

[54] **DIGITAL AMNIOTOME**

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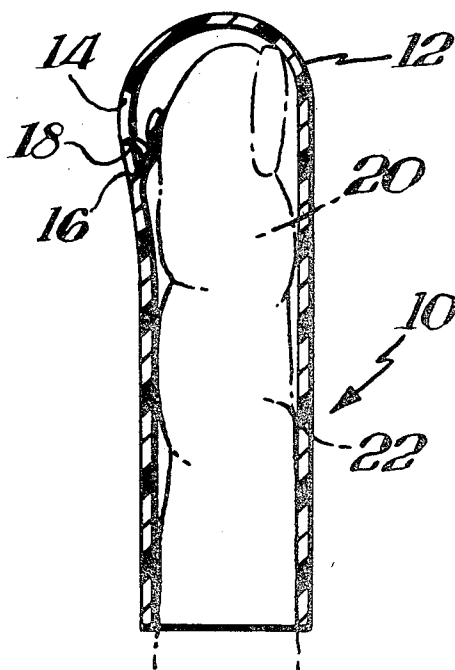
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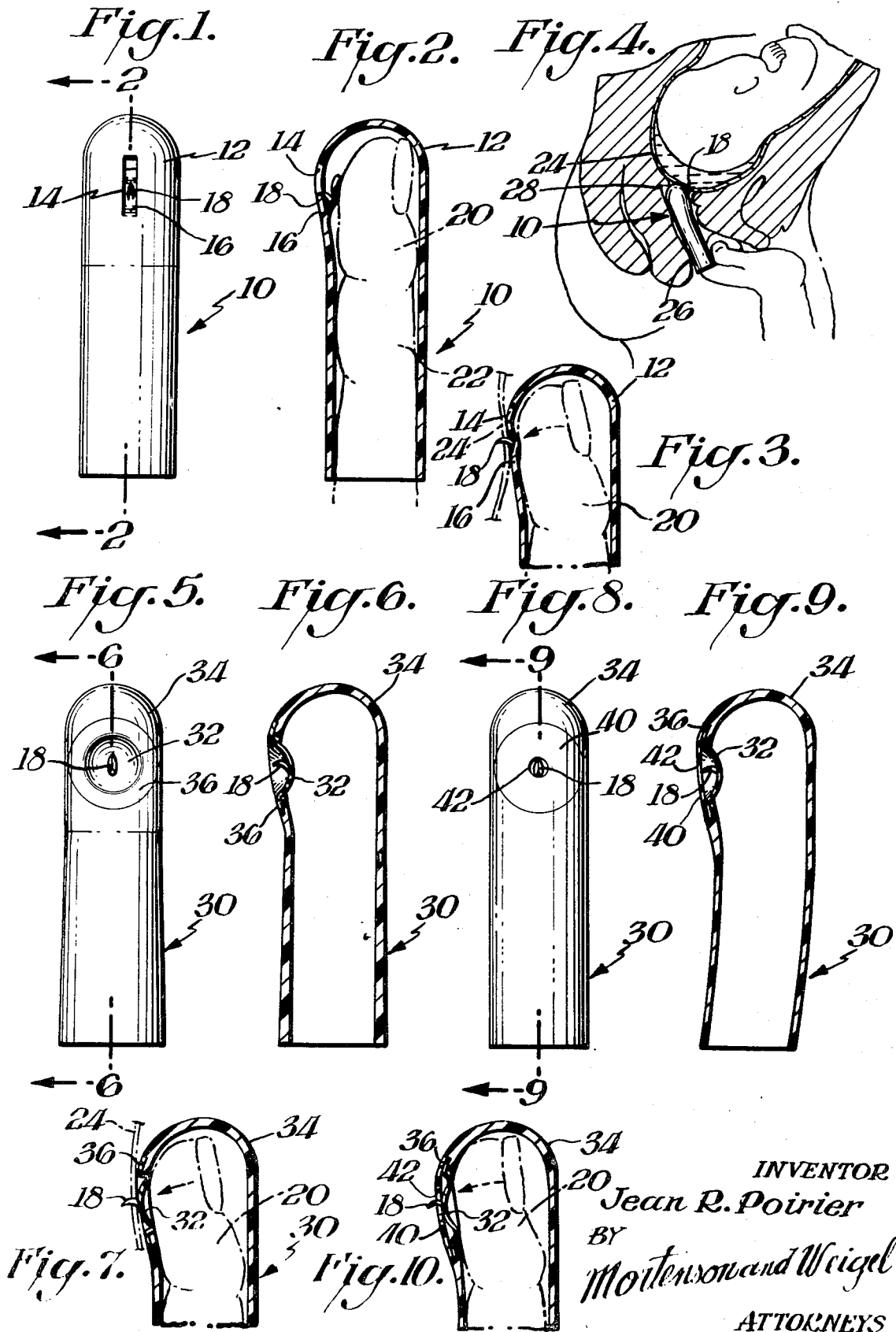
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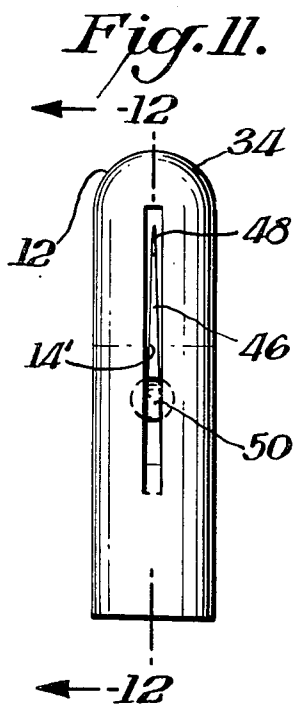
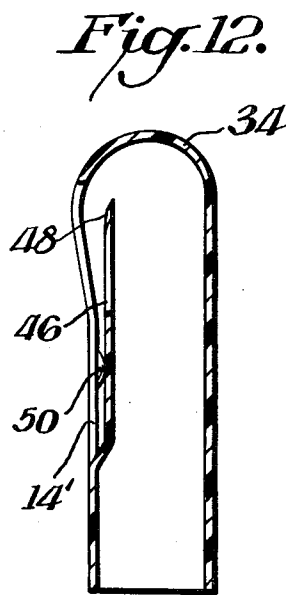
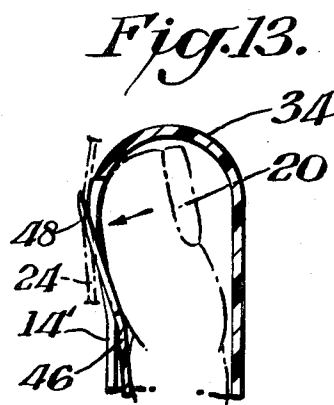
ABSTRACT

The digital amniotome described herein is a generally hollow, cylindrical finger-like device closed at one end adapted to be placed on and operated by a finger for rupturing the amniotic membrane during obstetrical procedures. The cylindrical device is adapted to extend over the second finger joint and preferably is formed of a plastic material that is stiffly flexible to aid in the flexure of the first finger joint which operates the device. Adjacent the closed end of the cylindrical device there is a resilient recessed portion in one wall having a sharp tipped, hook-like element secured thereto. When the fingertip is flexed, the resilient portion and sharp tipped element, which are normally in a retracted position, are extended radially to expose the sharp tip and permit its use in rupturing of the amniotic membrane.

11 Claims, 13 Drawing Figures







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DIGITAL AMNIOTOME

BACKGROUND OF THE INVENTION

The invention relates to a digital amniotome and, more particularly, to a digital amniotome having a recessed sharp member adapted to be extended to rupture the amniotic membrane during obstetrical procedures.

It is often desirable and/or necessary, for the purpose of hastening labor in a pregnant woman who is at term, to rupture the amniotic membrane. Various devices have been designed over the years for this purpose. One of the more commonly used devices is a stainless steel member having a finger loop at one end and a sharpened hook at the other. Other devices have included surgical gloves having a protruding sharpened point positioned on one of the fingers. Still other devices have included finger carried members having a sharp point on one end and plastic rods having a sharpened hook-like device on one end.

Although the hook-like devices have some advantages over the spear shaped or trocar-pointed devices because there is less chance of injuring the fetus or traumatizing the patient's cervix or vaginal wall, their mere appearance tends to frighten many patients. This is particularly true of the older stainless steel instruments that are available. Furthermore, the sterilization problems encountered with many of the instruments are difficult and with the increasing labor costs quite undesirable.

It is, therefore, an object of this invention to obviate many of the disadvantages of the prior art amniotic sac rupturing devices.

Another object of this invention is to provide an improved device capable of rupturing the amniotic sac during obstetrical procedures.

A further object of this invention is to provide an improved disposable device that is quite simply and easily used for rupturing the amniotic membrane during obstetrical procedures.

BRIEF DESCRIPTION OF THE INVENTION

In a preferred embodiment of this invention a finger carried and operated obstetrical device is adapted to rupture the amniotic membrane during obstetrical procedures. The device includes a finger carried member that is adapted to extend over substantially all of the first two finger phalanxes and to be frictionally retained on the finger. The member has a recessed resilient portion in its side wall adjacent the end of the member. A sharp tipped element is secured to the recessed portion whereby the operator by flexure of his fingertip may cause the normally recessed sharp element to protrude from the member thereby to facilitate rupturing of the amniotic membrane. In alternative embodiments the finger carried member may be lengthened and stiffened to facilitate the flexure operation of the finger tip.

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 front elevation view of a digital amniotome constructed in accordance with one embodiment of this invention;

FIG. 2 is a cross-sectional view of the digital amniotome illustrated in FIG. 1 taken along the section line 2—2 illustrating the manner in which the operator's finger is inserted;

FIG. 3 is a partial cross-sectional view of the digital amniotome illustrated in FIG. 1 illustrating the manner in which the end finger phalanx is flexed in order to actuate the amniotome;

FIG. 4 is a partial sectional view of the anatomy of a human female about to give birth with the amniotome positioned for use;

FIG. 5 is a front elevation view of an alternative embodiment to the digital amniotome illustrated in FIG. 1;

FIG. 6 is a cross-sectional view of the digital amniotome illustrated in FIG. 5 taken along the section line 6—6;

FIG. 7 is a partial cross-sectional view of the digital amniotome illustrated in FIG. 6 in an operated condition;

FIG. 8 is a front elevation view of still another alternative embodiment of the digital amniotome illustrated in FIG. 1;

FIG. 9 is a cross-sectional view of the digital amniotome illustrated in FIG. 8 taken along the section line 9—9;

FIG. 10 is a partial cross-sectional view of the digital amniotome illustrated in FIG. 8 in an operated condition;

FIG. 11 is a front elevation view of another alternative embodiment of the digital amniotome illustrated in FIG. 1 utilizing a cantilevered point for rupturing the amniotome membrane;

FIG. 12 is a cross-sectional view of the digital amniotome illustrated in FIG. 1, taken along the section line 12—12; and

FIG. 13 is a partial cross-sectional view of the digital amniotome illustrated in FIG. 11 in an operated condition.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

There is illustrated in FIGS. 1 through 3 one embodiment of the invention in which there is seen a finger carried member 10 in the general form of a hollow cylinder having one end closed by a generally spherical or rounded closure as seen at 12. The finger member 10 may be formed of rubber latex or any suitable plastic 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 essential requirement of the plastic is that it is somewhat flexible such that some slight bending is permitted, to facilitate the utilization of the device and to improve the operator's sense of feel when using the amniotome. The amniotome should be of sufficient length to at least extend over the first joint of the finger (usually the middle finger is used for this purpose).

Immediately adjacent the rounded end 12 of the amniotome a slot 14 is formed and a resilient spring-like member 16 is adapted to be operated into and out of the slot 14. As illustrated the resilient member 16 is in effect recessed within the amniotome such that the amniotome may be said to have a recessed portion. A sharp hook-like element 18 may be secured to the resilient member 16 such that when the member 16 is depressed as by the flexing of the last phalanx 20 (FIG. 2) of the operator's finger 22, the resilient member is moved to the left in the drawings radially of the amniotome such that the hook 18 extends outwardly and protrudes from the outer surface of the amniotome as is seen most clearly in FIG. 3.

It will be noted that the end portion of the amniotome is slightly bulbous in shape. This is to afford sufficient room for the last phalanx 20 of the operator's finger to be flexed to extend the hook 18. The resilient member 18 may be formed integrally with the amniotome, if the material employed is of sufficient resilience, so that the member is always able to return to the interior of the device after depression by the first phalanx. Alternatively, the resilient member 16 may be formed of a separate material and secured by a suitable adhesive to the remainder of the plastic. Many suitable adhesives are available for this purpose as is well known in the art.

In operation, when a pregnant woman is in labor and it is determined that rupturing of the amniotic membrane 24 (FIG. 4) is in order, the doctor or operator places the amniotome 10 on his finger, usually the middle finger, and inserts the amniotome into the vagina 26 and opening of the cervix 28 until the recessed portion is immediately adjacent the exposed region of the amniotic membrane 24 at the entrance to the cervix 28. The operator then flexes the first phalanx 20 of his finger thereby causing the resilient member 16 and sharp tipped element 24 (FIG. 3) to extend from its normally retracted position such that the sharp tip is exposed. It is not necessary to poke at the membrane but rather is only necessary that the doctor then move his finger such that the sharp element 24 snags the membrane. He then simply by drawing his finger back is able to rupture the membrane with little chance of injury to the fetus or to the walls of the vagina or cervix.

Once the membrane is ruptured, the operator merely relaxes the last phalanx of his finger, allows the resilient member 18 to again withdraw into its retracted position (FIG. 2) and the amniotome is withdrawn with absolutely no danger of traumatizing the walls of the cervix or vagina. This simple finger unit is seen to be easily used and, more importantly, is disposable after each use since it can be made relatively cheaply out of plastic or other suitable material.

The alternative embodiment shown in FIGS. 5 through 7 illustrates a digital amniotome 30 which may be of substantially the same construction and of the same material as that described hereinbefore. The essential difference between these embodiments is that in the latter embodiment, the sharp tipped element or hook 18 is positioned on a diaphragm-like element 32 which is at least partially recessed within the outer side wall of the amniotome 30 near the closed tip end 34. The diaphragm 32 is formed of a flexible, resilient material and may be a separate shallow cup-like piece

formed, as is seen most clearly in FIG. 6, such that the tip of the hook 18 does not protrude beyond the normal peripheral surface outline of the amniotome. If the diaphragm is formed separately from the remainder of the amniotome, it may be attached to a circular stepped portion 36 formed in the side wall of the amniotome.

The lower portion in the drawing, or the open end of the amniotome in this embodiment is illustrated as having a slightly thickened wall section. The purpose of this is to provide some additional stiffness or rigidity to the finger carried member such that when it is made of sufficient length to encompass both of the first two joints or knuckles of the finger, it acts as a finger splint to aid and facilitate the flexure of the last phalanx of the finger. The tip end portion of the amniotome is maintained as thin walled as possible while still retaining its general shape to permit the hook 18 to be recessed and yet have as much of a sensation of "feel" as possible. The unit is utilized in substantially the same manner as that described hereinbefore, namely, when the first phalanx 20 of the finger is flexed, the diaphragm 32 and hook 18 are moved from their relaxed and retracted position radially outward such that the hook is exposed to permit the amniotic membrane to be ruptured.

The embodiment illustrated in FIGS. 8 through 10 is similar to that illustrated in FIGS. 5 through 7, the essential difference being that a cover member 40 is secured to the exterior of the amniotome 30 so as to cover all of the recessed portion, including the diaphragm 32 and the sharp tipped element 18, with a smoothly contoured cover that maintains the surface continuity of the amniotome. The cover 40 is provided with a central orifice 42 to permit the hook 18 to be extended from its normally retracted position and exposed as seen in FIG. 10. Further, the cover may be formed of the same material as the amniotome and peripherally secured along with the diaphragm in the step 36 by a suitable adhesive. In still another modification, the amniotome is illustrated as having a curved axis at its open end. This often facilitates its use since the finger has a natural curvature which is more easily accommodated by the curved axis configuration. The usage of the amniotome illustrated in FIGS. 8-10 is the same as that of FIGS. 5-7 and need not be described further.

The hook 18, while illustrated in all embodiments as being hook-like, need not be so. It may, in fact, be straight, although the hook-like configuration is preferred. An alternative embodiment using a straight, sharp tipped member 46 is illustrated in FIGS. 11-13 inclusive. In this embodiment the sharp tipped member 46 is adapted to be depressed to extend outwardly through a slot 14', the amniotome being of substantially the same configuration as seen in FIGS. 1-3 except the slot is extended. The member 46 is in the form of a lever, formed integrally with the body of the amniotome, having a sharp pointed end 48. A fulcrum 50 is introduced through the slot 14 to permit the flexible end 48 of the lever 46 to be depressed to extend out of the amniotome for use. If desired the orifice in any of the embodiments may be in the form of overlapped film sections which are pushed outwardly as the hook or lever is activated or a unitary film covering the protru-

sion area can be pierced by the active hook or lever to form the orifice at the needed time, that is, concurrently with the piercing of the amniotic membrane.

The digital amniotome described is a unique, disposable unit which significantly reduces the possibility of injuring the fetus or traumatizing the patient's cervix or vagina. The sharp hook-like element which is utilized to rupture the membrane is in a protected, recessed position until the unit is used at which time it may be quickly and easily extended and operated to cause the rupture. After use, the hook-like element is allowed to again retract within the membrane so that danger of traumas are significantly reduced or eliminated, and withdrawal of the amniotome is facilitated. Although closure of the end 12 is preferred it is not essential. Closure facilitates use of the amniotome since it is more easily introduced into the vaginal orifice.

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, exemplary, 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 gynecological device adapted to be placed on and operated by a finger for rupturing the amniotic membrane during obstetrical procedures, said device comprising:

a finger carried member having an axis and adapted to extend over the first two finger phalanges, said member having a resilient recessed portion in one wall contiguous to the finger tip position, said recessed portion adapted to be flexed radially of said axis,

a sharp tipped element secured to said recessed portion, said element being normally retracted behind the outer surface of the wall of said member, whereby said recessed portion and element are adapted to be operated by flexure of the finger tip to protrude from said member, thereby to facilitate the rupture of said membrane, and thereafter to be released to retract within said outer surface, thereby to facilitate withdrawal of said device without trauma.

2. A device according to claim 1 wherein said element is hook-like.

3. A device according to claim 1 wherein said axis is normally curved to facilitate entry of said member into the vagina.

4. A device according to claim 1 wherein said member is stiffly flexible to facilitate its utilization.

5. A device according to claim 1 wherein the member is stiffly flexible and of sufficient length to extend over the second joint of the finger, thereby to facilitate flexure of the finger tip to operate said element.

6. A device according to claim 1 wherein said recessed portion includes a lever arm fulcrumed against the inner radial wall of said member, the tip of said lever arm having a sharpened point.

7. A device according to claim 1 wherein said element is integral with said recessed portion.

8. A device according to claim 1 which also includes a cover member defining an orifice for said element positioned over said recessed portion, whereby said element is in a normally retracted position thereby to reduce the possibility of traumatizing the cervix or vaginal vault.

9. A device according to claim 8 wherein said member has thickened walls to increase its stiffness in the region of the second finger joint, thereby to facilitate flexure of the finger tip for extending and exposing said element.

10. A device according to claim 9 wherein said recessed portion is in the form of a resilient diaphragm in said radial wall.

11. A gynecological device adapted to be placed on and operated by a finger for rupturing the amniotic membrane during obstetrical procedures, said device comprising:

a finger carried member having an axis and adapted to extend over the first two finger phalanges,

said member having an integral resilient recessed portion in one wall contiguous to the finger tip position, said recessed portion adapted to be flexed radially of said axis,

a sharp tipped element integral with said member secured to said recessed portion, whereby said recessed portion and element are adapted to be operated by flexure of the finger tip to protrude from said member, thereby to facilitate the rupture of said membrane.

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