Fig. 2.



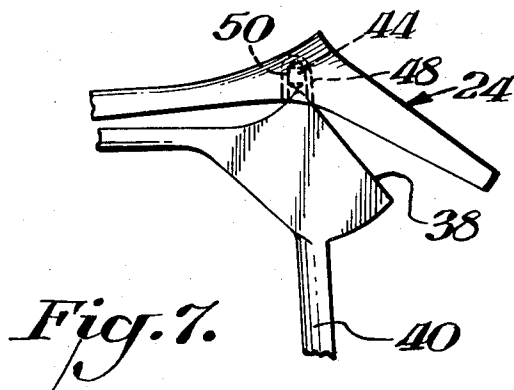
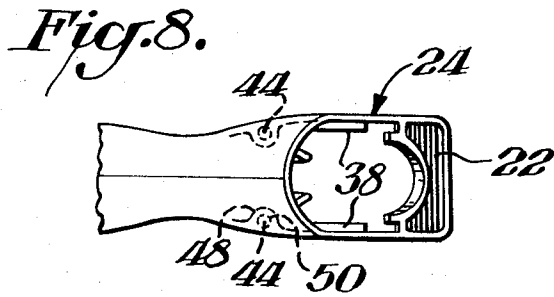
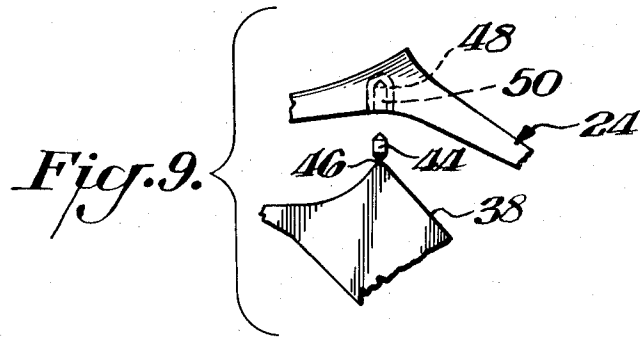


Fig. 11.

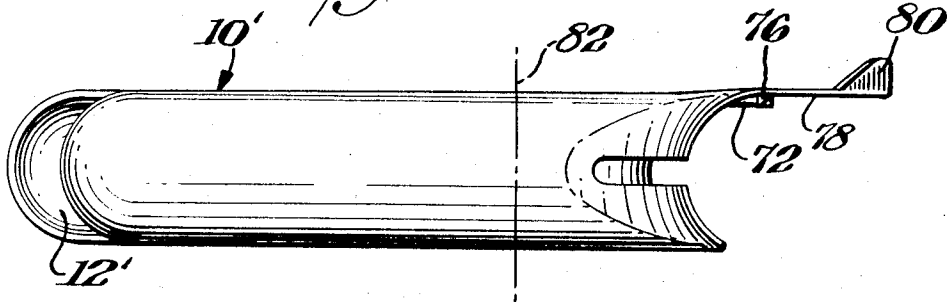


Fig. 10.

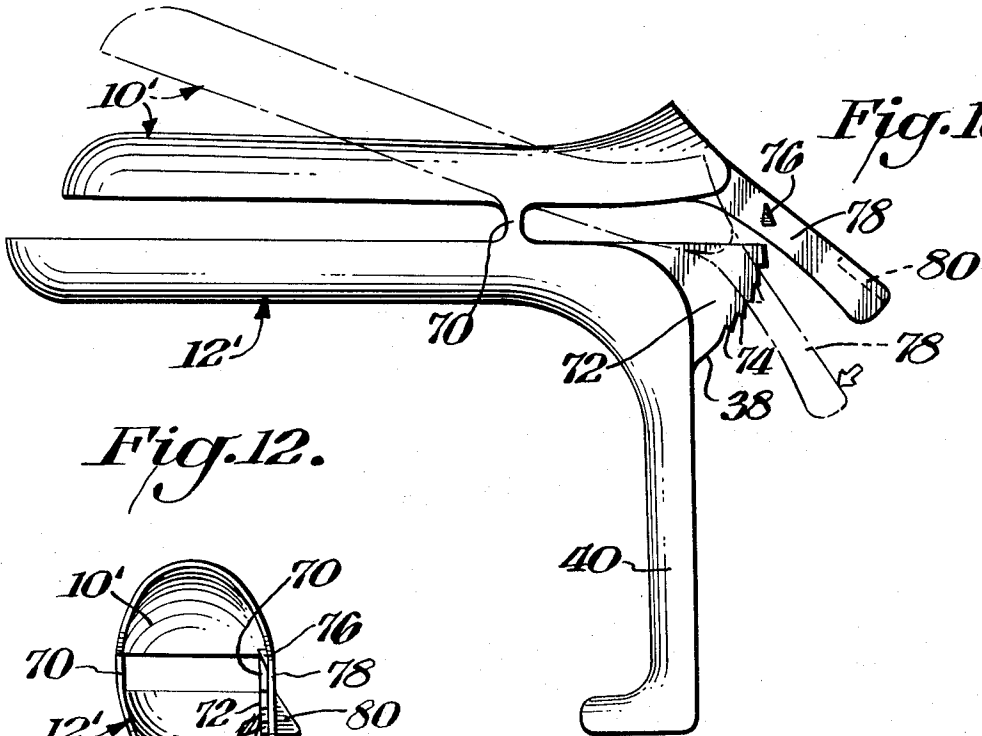
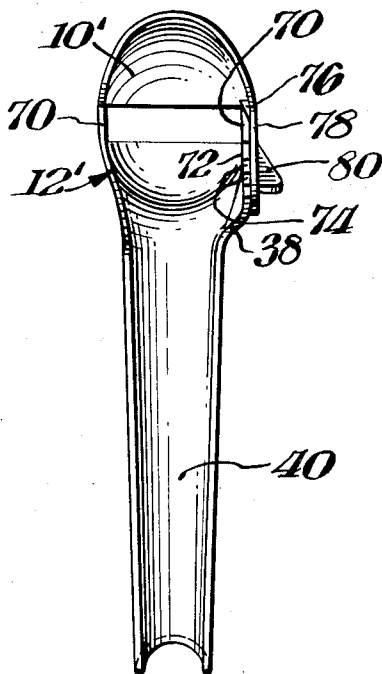


Fig. 12.



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SPECULUM

BACKGROUND OF THE INVENTION

This invention relates to an improved speculum which facilitates the examination of certain body passages and, more particularly, to a speculum, a portion of which incorporates an integrally formed hinge.

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 the instruments are, in fact, cross-infecting the woman under examination.

Furthermore, the cleaning problem is no small task. Even in the typical general practitioner's 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.

To avoid many of these cleaning problems, in recent years many plastic or disposable speculums have been offered on the market. Typical of these disposable speculums is one described in U.S. Pat. No. 3,528,409 issued Sept. 15, 1970, to Samuel M. Bruder. Bruder uses a pair of pivots and sockets which are snapped together to provide the pivot necessary to operate the blades of the speculum in a "duckbill" fashion. Unfortunately, when pivots and sockets of this type are formed, particularly of plastic, their fit is not precise and, hence, there is some looseness or "play" between the tips of the speculum blades. This renders the entire speculum less than desirable to use.

Accordingly, it is an object of this invention to obviate many of the disadvantages of the prior art speculums.

Another object of this invention is to provide an improved disposable speculum that is soundly constructed and has a sure, precise pivot action.

Still another object of this invention is to provide improved disposable speculum that facilitates latching the blades in a spread position.

A further object of this invention is to provide an improved speculum that can be produced for a relatively low cost.

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BRIEF DESCRIPTION OF THE INVENTION

According to a preferred embodiment of this invention, a disposable speculum includes first and second members each having an elongated blade with a convex outer surface and a rear portion. One of the members includes pivot means integral with at least one of the members disposing said members in a side-by-side relationship for pivotal movement of the blades about the rear portion between spread and closed positions. In one form of the invention, the members are both plastic and the pivot means connects the blades together along an elongated axis that is perpendicular to the plane of movement of the blades. In another form of the invention the members and pivot means are integral.

In still another form of the invention, the pivot means has a linking pin that is adapted to engage a socket in the rear portion of the second member adapted to receive the linking pin. With the two members thus fixedly joined together by the linking pin and by the use of a pivot means that is integral with the first blade, little or no sidewise movement or "yaw" of the blades is permitted. Rather, the blades pivot only within their plane of movement and the resulting speculum is a relatively stable, sturdy unit. Alternatively, the pivotal movement may occur by flexing the pins themselves.

The blades may be latched by forming an elongated arm member extending angularly from the rear portion of the blade which defines a slot opening in the direction of the pivot means. Next an arcuate web-like portion is formed at the rear of the second blade and is adapted to frictionally engage the slot during pivotal movement of the blades. This permits the friction between the slot and the arcuate member to releasably secure the blades in an open position. Alternatively, latching may be accomplished by forming a locking protuberance on the arm member that is adapted to engage teeth formed in the web-like portion. The speculum may be unlatched by flexing the arm member to disengage the teeth.

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 pictorial view of a speculum in closed position constructed in accordance with this invention;

FIG. 2 is a side elevation view of the speculum illustrated in FIG. 1 in a closed position and phantom representation of the speculum in an open position;

FIG. 3 is a top plan view of the speculum illustrated in FIG. 1;

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

FIG. 5 is a rear elevation view of the speculum illustrated in FIG. 1;

FIG. 6 is a fragmentary exploded view of the pin and socket portion of the speculum illustrated in FIG. 1;

FIG. 7 is a fragmentary side elevation view of a speculum constructed in accordance with another embodiment of this invention, the speculum being illustrated in a closed position;

FIG. 8 is a fragmentary top plan view of the speculum illustrated in FIG. 7;

FIG. 9 is a fragmentary exploded side view of the pin and socket portion of the speculum illustrated in FIG. 7 particularly depicting the living hinge that is provided by the pin;

FIG. 10 is a side elevation view of a single piece speculum formed in accordance with still another embodiment of this invention;

FIG. 11 is a top plan view of the speculum illustrated in FIG. 10; and

FIG. 12 is a rear elevation view of the speculum illustrated in FIG. 10.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As can be seen most clearly in FIGS. 1 through 5, the speculum constructed according to this invention is formed preferably of two separate members, a first member 10 and a second member 12. The first or upper member 10 includes an elongated blade 14 having at the rear portion thereof a hinge or pivot 16 integrally formed with the blade. The hinge or pivot 16 has a rear leaf 18 (the front leaf being formed by the blade 14) and pivots about an axis 17. Extending angularly downwardly (in the drawing) from the rear portion of the upper blade 14 are a pair of laterally spaced arms 20 which are integrally connected together as at 22 at the rear portion thereof thereby to form a thumb rest 24. The thumb rest 24 may have a knurled surface. On either arm 20 contiguous the integral rear portion 22 are a pair of slots 26 lying in a vertical plane and opening in the direction of the axis 17 of the hinge 16.

Secured to the lower portion of the rear leaf 18 of the hinge are a pair of assembly pins 30 (FIGS. 2 and 6) which in this embodiment may be cylindrical in form. These pins are adapted to engage respective sockets 32 formed in tubular bosses 34 in the rear portion of a second member 12. The second member 12 has at the forward end a blade portion 36. Each of the blades 14 and 36 are generally hollow and shell-like to provide a convex exterior of the required shape for the purpose intended. Typically, also, the upper blade 14 may be shorter in length than the lower blade 36 such that it may fit into the lower blade 36 when the speculum is in a closed position. This shortened blade 14 is the design typically used for conventional vaginal speculums.

Arcuate web-like members 38 are formed in generally parallel relationship on either side of the rear portion of the second member 12 and are so aligned that their peripheries are adapted to frictionally engage the slots 26 in the thumb rest 24. When the two-piece speculum is assembled by inserting the assembly pins 30 into the sockets 32, as will be described hereinafter, and the thumb rest 24 is depressed, the blades 14 and 36 open in a duckbill fashion. To complete the speculum, a handle having a U-shaped cross-section is formed extending downwardly (in the drawing — 40) from the rear portion of the second member 12 and the arcuate web-like members 38. It may be noted that both the first and second members are formed to have a relatively constant thickness. Preferably, they are formed of individual pieces of stiffly flexible plastic material such as polyamid sold under the tradename "Nylon," a polytetrafluoroethylene sold under the trademark "TEFLON," or perhaps most preferably, a poly-

propylene plastic may be used. Whatever the plastic, they are molded in suitable molds according to known techniques to have the desired constant thickness and shape. When formed of a plastic material as described, the hinge, being integral with one of the blades, functions by bending the material of which it is formed. A hinge of this type is often referred to as a "living hinge."

Preferably, multiple capillary sized water retention dimples or holes 42 may be formed on the front and forward portions of the blades. This aids in lubricating the speculum for ease of penetration into the vaginal tract. The use of other lubricating preparations tends to interfere with the accuracy of the Pap Test.

As noted hereinbefore, the hinge 16 preferably is formed integrally with the first member 10 and is formed during the molding or fabrication to have a relatively thin wall thickness dimension or groove as seen most clearly at 42. In this manner, the plastic which is stiffly flexible to begin with, can be more easily flexed along the groove 40 which provides the axis 17. Preferably, the hinge has a length corresponding approximately to the width of the top blade. The hinge, being continuous, prevents the two blades from undergoing any significant sidewise movement, usually termed "yaw," as is a characteristic problem of many of the plastic speculums on the market today.

To manufacture the speculum, the assembly pins 30 are formed to have a diameter slightly greater than the diameter of the sockets 32. As the two members 10 and 12 are removed from their molds, they are immediately, while still hot, assembled by forcibly inserting the assembly pins 30 into the sockets 32. Thus, as the cooling takes place, the sockets 32 which are normally enlarged because of the heat, contract as they cool thereby forming a tight, secure interlock whereby the two members 10, 12 are now rigidly and fixedly secured together. Alternatively, of course, the pins and sockets may be secured as by a suitable cement or other material.

It may be noted that the arc of the arcuate members has a radius, with respect to the axis 17 of the hinge 16, which is approximately the same as the radius of the slots 26 with respect to the same axis 17. The integral hinge utilized in this speculum is capable of many flexures over an extended period of time without the plastic material fatiguing or breaking.

In use, the physician or operator need only grasp the handle 40 in either hand and with the blades 14 and 36 in a closed position as illustrated in FIG. 1 and in FIG. 2 by phantom lines, introduce the speculum into the body cavity in a conventional manner. To open the cavity for better visual access, he places his thumb upon the thumb rest 24 and presses the thumb rest downwardly. This causes the upper blade 14 to pivot about the axis 17 of the hinge 16 thereby pivoting the upper blade 14 upwardly in the drawing. As the opening continues, the slots 26 frictionally engage the arc-like web member 38 such that when the physician ceases to apply further force to the thumb rest, the blades are latched in an open position. After the examination is completed, or the smear taken in the case of a vaginal smear, the thumb rest may be raised to again close the blades and the speculum withdrawn. To aid in the initial insertion, the tip of the speculum may be moistened with water which tends to collect in the water retention dimples 52 in the front portion of the blades.

It is to be understood that essential roles of the two members may be reversed and the integral hinge formed in the lower member. Also, the hinge may be separately formed of plastic or other material and secured to the blade, although the integral hinge is preferred for reasons of ease of manufacture, cost and superiority of operation.

In an alternative embodiment of the invention, depicted particularly in FIGS. 7 through 9, a speculum may be constructed similarly to that previously described. The difference in this case is the hinge mechanism. In the embodiment of FIGS. 7 through 9, pins 44 are secured to the upper portions of each of the web-like members 38 of the bottom member 12. These pins 44 are integrally formed with the member 12 and have a constricted portion 46 which is transverse to the axis of the pin to facilitate the bending or living hinge action of the pin. In the alternative, of course, the pins themselves being slightly flexible, particularly when formed of plastic, may be used to provide the hinge action.

The pins 44 are adapted to engage sockets 50 formed in bosses 48 formed on the lower side of the upper member 10. The particular location of the pins 44 and the sockets 50 on the speculum is optional. In many cases it may be desirable that they be located well forward of the handle 40 and away from the rear portion of the speculum. This location permits the cross-sectional area of the speculum, when in an open position, to be as small as possible. This small cross-sectional area often is desirable, since when used as a vaginal speculum, this is the portion of the speculum which is at the lip of the vagina. This is the most sensitive part of the vagina and often causes discomfort to the patients under examination. The same friction lock previously described in FIGS. 1 through 6 is useful with this embodiment as is seen most easily in FIG. 8. The manufacture of this speculum is accomplished in the manner described above. The pins and socket may be assembled either while the materials are hot, immediately after molding, or they may be secured by suitable cement or other material.

The important advantages offered by the speculum of this invention are provided by the "living" hinge in that it provides a great stability to the operation. Also, the small cross-sectional area at the hinge point is advantageous. The speculum has a positive action and little tendency for the blades to slip or to disengage as is often the case with speculums that are presently available. The speculum is a relatively stable, simple, low-cost disposable speculum which is free of the normal yaw problems often encountered in disposable speculums. The speculum is easy to use and permits good visual access to the interior of body cavities.

A still further alternative embodiment of the invention is illustrated in FIGS. 10 and 11 in which there is shown a speculum formed of a single piece of material, i.e., such that the speculum is an integral unit. This speculum may be constructed in substantially the same manner, e.g., by molding, as those illustrated in the preceding figures. Alternatively, the two blades 10' and 12' may not be contoured and may be straight such as to have a substantially constant cross-section, if desired. This constant cross-section or width of the blades facilitates molding of the unitary speculum. Alternatively, they may be tapered, if desired, toward the tips. In this embodiment the two blades 10' and 12' are connected by pivot means or a pair of "living" hinges 70

which are integrally formed and join the two blades. The width of the living hinge 70 is smaller, preferably less than $\frac{1}{4}$ inch measured along the axis of the blade, to permit the necessary flexure of the material forming the blades. The same material as previously described may be used, i.e., one of the plastics is preferred.

The lower blade 12' is integrally connected with a downwardly extending handle 40 which has a U-shaped cross-section as previously described. Furthermore, one side, preferably the right side as viewed from the rear, of the lower blade 12' has a rearwardly extending, arcuate web-like flange 72, the arcuate edge of which has teeth 74 formed therein. These teeth 74 are adapted to engage a locking member or protuberance 76 formed in the side of a rearwardly extending arm 78 which is integrally formed with the right side (as viewed from the rear) of the top blade 10'. The extreme end portion of the arm 78 has a thumb rest 80 formed therewith to facilitate its use.

In use the speculum is inserted into the body cavity and with the physician's hand gripping the handle 40, he depresses the thumb rest 80 causing the blades 10' and 12' to open. The material forming the hinges 70 flexes to provide the hinge-like action. As the blades open, the latching protuberance 76 engages the teeth 74 such that the speculum remains latched in a desired open location during the examination. When it is desired to withdraw the speculum, the physician merely need press the arm 78 outwardly thereby disengaging the protuberance 76 from the teeth 74, and the speculum immediately snaps closed. It will be noted that the pivoting of the speculum occurs along the center points of the material forming the living hinge 70, the pivot axis being depicted by the dash-dot line 82.

Since the blades 10' and 12' are joined by the same material of which they themselves are formed, which joining material forms the hinge 70, the two blades are held firmly in their relative positions and little sidewise movement or yaw is permitted during operation. Furthermore, it may be noted that the center line 82 of the pivot action of the speculum is well forward of the rear portion of the blades. This permits, particularly in the examination of the vaginal orifice, for the blade opening to occur within the lips of the vagina thereby reducing the discomfort to the patient as previously noted. Another advantage accrued from the unitary speculum is its low cost of production since no labor, other than molding which is an automated operation, is required in assembling the speculum — the speculum is completely formed in the mold itself.

It is obvious that many embodiments may be made of this inventive concept, and that many modifications may be made in the embodiments hereinbefore described. Therefore, it is to be understood that all descriptive material herein is to be interpreted merely as illustrative, exemplarily and not in a limited sense. It is intended that various modifications which might readily suggest themselves to those skilled in the art be covered by the following claims as far as the prior art permits.

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 and a rear portion, and

- flexible means for pivotal movement of said blades about said rear portions between spread and closed positions, said flexible means being integral with at least one of said members and fixedly interconnected with the other of said members for disposing said members in side-by-side relationship. 5
- 2. A speculum according to claim 1 wherein said members are plastic.
- 3. A speculum according to claim 1 wherein said flexible means connects said blades together along a pivot axis that is perpendicular to the movement of said blades. 10
- 4. A speculum according to claim 3 wherein said elongated axis has a physical length approximating the width of said blades, thereby to reduce yaw in the movement of said blades. 15
- 5. A speculum according to claim 1 wherein said flexible means has an integral linking pin and said other member defines an integral socket in said rear portion adapted to fixedly receive said linking pin, thereby to secure said members together. 20
- 6. A speculum according to claim 5 which includes:
 - an arcuate web-like member extending from the rear portion of said first blade,
 - latching means having an elongated arm member extending angularly from the rear portion of said second blade and defining a slot opening in the direction of said flexible means and adapted to frictionally engage said web-like member during pivotal movement of said blades, thereby to releasably maintain the open position of said blades. 30
- 7. A speculum according to claim 1 wherein said flexible means is integral with each of said members.
- 8. A speculum according to claim 7 which includes: 35
 - latching means having an arcuate web-like member extending from the rear portion of said second blade and having a toothed edge, and
 - an elongated arm member extending angularly from the rear portion of said first blade and defining a latching protuberance adapted to engage said edge during pivotal movement of said blades, thereby to releasably maintain the open position of said blades. 40
- 9. A speculum according to claim 8 wherein said members are plastic.
- 10. A speculum according to claim 7 which also includes latching means comprising interengaging parts integral with respective ones of said blades, and wherein said flexible means interconnects corresponding sides of said blades. 50
- 11. A speculum according to claim 1 which includes:

- a pair of laterally spaced, arcuate web-like members extending from the rear portion of said one blade,
- latching means having a pair of laterally spaced arm members extending angularly from either side of the rear portion of the other one of said blades and terminating in an integral extension, each of said arms defining a slot contiguous said integral extension opening in the direction of said flexible means and adapted to frictionally engage respective ones of said web-like members during pivotal movement of said blades, thereby to releasably maintain the open position of said blades.
- 12. A speculum according to claim 11 wherein said first member and said arm members are integral, and said second member and said web-like members are integral.
- 13. A speculum according to claim 1 wherein said flexible means is a linking pin and said other member defines an integral socket adapted to receive said linking pin, thereby to secure said members together.
- 14. A speculum according to claim 13 wherein said socket is located away from the rear portion of said second member to facilitate reducing the cross-section of said speculum in the region of said flexible means when in an open position, thereby to reduce discomfort caused by the speculum.
- 15. A speculum which facilitates the examination of certain body passages comprising:
 - an integral hinge having a pair of leaves and a pivot axis,
 - a second member having a rear portion, one of said leaves and said second member each having an elongated blade with a convex outer surface, and
 - the other of said leaves being secured to the rear portion of said second member to pivotally dispose said blades in side-by-side relationship for pivotal movement about said hinge.
- 16. A speculum according to claim 15 wherein said members are plastic.
- 17. A speculum according to claim 15 wherein:
 - said one leaf includes an elongated arm member defining a slot opening in the direction of the pivot axis, and
 - said other member includes an arcuate web-like member extending from the rear portion of said second blade adapted to frictionally engage said slot during pivotal movement of said blades thereby to releasably maintain the open position of said blades.

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