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Cognat

[11] **3,774,600**

[45] **Nov. 27, 1973**

[54] **GYNAECOLOGICAL SURGICAL DEVICE**

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[73] Assignee: **Rhone-Poulenc S.A.,** Paris, France

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[21] Appl. No.: **193,064**

[30] **Foreign Application Priority Data**

Oct. 27, 1970 France 7038735

[52] **U.S. Cl.**..... **128/131,** 128/130, 128/341, 128/350

[51] **Int. Cl... A61f 5/46,** A61m 29/00, A61m 27/00

[58] **Field of Search**..... 128/130, 132, 131, 128/341, 350, 127, 1, 349

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Primary Examiner—Aldrich F. Medbery

Attorney—Stevens, Davis, Miller & Mosher

[57] **ABSTRACT**

A gynaecological surgical device to avoid Fallopian tubes becoming blocked again during cicatrisation following a tuboplasty operation, such device comprising a hollow cone of a flexible sheet material and a cord firmly fixed to the apex of the cone. In use after performing a salpingostomy of the blocked portion of a patient's Fallopian tube, the device is placed with the apex extending into the cut end of the tube with the cord extending to the abdominal wall. The base edge of the cone is folded around the end of the tube and secured to the tube exterior to prevent blockage during cicatrisation of the tube. When this is completed, the device can be removed simply by pulling the cord.

12 Claims, 9 Drawing Figures

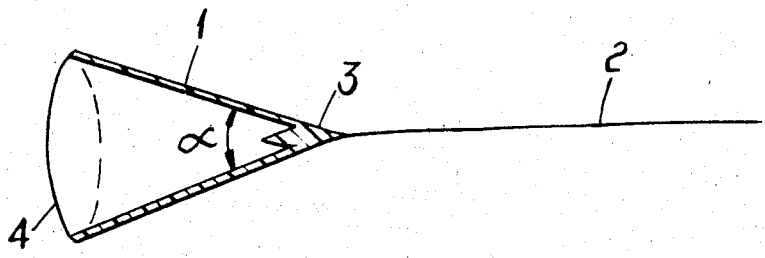

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Fig. 1.

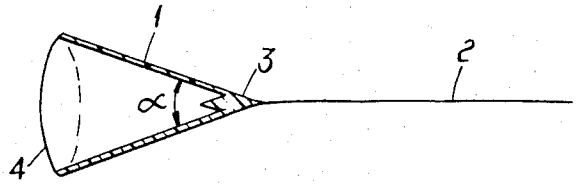


Fig. 2.

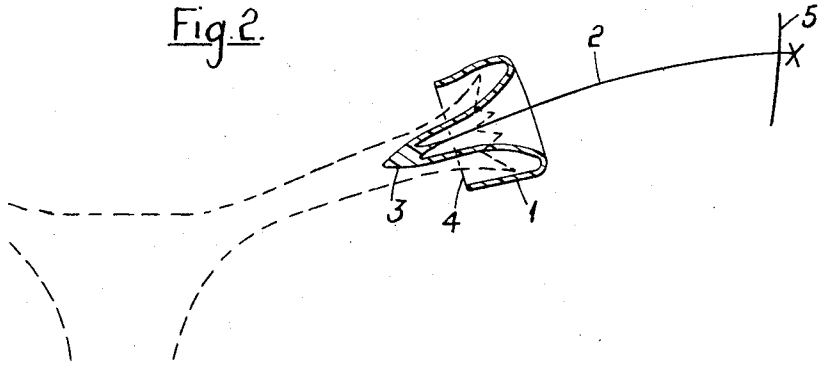


Fig. 3

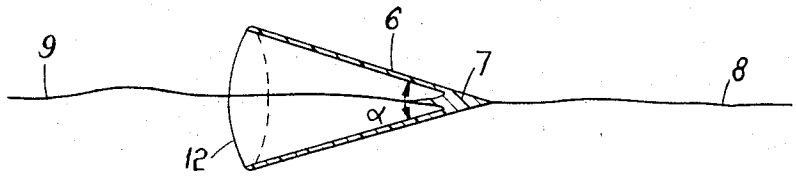


Fig. 4

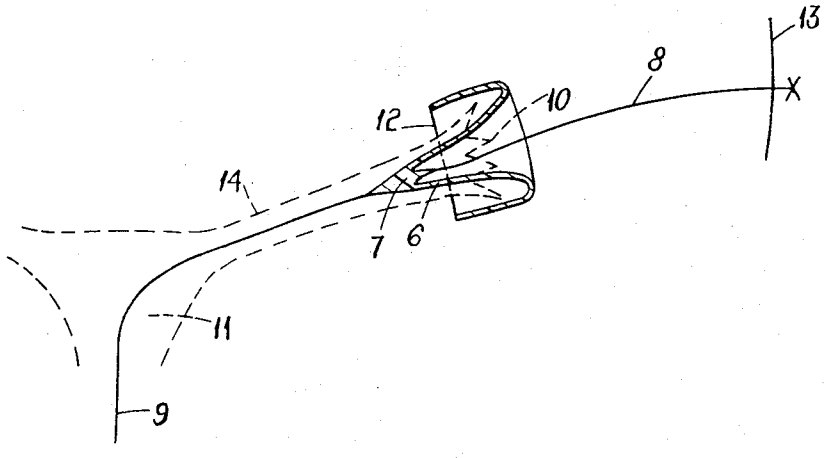


Fig. 5

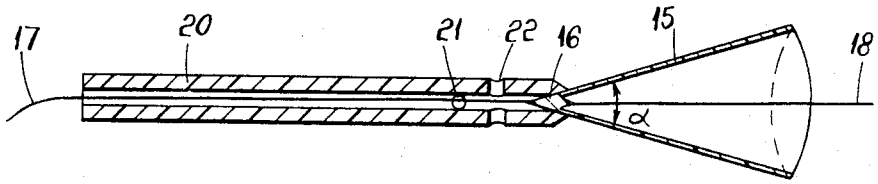


Fig. 6

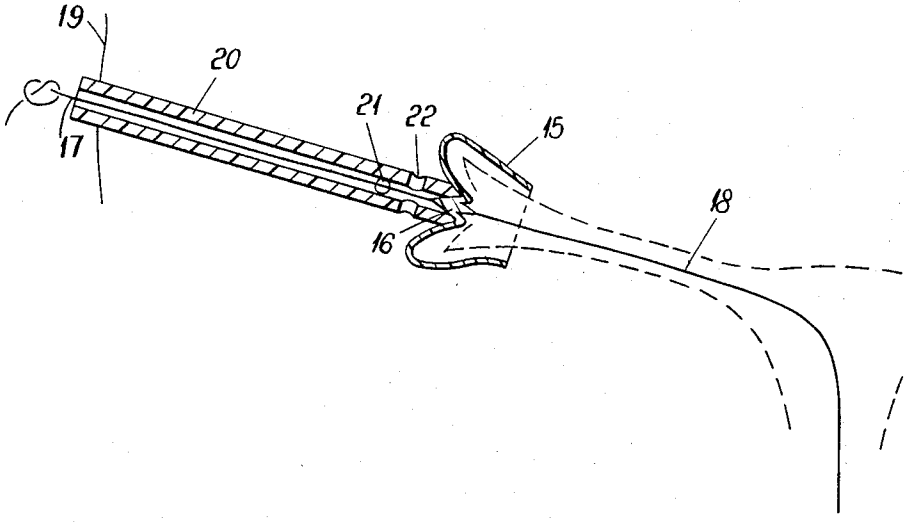


FIG.7

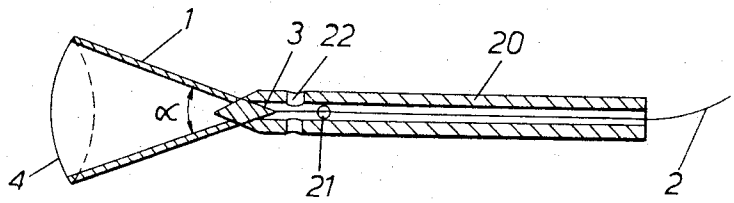


FIG.8

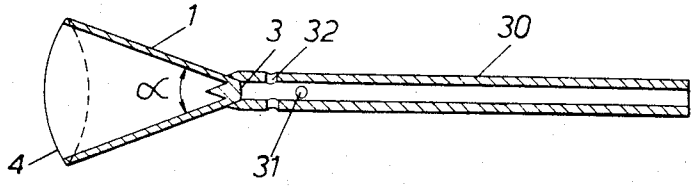
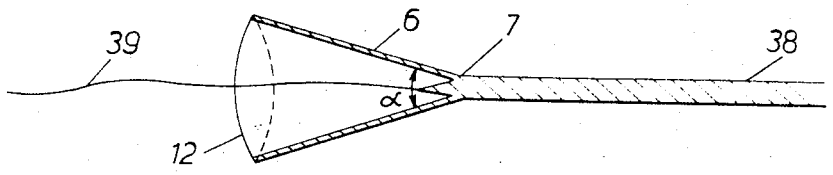


FIG.9



GYNAECOLOGICAL SURGICAL DEVICE

The present invention relates to a gynaecological surgical device intended to facilitate the surgical treatment of female sterility of tubal origin. It relates, more especially, to a surgical device which makes it possible to avoid the ends of the Fallopian tubes becoming blocked again after a tuboplasty operation (in particular, a salpingostomy) as a result of rapid and correct cicatrisation in the open position of the tubes.

If the blockage is an internal tubal blockage, the surgical devices described in U.S. Pat. Nos. 3,182,662 and 3,349,770 allow tubo-uterine anastomosis to be carried out.

If the blockage is external tubal blockage, the end of the tubes is opened and a surgical device is placed in position which protects the open end until cicatrisation is complete and which prevents the tube from becoming blocked again. In order to place such a surgical device in position, it is necessary to carry out a laparotomy.

MULLIGAN W. J., ROCK J. and EASTERDAY C. L. (Use of polyethylene in tuboplasty — Fertility and Sterility 4 : 428, 1953) have in this case proposed a rigid surgical device in the form of a cone which covers the end of the tubes and which is withdrawn after cicatrisation, after a period of 2 to 3 months, by carrying out a second laparotomy.

CLYMAN M. J. (Silastic hoods in tuboplasty: A new approach to their removal. Fertility and Sterility vol. 19, No. 4, 1968) has proposed replacing the second laparotomy by a colpotomy. However, this latter technique is very delicate to carry out and requires the use of special forceps which are introduced through the natural passages in order to withdraw the surgical devices 2 to 5 months after it is placed in position. Furthermore, this technique cannot be practised successfully, especially if the surgical device is covered by adhesions or if it has shifted; it is then necessary to resort to a second laparotomy.

According to the invention there is provided a surgical device to avoid Fallopian tubes becoming blocked again during cicatrisation following a tuboplasty operation, such device comprising a hollow cone of flexible sheet material and a cord-like member firmly fixed to the apex of the cone.

Such a surgical device only requires a single operation (when it is placed in position), it is easily held in position in the patient, it can be withdrawn very easily and it ensures rapid cicatrisation (within a period of 1 to 3 weeks) of the end of the tubes in the open position.

The invention also provides a method of surgically treating female sterility of tubal origin comprising performing a salpingostomy on the blocked portion of a patient's Fallopian tube, placing a surgical device according to the invention with the apex of the cone extending into the end of the tube and the cord extending to the abdominal wall, folding the edge of the cone around the end of the tube and securing it to the exterior of the tube to prevent blockage during cicatrisation of the tube.

The invention will be better understood from the following description, which is given by way of example, reference being made to the accompanying drawings, in which:

FIGS. **1, 3 5, 7, 8** and **9** are schematic perspective views of three embodiments of the device according to the invention; and

FIGS. **2, 4** and **6** are similar views showing the devices of FIGS. **1, 3** and **5** respectively after being placed in position in the patient.

The surgical device shown in FIG. **1** consists of a flexible sheet rolled up in the shape of a cone **1**, the angle α at the apex being between 5° and 80° and preferably between 10° and 50°. A cord **2** is firmly fixed to the apex **3** of the cone **1**, the length of this cord being between 200 and 600 mm, and its diameter being generally between 0.2 and 6 mm. This cord **2** for example consists of polyamide, which gives it a certain flexibility as well as sufficient tensile strength during removal of the device.

The cone **1** consists of a sterilisable plastic tolerated by the organism, which is sufficiently flexible that it can easily be folded over on itself and remain in this position when it has been brought thereto when placing the device in position. Organopolysiloxane elastomers, in particular, are suitable for this application. Generally, the thickness of the wall of the cone **1** is between 0.1 and 0.8 mm, whilst its height is between 20 and 200 mm.

The cone **1** can, for example, be obtained by the so-called "slush-coating" technique, that is to say, by depositing successive thin layers of material on a shaping device of the desired shape. It is also possible to obtain the cone from a sheet which is cut and of which the edges are joined by welding or gluing.

The apex **3** of the cone can be attached to the cord **2** by, for example, passing the cord **2** through the apex **3** of the cone and knotting the cord two or three times onto itself at its end which is near the apex of the cone. Then some silicone elastomer, for example, is deposited on the excess thickness formed by the knots and the part of the cord which is outside the cone is pulled gently so that the knotted end comes to lie against the apex of the cone and to stick thereto, either under hot or under cold conditions, depending on the type of elastomer used. A "knob" is thus obtained at the apex of the cone.

It is also possible, after knotting the end of the cord, to pre-mould the knob on the knotted thread and to fix it thereafter to the end of the cone by wedging and gluing. It is thus possible to impart the desired shape to the knob and to proceed in such a way that when the device is placed in the partially invaginated position in the patient (FIG. **2**) is practically has a first, solid cone (forming the knob) of which the angle at the apex is less than that of the cone **1**.

FIG. **2** shows the device of FIG. **1** after being placed in position. To achieve this, the surgeon carries out a laparotomy and then a salpingostomy (he cuts the end of the blocked tube). He places the device, which has previously been sterilised (by heat or by γ-rays) and entirely invaginated, in position by introducing the apex **3** of the cone into the open tube for a distance of 10 to 40 mm. He then turns the base edge of the cone **1** over around the end of the tube (shown in broken lines) so that the tube end is entirely enveloped by the cone. The surgeon is able to adapt the cone to the size which he considers necessary by cutting it near its base edge **4** and, if necessary, along a generatrix in order that it shall cover the tube better. He then attaches the cone **1** to the end of the tube by making a few stitches (not

shown in FIG. 2) using a resorbable material, for example catgut, the resorption time of this material corresponding substantially to the time required for cicatrisation. The cord **2** is thereafter anchored to the abdominal wall **5.** The surgeon places an identical surgical device in position in the same manner on the other tube if the blockage is bilateral.

When sufficient cicatrisation has occurred, which merely requires from about 1 to 3 weeks (thanks to the flexible cone, which completely covers the end of the tube), the surgical device is withdrawn by simply pulling the cord **2** through the abdominal wall **5** in the manner of a simple drain, without anaesthetic.

FIG. **3** represents a preferred embodiment of the surgical device. This comprises all the elements described in the preceding device of FIG. **1,** that is to say a cone **6** with a cord fixed firmly to its apex **7.** However, the cord of this embodiment passes through the cone practically along its axis and has substantially equal portions (marked **8** and **9**), of between 200 and 600 mm, extending on either side of the apex. The sizes and the materials of which this device is made up are the same as those mentioned for the device of FIG. **1.**

In order to place the device in position (see FIG. **4**), if only the end (**10**) of the tube (shown in broken lines) is blocked, the surgeon follows substantially the same procedure as when placing the device of FIG. **1** in position. He first of all carries out a laparotomy and then cuts the end of the tube. He now leaves the cord **9** to be the length required so that after it has been introduced through the end **10** of the open tube, it can reach into the uterine cavity **11** if the cone **6** is in position on the end of the tube. The cone **6** is folded over onto the tube, the surgeon being able to cut its base **12** to the desired length. The surgeon now attaches the cone to the end of the tube by a few stitches (not shown in FIG. **4**) using a resorbable material, for example catgut, and anchors the other end of the cord **8** to the abdominal wall **13.** To withdraw this surgical device, the surgeon follows exactly the same procedure, and with equal ease, as for withdrawing the device previously described.

The device of FIG. **3,** whilst it can be withdrawn as easily as that of FIG. **1,** has the advantage of allowing the cone **6** to be positioned better during the period of cicatrisation and of resorption of the stitches. The part **9** of the cord which is in the tube in effect assists better stability of the device during cicatrisation.

This device can be used with advantage in the case where the external and internal portions of one and the same tube are blocked. In effect the cord **9** acts as a cicatrisation tutor for the duct **14** whilst the cone **6** ensures rapid cicatrisation in the open position of the tube. In order to place the prosthesis in position, the surgeon can operate as follows: he carries out a laparotomy and then a salpingostomy, he adjusts the part **9** of the cord to the desired length for it to reach the uterine cavity **11,** he introduces the part **9** of the cord through the open tube until it can slide no further in the duct, he cuts the duct in two places so as to remove the obstructed part, effects a termino-terminal anastomosis and continues to slide the cord **9** until the cone **6** is in position on the end of the tube. The continuation of the operation is then identical to that previously carried out.

It is also possible to use this surgical device if only the duct is blocked.

Another embodiment of the invention is shown in FIGS. **5** and **6.** The cord **17** extending from externally beyond the apex **16** of the cone **15** to the abdominal wall **19** is surrounded by a sheath **20,** for example consisting of an organosilicon elastomer. This sheath forms a drain as a result of transverse orifices **21** and **22** located near the apex of the cone **15.**

This latter device, in addition to having the advantages quoted for the device shown in FIGS. **3** and **4,** additionally makes it possible to inject, from the abdominal wall **19,** any liquid which can, for example, activate cicatrisation or arrest a possible infection.

This latter embodiment furthermore has the advantage of making it even easier to withdraw the device because the external diameter of the sheath **20** forming the drain is substantially the same as the cross-section which th cone assumes if it is folded up on itself during its removal.

As materials for making these devices it is possible to use plastics of medical quality, which can be sterilised and which do not allow adhesions of human tissues to their surface, whilst being well tolerated by the organism. The cone must have sufficient flexibility that it can easily be folded onto itself and can maintain this position after it has assumed it. The cord must have sufficient tensile strenth after sterilisation to allow the surgical device to be withdrawn; it must also have sufficient flexibility to match the shape of the duct of the tube all the way into the uterine cavity (in the case of the devices shown in FIGS. **3** and **5**) and to remain as far as possible in the position in which it has been placed.

For example, organopolysiloxane elastomers are used for the manufacture of the cone and of the drain. The cone can also be produced from a textile material, for example a polyethylene terephthalate fabric, which is coated with organopolysiloxane elastomer.

The cord can for example be made of polyamide or of polyester.

Numerous embodiments will suggest themselves to those skilled in the art. It is for example possible to make up a surgical device, such as that shown in FIG. **7** in which the cord **2** is sheathed with a drain **20** provided with lateral orifices **21** and **22** in the zone located near the apex of the cone. A further embodiment of the device (FIG. **8**) replaces the solid cord by a hollow cord **30** forming a drain and provided with lateral orifices **31** and **32** in the zone located near the apex of the cone **6.**

A modification of the device of FIG. **3** is shown in FIG. **9** in which a cord **38** extends from the apex of the cone to the abdominal wall, of greater diameter than the part of the cord **39** which extends from the tube into the uterine cavity. This favours the withdrawal of the surgical device, the cross-section of the cord **38** being of greater diameter, for example corresponding substantially to the cross-section which the cone assumes when it is folded up on itself during its withdrawal.

It is also possible to provide all these devices with a mark which is opaque to X-rays, for example in the position of the knob or on the wall of the cone, longitudinally or transversely.

EXAMPLE 1

A device corresponding to that shown in FIG. 3, was produced, the cone having an angle of 20° at the apex, being 150 mm high and having a wall thickness of 0.16 mm.

The cord was passed through the cone 6 at its apex 7 along its axis and then extended on either side of the apex 7 to equal lengths of 500 mm. The cord was 0.5 mm in diameter and consisted of polyamide 6,6, its tensile strength being 45.3 kg/mm² before sterilisation and its elongation being 40 percent.

The cone was obtained by the slush-moulding technique, that is to say by successively steeping a shaping device into a liquid elastomer until the desired thickness was obtained. For this, a diluted hot-vulcanisable organopolysiloxane elastomer, of the same composition as that described in the example of French Patent No. 1,499,305, was used.

The shaping device used was of polished stainless steel.

It was steeped in the elastomer and then left to drain for 20 seconds, and the shaping device was rotated so as to distribute the material well and allow the solvent to evaporate. The operation was repeated six times so as to obtain a thickness of 0.16 mm. The article was vulcanised in a ventilated oven at 140°C for 30 minutes and was then reheated for 18 hours at between 180° and 200°C.

In order to attach the cone to the cord, the cord was first of all passed through the end of the cone and was knotted substantially in its middle, on the inside of the cone. A ball of undiluted silicone elastomer was placed around the knot and was shaped into an olive-shaped knob. The part of the cord which was outside the cone was then pulled until the knob obtained pressed against the apex of the cone. The whole was vulcanised at 180° – 200°C for 4 hours.

This prosthesis was heat-sterilised at 180°C for 4 hours. The tension required to break the cord was then 16.6 kg/mm² and the elongation of the cord was 17 percent.

The same device can be sterilised with γ rays. The tension to break the cord was then 41 kg/mm², its elongation being 36 percent, after an irradiation under 2.5 Megarads.

EXAMPLE 2

A device as shown in FIG. 5, was made starting from a device identical to that described in Example 1, of the same dimensions and made of the same materials.

A drain of heat-vulcanisable organopolysiloxane elastomer of 3 mm internal diameter, 5 mm external diameter and 300 mm length was added. The distal end of the drain was provided with two pairs of lateral orifices (as shown in FIG. 5), the first pair being located 20 mm from the end and the second 30 mm from the end.

The drain was attached to the cone by gluing by means of undiluted silicon elastomer. For this gluing, the material was vulcanised for 4 hours at 180° – 200°C.

I claim:

1. A gynaecological surgical device to avoid Fallopian tubes becoming blocked during cicatrisation following a tuboplasty operation, said device comprising a single hollow cone of flexible sheet material having an apex and a base edge and closed at its apex, ane a cord-like member fixed firmly to the apex of the cone.

2. A device as claimed in claim **1,** and further comprising a drain tube sheathing the cord and means defining lateral orifices in the tube located near the apex of the cone.

3. A device as claimed in claim **2,** wherein said drain tube is formed of organosilicon elastomer.

4. A device as claimed in claim **1,** wherein said cord is hollow effective to form a drain tube and further comprising means defining lateral orifices in the tube located near the apex of the cone.

5. A device as claimed in claim **1,** wherein said cord comprises a first portion extending externally beyond the apex of the cone and a second portion extending through the interior of the cone.

6. A device as claimed in claim **5,** wherein the first portion is of larger diameter than the second portion, the cross-section of the first portion corresponding substantially to that of the cone folded upon itself.

7. A device as claimed in claim **5,** and further comprising a drain tube sheathing the first portion of the cord and means defining lateral orifices in the tube located near the apex of the cone.

8. A device as claimed in claim **5,** wherein the apex angle of the cone is between 5° and 80°, wherein the height of the cone is between 20 and 200 mm, wherein the wall thickness of the cone is between 0.1 and 0.8 mm and wherein the first and second portions are of substantially equal length of between 200 and 600 mm.

9. A device as claimed in claim **1,** wherein the cone consists of organosilicon elastomer and the cord of polyamide.

10. A device as claimed in claim **1,** wherein the apex angle of the cone is between 5° and 80°, wherein the height of the cone is between 20 and 200 m.m. and wherein the wall thickness of the cone is between 0–1 and 0–8 m.m.

11. A method of surgically treating female sterility of tubal origin said method comprising the steps of performing a salpingostomy of the blocked portion of the patient's fallopian tube, providing a surgical device comprising a single hollow cone of flexible sheet material having an apex and a base edge and closed at its apex with a cord-like member fixed firmly to the apex of the cone, placing said device with the apex of the cone extending into the end of the fallopian tube and extending the cord - like member from the inside of said cone to the abdominal wall, folding the base edge of the cone around the end of said tube and securing it to the exterior of the tube to hold it in place to prevent blockage during cicatrisation of the tube, and when cicatrisation has occurred, pulling said cord-like member through the abdominal wall to withdraw the device.

12. A method as claimed in claim **11,** wherein the cord-like member extends through the cone apex and has portions projecting both inwardly and outwardly of the apex, and wherein the cone is placed in position over the end of the fallopian tube with one of said portions extending along the fallopian tube into the uterine cavity and the other of said portions extending outwardly to the abdominal wall.

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