United States Patent

[11] 3,592,198

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[54] **OBSTETRICAL INSTRUMENT FOR FETUS EXTRACTION**
8 Claims, 6 Drawing Figs.

[52] **U.S. Cl.** **128/352,** 128/20, 128/361
[51] **Int. Cl.** **A61b 17/42**
[50] **Field of Search** 128/303, 352, 324, 361, 2, 87, 90, 20; 18/5.1; 264/222

[56] **References Cited**

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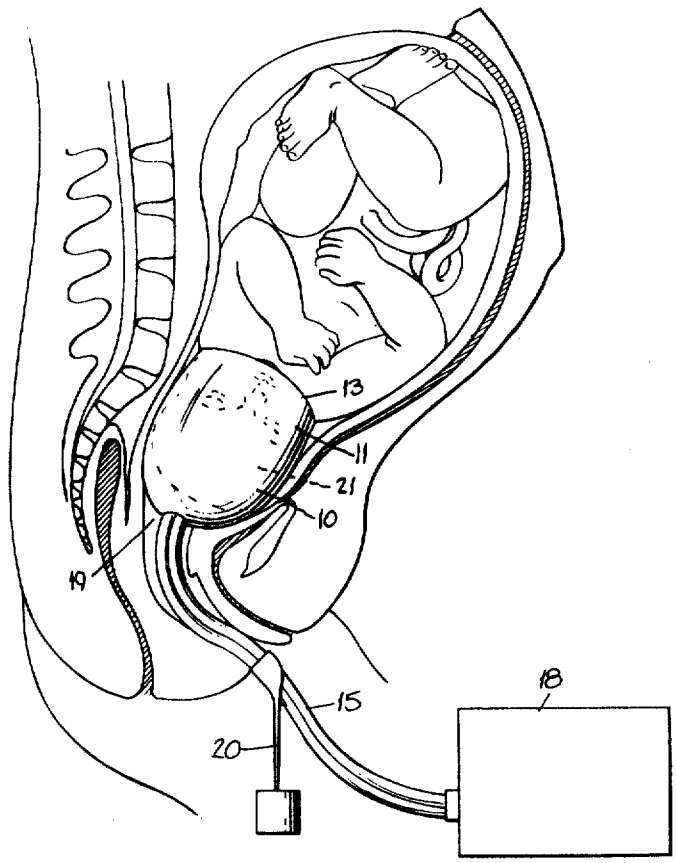
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ABSTRACT: A surgical instrument, such as an obstetrical forceps has a flexible member made of vinyl plastic sheets. The member has closed wall portions that form a caplike shape. A capillary network inside the walls of the member is connected through a flexible tube to a source of temperature-controlled circulating water. A thermosensitive compound surrounds the network and forms a matrix of compound that is softened or hardened by changes in the water temperature. While the matrix is soft, the caplike member is fitted like a glove on the fetal skull; the matrix is then hardened, making the forceps self-retaining.



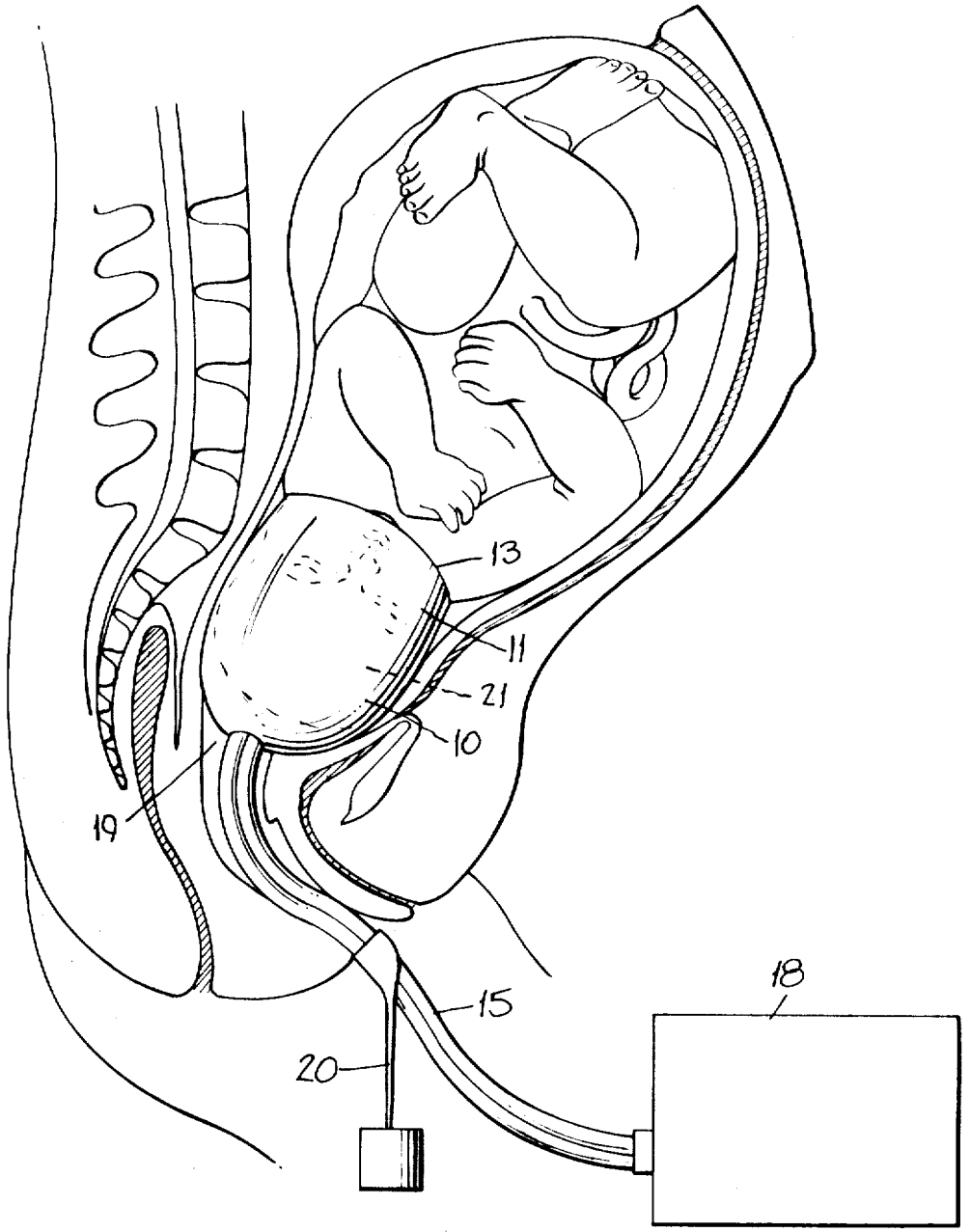
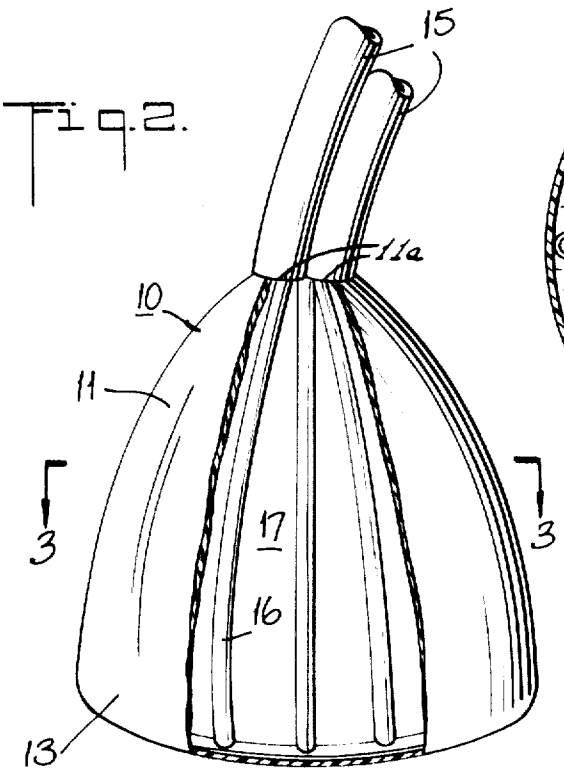


Fig. 1.

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Fig. 2.



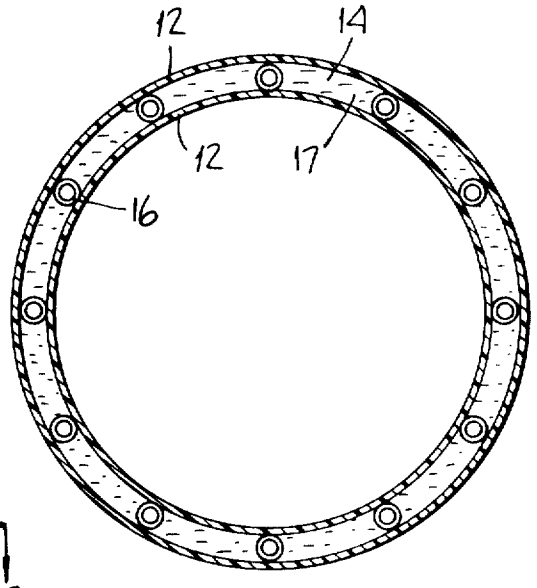
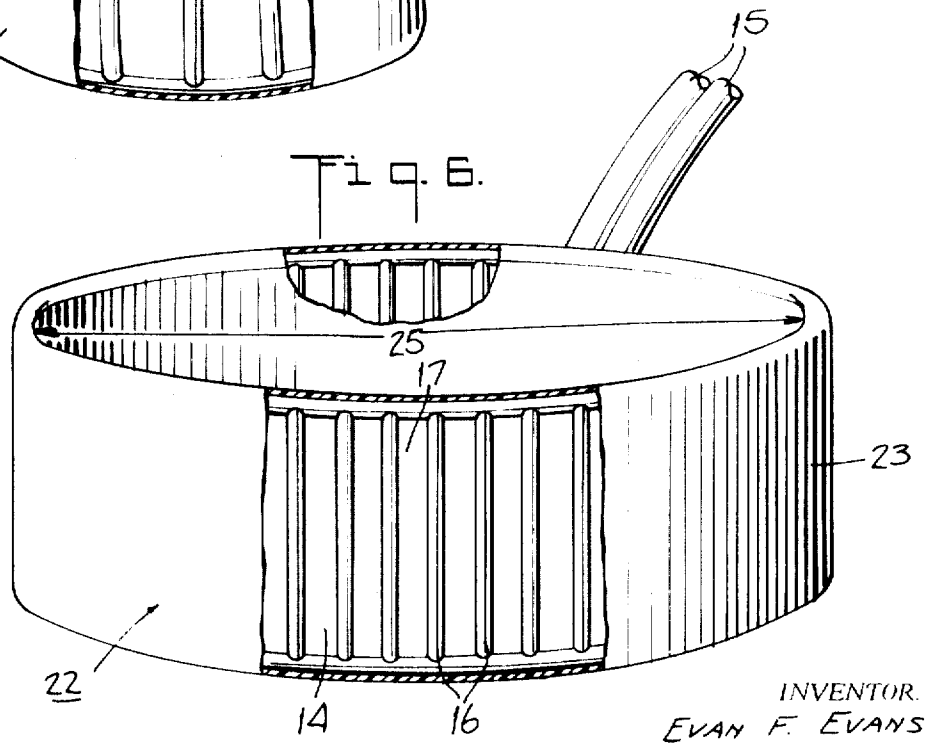


Fig. 3.

Fig. 6.



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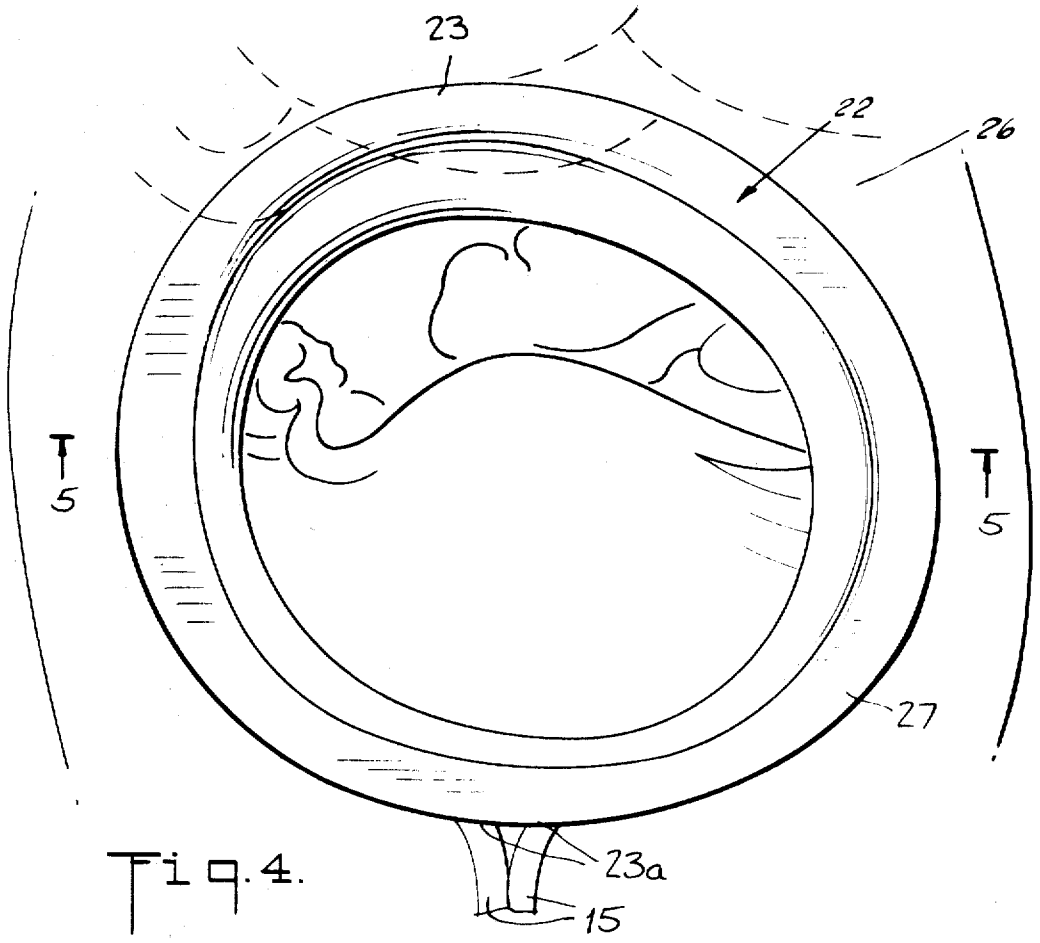


Fig. 4.

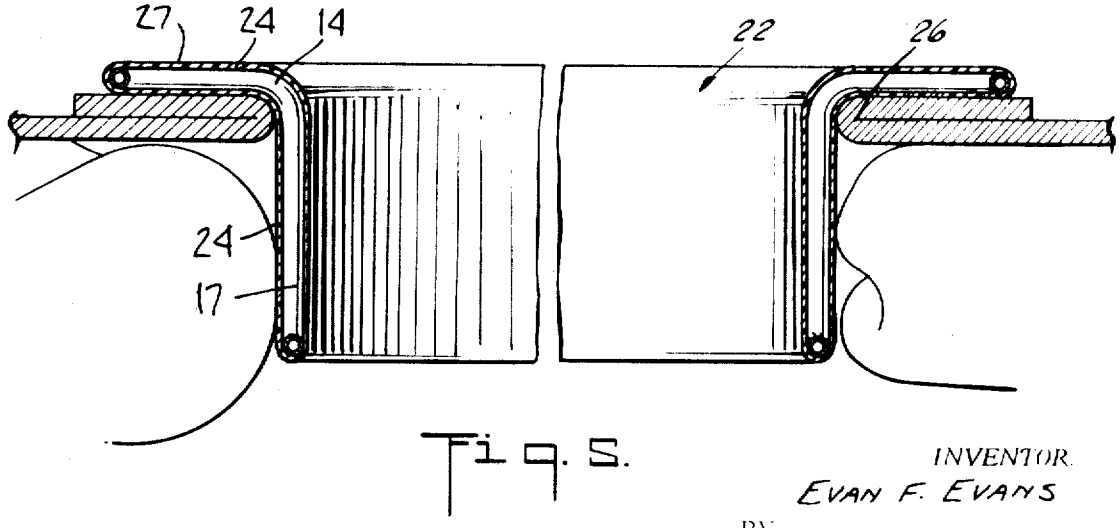


Fig. 5.

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OBSTETRICAL INSTRUMENT FOR FETUS EXTRACTION

BACKGROUND OF INVENTION

The invention relates to surgical instruments and in particular to self-retaining surgical instruments, as well as to surgical techniques and methods for using such instruments.

One conventional surgical instrument used in abdominal surgery is the Balfor self-retaining retractor. This retractor holds open the abdominal incision; the surgical procedure involved in using this retractor requires the use of laparotomy sponges to pack off organs, such as the bowel, from the surgical field.

Since metal support members hold the Balfor retractor rigid, these members, which impinge upon the pelvic veins, can produce thrombophlebitis, if the retractor is not very carefully used; moreover, the cloth laparotomy sponges used with the Balfor retractor are irritating to the bowel and often produce postoperative ileus, so that the patient is not able to eat before three or more days after the operation.

Another conventional surgical instrument is the obstetrical forceps used to assist fetal delivery in the process of child birth, which occurs in three natural stages. In the first stage, the cervical orifice of the uterus opens, preparatory to expulsion of the fetus; the fetus is expelled in the second stage, and the placenta displaced in the third stage.

Although known obstetrical forceps have various shapes, sizes, and operating principles, none of these can be used during the first stage of child birth, prior to complete dilation of the maternal cervix. Consequently, a persistent occiput posterior presentation of the fetal skull cannot be corrected prior to entry of the fetus into the vaginal canal. Inability to change the presentation of the fetal skull, at the most auspicious time, results, especially in the delivery of a first born child, in extending the labor for by 2 to 12 hours.

Furthermore, conventionally used forceps, that have metal portions or that are based on vacuum suction principles, involve serious risk of injury to both the mother and child.

SUMMARY OF INVENTION

It is an object of the invention to provide self-retaining plastic surgical instruments, and in particular, disposable instruments of such kind.

It is a further object of the invention to provide a self-retaining plastic obstetrical forceps, usable during the first stage in the process of child birth.

It is another object of the invention to provide a self-retaining plastic surgical retractor, whose use in abdominal surgery minimizes the development of vena thrombophlebitis and postoperative ileus.

Still another object of the invention is to provide a method for shortening the duration of labor by correcting a persistent occiput posterior presentation of the fetal skull during the first stage of child birth.

In accordance with the invention, a surgical instrument comprises a flexible member, having closed wall portions, made of a physiologically inert nontoxic material. A hardenable compound is placed in the cavity defined by the wall portions of the member, that additionally has a sealable opening therein, including means for supplying a hardening agent to the cavity, thereby to harden the compound, making the instrument self-retaining.

Other objects and a complete understanding of the invention are had by reference to the description and claims taken with the drawings.

DESCRIPTION OF DRAWINGS

FIG. 1 shows, in schematic form, the use of one embodiment of surgical instrument constructed in accordance with the invention.

FIGS. 2, 3 show details of the forceps portrayed in FIG. 1, FIG. 3 being taken along section line 3–3.

FIG. 4 shows, in schematic form, the use of another embodiment of surgical instrument constructed in accordance with the invention.

FIGS. 5, 6 shown details of the retractor portrayed in FIG. 4, FIG. 5 being taken along section line 5–5.

In these drawings, like reference numbers are used to identify like parts of the structures shown.

DESCRIPTION OF EMBODIMENT

Referring to FIGS. 1, 2 and 3, a surgical instrument such as an obstetrical forceps **10**, has a flexible member **11** made of a physiologically inert and nontoxic material, such as vinyl plastic in sheet form. The sheets are folded to form closed wall portions **12**, giving the members a caplike shape **13**. The member **11** has a sealable opening **11***a*, including means for supplying a hardening agent to the cavity **14** defined by the wall portions **12** of the member.

The supplying means can include flexible tubes **15**, connected to a capillary network **16** in the cavity **14**. A hardenable compound, placed in the cavity **14**, surrounds the capillary network forming a matrix **17** of the hardenable compound.

Various compositions are usable as the hardenable compound and hardening agent. For example, the hardenable compound can be selected from a group of thermosensitive organic compositions, that reversibly change from solid to liquid phase in a temperature range, for example from 90° F. to 120° F. In this case, the hardening agent can be water or other similar fluid or gas circulating from pump source **18**, through tubes **15** to the capillary network **16**, thence back to the pump source **18** for recirculation. The pump source **18** can contain a heater element and a thermostat control (not shown) for regulating the temperature of the agent used, over the temperature range appropriate for the hardenable compound selected.

The forceps member **11** is applied to the fetal skull, when the matrix **17** of hardenable compound is liquefied by the circulation of the hardening agent, as described; after application of the forceps, the member **11** is made self-retaining by lowering the temperature of the circulating hardening agent, thereby to solidify the matrix **17** of hardenable material. The forceps can be removed after use by raising the temperature of the circulating hardening agent, thereby to liquefy the matrix **17** of hardenable material.

Specific examples of thermosensitive organic compositions, for purposes of illustration are 2,3-Dimethyl-2,3-butanediol and 1-Tetradecanol; the former reversible changes from solid to liquid phase with a temperature change from 100° F. to 110° F., and the latter reversibly changes from solid to liquid phase with a temperature change from 96° F. to 98° F.

This example of obstetrical forceps can be used during the first stage of childbirth to correct a persistent occiput posterior presentation of the fetal skull, shown schematically in FIG. 1, thereby shortening the labor from 2 to 12 hours. Conventional forceps cannot be used prior to complete dilation of the maternal cervix, for example, 10 centimeters; however, by circulating fluid or gas at an appropriate temperature, through the capillary network **16**, the hardenable compound is placed in its liquid state. Hence, the flexible member **11** can be inserted into the uterus through the cervical opening **19** prior to complete dilation of the cervix, for example, when the opening is 5 centimeters in diameter. A means, secured to the member **11**, for manipulation thereof such as, for example, tubes **15** or supplementary flexible handle **20**, allows placement of the caplike flexible member **11**, over the fetal skull **21**, which it fits like a glove. At this time, the temperature of the circulating fluid or gas is lowered to the appropriate point, thereby solidifying the hardenable compound matrix, making the forceps member **11** self-retaining. By applying light traction, for example, 2 pounds weight, and rotation to the tubes **15** or flexible handle **20**, the fetal skull can be rotated to present a smaller skull diameter to the maternal pelvis, for example, from 13 centimeters to 9.5 centimeters diameter, thereby to shorten the labor.

Other kinds of thermosensitive hardenable compounds and hardening agents can be used in the surgical instruments constructed in accordance with the invention. For example, the compound and agent respectively can be the chemical reactants necessary to produce a polyurethane foam composition, upon mixing thereof. In another example, the hardenable compound can be a polyepoxide resin, and the hardening agent can be the resin's curing agent, that reacts with the resin to produce a hardened epoxy composition.

In these cases, a chemical reaction between the hardenable compound and the hardening agent changes the matrix **17** of hardenable compound from its liquid phase to the hardened product of the chemical reaction. To effect mixing, a large number of holes can be formed in the walls of the capillary network **16**; the hardening agent is added, after the surgical instrument is fitted, through the tubes **15** to the capillary network **16**, thence to the matrix **17** to initiate the chemical reaction, thereby making the instrument self-retaining.

Since the resultant chemical product is fairly brittle or easily torn, the instrument can be removed by fracturing the resultant product. Moreover, the instrument can be provided with zipperlike fittings to facilitate fracturing and removal of the instrument.

It is preferred that generally flexible polyurethane foams be used, for example, such as those obtained by reacting a thermosensitive isocyanate or prepolymer thereof with a moderately high molecular weight thermosensitive polyol, having a low degree of branching, such as a polyether based on condensates of polyhydric alcohols, as compared to the generally rigid and inflexible polyurethane foams produced by the chemical reaction between crude polymeric isocyantes, such as crude toluene diisocyanate, and a low molecular weight polyol, having a high degree of branching.

Another embodiment of surgical instrument, a surgical retractor used in abdominal surgery, is shown schematically in FIGS. **4**, **5**, **6**. The surgical retractor **22** includes a flexible member **23**, having closed wall portions **24** made of a physiologically inert and nontoxic material, such as vinyl plastic in sheet form. The member **23** has a ring or O-shape; the member **23** has a sealable opening **23***a*, including means for supplying a hardening agent to the cavity **14** defined by the wall portions **24** of the member **23**. The supplying means can include flexible tubes **15**, connected to a capillary network **16** in the cavity **14**. A hardening compound, placed in the cavity **14**, surrounds the network **16**, forming a matrix **17** of hardenable compound.

The various compositions listed above, as respective hardening compounds and hardening agents, can be used in this embodiment of surgical instrument; the hardening agent can be added through tubes **15** in the manner described above with respect to the forceps.

During abdominal surgery, the above described retractor **22**, whose flexible member **23** can be made in various size diameters **25**, is placed, while the hardening compound is in its liquid state, in the incision **26**, with a portion **27** of the member **23** cupped over the wound edge. Since the hardenable compound is in liquefied form the retractor member **23** can be easily fitted to the contours of the incision; moreover, the member wall portions **24** serve as a smooth plastic dam to hold organs, such as the small bowel, out of the field of surgery, obviating the need for cloth laparotomy sponges. After the retractor is fitted to the incision, the hardening agent is supplied to the capillary network to solidify the matrix **17** of hardenable compound, making the retractor member **23** self-retaining.

After the use of the surgical instruments here described, they can be removed, for example, by liquefying the hardenable matrix **17** or by fracturing the matrix of chemically solidified compound.

Furthermore, it is obvious that when chemically solidifiable compounds are used to form matrix **17**, other means, for supplying a hardening agent to the cavity **14**, can be used in place of the tube **15**, capillary network **16** structure.

For example, tube **15** can terminate in a flexible bulbous appendage, that is filled with a suitable hardening agent; a clamp on the tube **15** can be used to prevent entry of the agent into the cavity **14** until desired. Opening the clamp and squeezing the appendage results in forcing the agent into the cavity **14**, thereby to solidify the hardenable compound therein, making the surgical instrument self-retaining.

Furthermore, when the thermosensitive hardenable compound is hardened by chemical reaction, the capillary network **16** can be used to circulate a heated fluid through the flexible member, during the chemical reaction, to decrease the reaction time.

It is to be understood that, while specific embodiments of the invention have been described and shown, variations in structural detail within the scope of the appended claims are possible and are contemplated. There is no intention, therefore, of limitation to the exact abstract or disclosure herein presented.

What I claim is:

1. An obstetrical forceps comprising,

a. a flexible member, having closed wall portions defining a cavity and forming a caplike shape, made of a physiologically inert and nontoxic material;

b. means, secured thereto, for manipulating the member;

c. a hardenable compound in said cavity; and

d. a sealable opening in the member, including means for supplying a hardening agent to said cavity, thereby to harden the compound, making the forceps self-retaining.

2. The obstetrical forceps according to claim **1** in which the hardenable compound is a thermosensitive composition.

3. The obstetrical forceps according to claim **2** in which the hardenable compound comprises **2,3**-Dimethyl-**2,3**-butanediol.

4. The obstetrical forceps according to claim **2** in which the hardenable compound comprises **1**-Tetradecanol.

5. An obstetrical forceps comprising:

a. a flexible member, having closed wall portions defining a cavity and forming a caplike shape, the member being made of a physiologically inert and nontoxic material;

b. a capillary network in said cavity;

c. means, secured thereto, for manipulating the member;

d. a hardenable compound surrounding the network in said cavity, thereby forming a matrix of hardenable compound; and

e. a sealable opening in the member, including means, coupled to the capillary network, for supplying a hardening agent to the capillary network, thereby to solidify the matrix of compound, making the forceps self-retaining.

6. The obstetrical forceps according to claim **5** in which the hardenable compound is a thermosensitive composition.

7. The obstetrical forceps according to claim **6** in which the hardenable compound comprises **2,3**-Dimethyl-**2,3**-butanediol.

8. The obstetrical forceps according to claim **6** in which the hardenable compound comprises **1**-Tetradecanol.