United States Patent

[11] 3,533,411

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[54] **SURGICAL INSTRUMENT FOR RUPTURING MEMBRANES**
8 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **128/361,** 128/329
[51] **Int. Cl.** **A61b 17/42**
[50] **Field of Search** 128/303, 305, 307, 314, 315, 329, 353, 361, 356; 66/116–118

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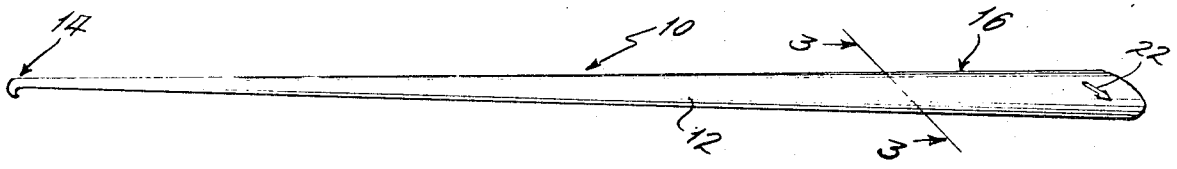
ABSTRACT: An elongated surgical instrument having a hook or barb portion on one end and a handle portion on the other end, said instrument being for inserting into the vagina of a full term pregnant women to rupture the amniotic membrane to facilitate giving birth. The subject instrument is a relatively simple inexpensive instrument preferably of one piece construction and well suited for packaging in a sterile condition.



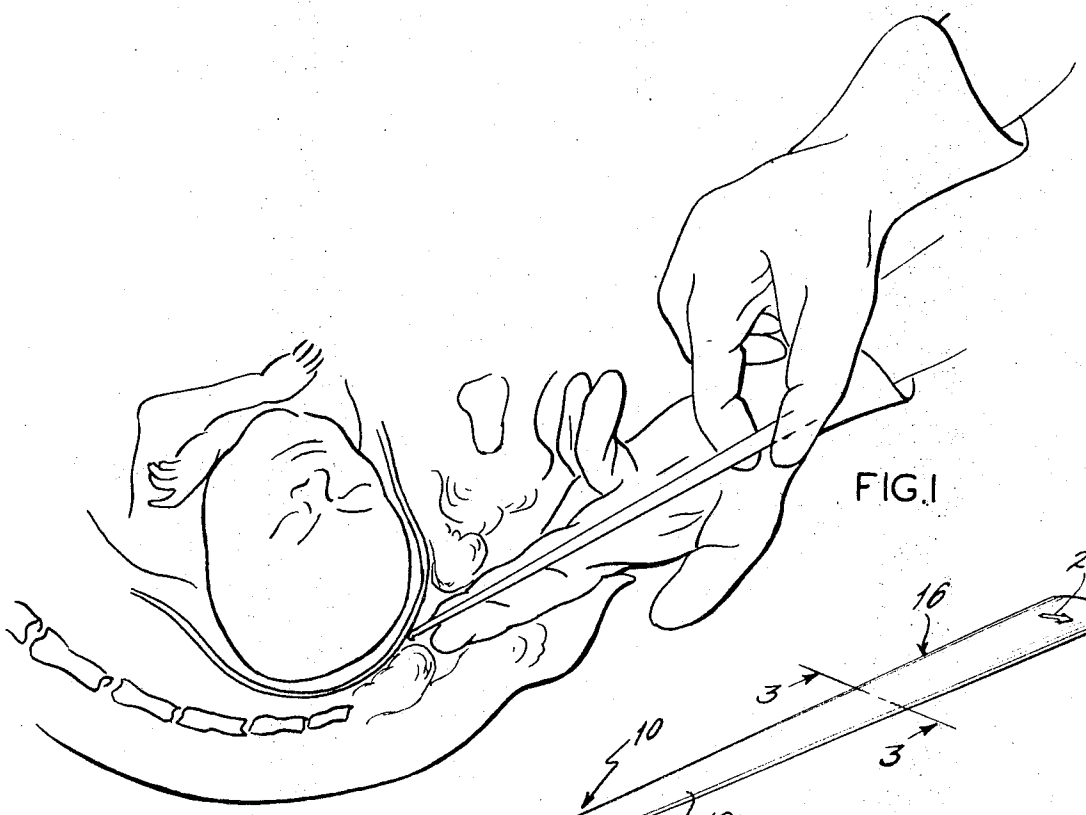


FIG. 1

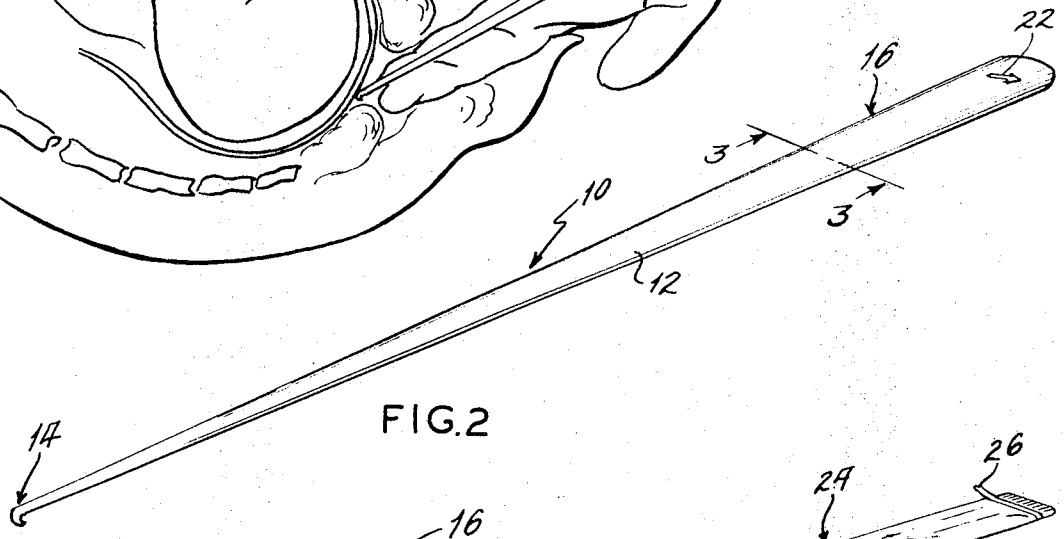


FIG. 2

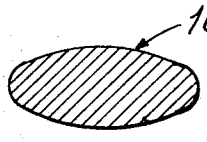


FIG. 3

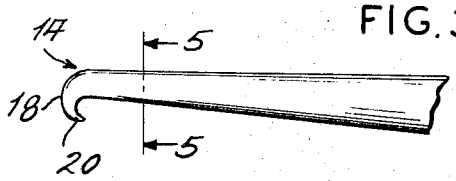


FIG. 4

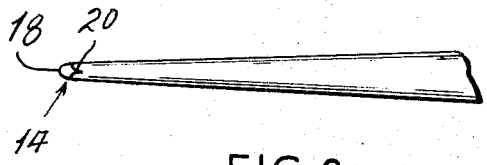


FIG. 6

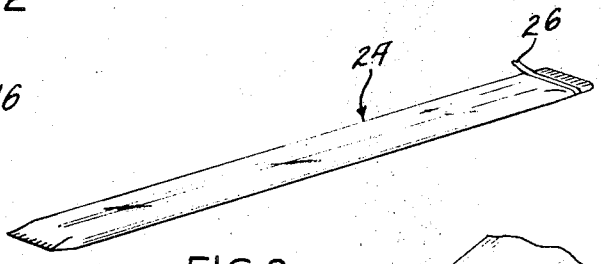


FIG. 8

FIG. 5

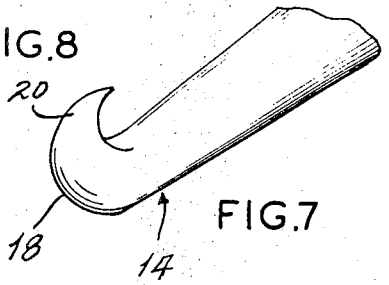


FIG. 7

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SURGICAL INSTRUMENT FOR RUPTURING MEMBRANES

In the practice of obstetrics it is frequently necessary to facilitate the delivery process by rupturing the amniotic membrane so that the fluids trapped therein can be expelled. Frequently this happens naturally without requiring the help of the attendent doctor, and it is in those cases where the membrane fails to rupture naturally that the doctor is called upon to rupture the membrane. Various devices and means have been used in the past for rupturing amniotic membranes many of which have been fashioned and constructed by the doctor from his supply of surgical instruments and from other devices. For the most part, the devices that have been used for this purpose have been relatively cumbersome and difficult to operate, are not designed for this specific operation, and are relatively expensive and must be resterilized after each use. The known devices are also usually relatively large and often difficult to insert into the vagina and properly locate and frequently are difficult to manipulate into the best position to perform the desired operation. Also because they are not disposable the known devices must be sterilized before each use and this means that the hospital staff must keep track of them and make sure they are always available and in sterile condition when they are needed. This requires considerable staff time, equipment and hospital routine.

The present invention overcomes these and other disadvantages and shortcomings of the prior art by teaching the construction and use of a relatively simple, inexpensive, disposable instrument that can be supplied in quantity for storage at a convenient location in a hospital, at a relatively low cost, and in sterile condition without requiring further handling or sterilization at the hospital. Furthermore, after one of the subject instruments has been used it can be thrown away without great loss and without having to be rehandled. The subject instrument is also relatively small and can be easily inserted into the vagina along side of the doctor's inserted fingers which act to guide and position it, and the subject instrument is easily and accurately controllable by the doctor even though it must be operated almost entirely by feel without being able to see the membrane to be ruptured or the part of the instrument that ruptures the membrane. The subject instrument is also constructed to minimize the possibility of causing injury to the unborn fetus.

It is, therefore, a principal object of the present invention to provide an inexpensive disposable surgical instrument primarily for rupturing the amniotic membrane.

Another object is to provide a relatively simple surgical instrument that can be controlled and manipulated with a high degree of accuracy and can be used in body cavities where space is very limited.

Another object is to provide an instrument for rupturing the amniotic membrane with minimum chance of injuring the unborn fetus.

Another object is to minimize the hospital staff time and equipment required for maintaining a supply of sterilized surgical instruments.

Another object is to provide improved means for handling and guiding surgical instruments used in performing operations in body cavities.

Another object is to minimize the size of instrument required for rupturing the amniotic membrane.

Another object is to encourage uniform surgical procedures in the rupturing of the amniotic membrane in obstetrical cases.

These and other objects and advantages of the present invention will become apparent after considering the following detailed specification which covers a preferred embodiment thereof in conjunction with the accompanying drawing, wherein:

FIG. 1 is a cut away view showing a portion of the anatomy of a full term pregnant women and illustrating use by the doctor of a surgical instrument to rupture the amniotic membrane, said instrument being construction according to the present invention;

FIG. 2 is a side view of the subject surgical instruments;

FIG. 3 is an enlarged cross-sectional view taken on line 3–3 of FIG. 2;

FIG. 4 is an enlarged fragmentary side view of the head end portion of the same instrument;

FIG. 5 is an enlarged cross-sectional view taken on line 5–5 of FIG. 4;

FIG. 6 is an enlarged bottom view of the head end portion of the same instrument shown in FIG. 4;

FIG. 7 is a further enlarged perspective view of the head end portion of the instrument; and,

FIG. 8 is a view showing the subject instrument wrapped in a sterile prepackaged condition.

Referring to the drawing more particularly by reference numbers, number **10** refers to a surgical instrument constructed according to the present invention. The instrument **10** includes an elongated body **12** formed preferably of some relatively inexpensive material such as plastic. The subject instrument is shown as being straight from end to end and this is the desired form. It is contemplated, however, that the instrument could be constructed with a slight bend or bow in it without changing the basic characteristics. The body also is preferably tapered from end to end with a smaller head portion **14** at one end and a larger handle portion **16** at the other end. Referring to FIG. 3 it can be seen that the handle portion **16** is oval or flat shaped so that the doctor using the instrument can tell in which direction the head end is facing and the handle portion **16** also enables the doctor to more easily and accurately control and manipulate the instrument as will be explained. The length of the instrument is not critical but it should be long enough so that when it is inserted into a vagina to the depth of the cervix a convenient length of the handle portion extends out from the vagina and can be used for manipulating the instrument as shown in FIG. 1.

The details of the smaller head end **14** are shown in FIGS. 4–7 and include a blunt end surface **18** and a sidewardly and rearwardly projecting hook portion **20**. The blunted end surface helps to prevent possible injury to an unborn fetus when the instrument is inserted into the vagina and moved into the cervix and against the amniotic membrane.

The hook portion **20** is preferably made relatively short and sharp and is positioned close to or at the end of the instrument so that when the instrument is moved against the membrane the hook will also be against the membrane. Thereafter, when the instrument is rotated it will be relatively easy to snag the membrane, and thereafter as the instrument is withdrawn with the membrane snagged the membrane will rupture and permit the fluids contained therein to escape. The pointed hook portion **20** should preferably also be formed with a slight rearward bend or angle as a further safety feature to prevent injury to the fetus and to better enable it to snag the membrane.

The relatively flat form of the handle portion **16** of the instrument is preferably oriented to have a particular relationship relative to the direction in which the hook **20** faces. This helps the doctor know in which direction the hook is facing after the instrument is inserted, and it also helps the doctor know how he should manipulate the instrument since he must rely mainly on feel rather than sight when performing the operation. If desired some other means may also be provided to indicate the orientation of the hook. Such other means may include an arrow **22** as shown in FIG. 2. The arrow **22** can be printed on the tool adjacent the handle end or it can be molded on the instrument at the time it is made.

The subject instrument as stated is usually used by the doctor at some time before the actual delivery is expected to prepare the patient for delivery. The manner in which the instrument is used is illustrated in FIG. 1. This may be done as part of an examination the doctor will make. In performing the operation the doctor will usually insert two fingers into the vagina to determine by feel if the cervix is dilated and the extent of the dilation. If the cervix is dilated the inserted fingers will come in contact with a portion of the amniotic membrane or sack in which the fetus is positioned. Before birth can take place this member must rupture or be ruptured so that the

fluids surrounding the fetus can escape. If the doctor determines that the membrane should be ruptured he will insert the subject instrument into the vagina along side his inserted fingers, head end first with the hook portion extending sidewardly toward the groove formed by his inserted fingers. With his free hand on the handle portion the doctor will then guide the instrument into the vagina into a position in which the blunt end **18** is positioned in the dilated cervix and engaged with the membrane. He will now rotate the instrument using the handle portion **16** and at the same time will use his inserted fingers to guide and support the head end and to apply the necessary pressure against the head end so that the hook **20** will snag the membrane without doing injury to the fetus. After the membrane has been hooked the instrument will be manipulated to rupture the membrane and will then be withdrawn again with the hook portion following the channel or groove formed by the inserted fingers. This is done both during insertion and removal to prevent the hook from contacting and damaging any of the sensitive internal tissues present in this region of the body. After the instrument is withdrawn it can be discarded by throwing it in a waste container or the like. FIG. **1** illustrates the instrument being used in relation to the pertinent portions of the female anatomy.

FIG. **8** shows a wrapper or package **24** in which the subject instrument is positioned at the factory prior to delivery to a hospital. The wrapper includes an elongated container somewhat similar to those used for packaging other articles in a sterilized condition. The wrapper **24** may include a tear strip such as the tear strip **26**. The tear strip **26** may be located adjacent to the handle end of the subject instrument so that when it is pulled to sever the wrapper the instrument can be removed by the handle portion rather than by the end with the hook. Other forms of wrappers and packages can also be used including a package having a tear strip that runs from end to end, a package without a tear strip which is opened simply by tearing off a portion of one end and a tube type package with a cap on one end.

Thus, there has been shown and described a novel surgical instrument which fulfills all of the objects and advantages sought therefor. There has also been shown novel means for packaging said instrument to maintain it in a sterile condition until it is ready to be used and to provide more convenient means for handling and storing same. Many changes, modifications, variations, and other uses and applications of the subject instrument will, however, suggest themselves to those skilled in the art after considering this specification and the accompanying drawing. All such changes, modifications, variations, and other uses and applications which do not depart from the spirit and scope of the invention are deemed to be covered by the invention which is limited only by the claims which follow.

We claim:

1. A one piece surgical instrument for rupturing an amniotic membrane comprising an elongated relatively straight tapered rod member having one end smaller in cross section than the opposite end, said rod members having a sidewardly extending hook portion formed thereon adjacent to the smaller end, said larger opposite end being formed into a handle portion, means forming a blunt surface on the end of the rod member adjacent to the hook portion, one side of said hook portion being formed on an extension of said blunt end surface, said hook portion extending sidewardly from said rod member and terminating in a pointed end which is directed generally away from the blunt end surface back toward the handle portion of the rod member, the handle portion of the rod being relatively flat in cross section in the direction in which the hook portion extends so that it can be used to manipulate the instrument during insertion into a vagina to a position in which the blunt end surface is moved against the amniotic membrane surrounding an unborn fetus, and thereafter the handle portion can be further manipulated using the doctor's fingers which have also been inserted into the vagina to move the hook portion sidewardly while the blunt end surface is engaged with the membrane to snag and tear the membrane on the pointed end of the hook portion.

2. The surgical instrument defined in claim **1** wherein the hook portion extends sidewardly from the rod member and is curved slightly toward the handle portion, said hook portion extending sidewardly.

3. Means for rupturing an amniotic membrane comprising a surgical instrument including a substantially straight elongated rod-like member adapted to be used by being inserted into a female vagina, said member having a length to extend from adjacent to a female cervix at one end to a position extending out from the mouth of the vagina at the other end, said one end having a blunt end surface and a hook portion extending sidewardly from adjacent to the blunt end surface terminating in a sharply pointed end which is directed away from the blunt end surface in a direction that is generally toward the said other end, the other end of said member including a handle portion which is larger in cross-sectional area than the cross-sectional area of the end of the rod-like member adjacent to the hook portion for manipulating the instrument, said handle portion having means thereon oriented to indicate the direction in which the hook portion is facing, said handle portion being used to manipulate the instrument by guiding it into a proper position inserted in a female vagina to a position in which the blunt end surface thereof engages the amniotic membrane surrounding an unborn fetus, said handle portion being used thereafter to help manipulate the hook portion by moving the hook portion sidewardly while maintaining the blunt end surface engaging the membrane so that the membrane will bulge up and overlap the pointed end of the hook portion and be snagged thereby and tear so that the fluids contained therein can escape.

4. The means defined in claim **3** wherein said elongated member is molded of a plastic material.

5. The means defined in claim **3** including packaging means for maintaining the elongated rod-like member in sterile condition, said packaging means including an airtight container formed of a flexible material.

6. The means defined in claim **5** wherein said container includes a wrapper with a tear strip that can be operated to open the wrapper.

7. The means defined in claim **6** wherein the tear strip is positioned in the wrapper adjacent to the handle portion of the rod-like member.

8. The means defined in claim **6** wherein the tear strip extends longitudinally along the wrapper.