

[54] CONTRACEPTIVE

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[58] Field of Search..... 128/127, 128, 130,  
128/260, 285; 273/160; 2/151, 154; 161/7, 9

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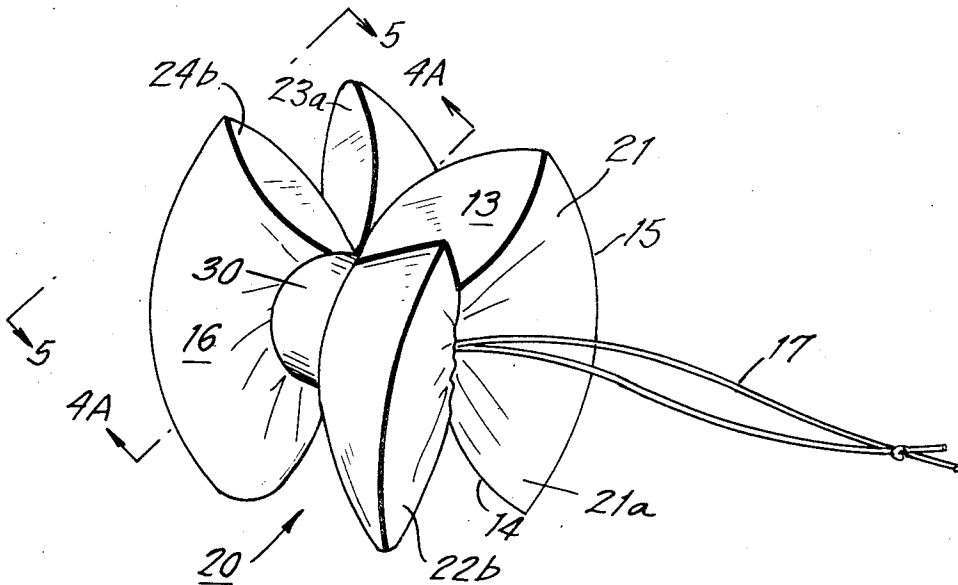
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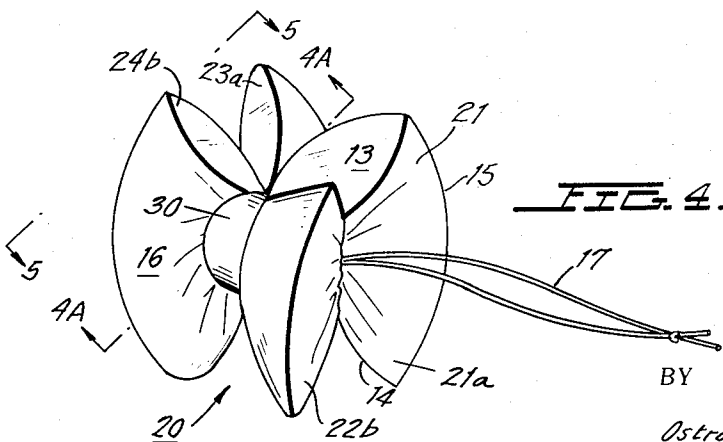
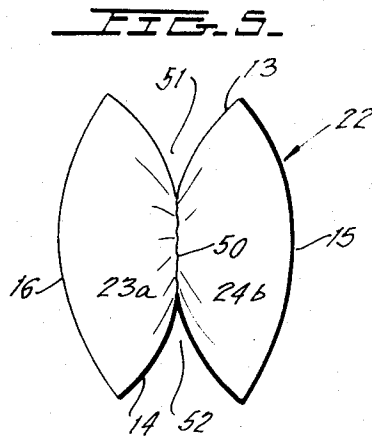
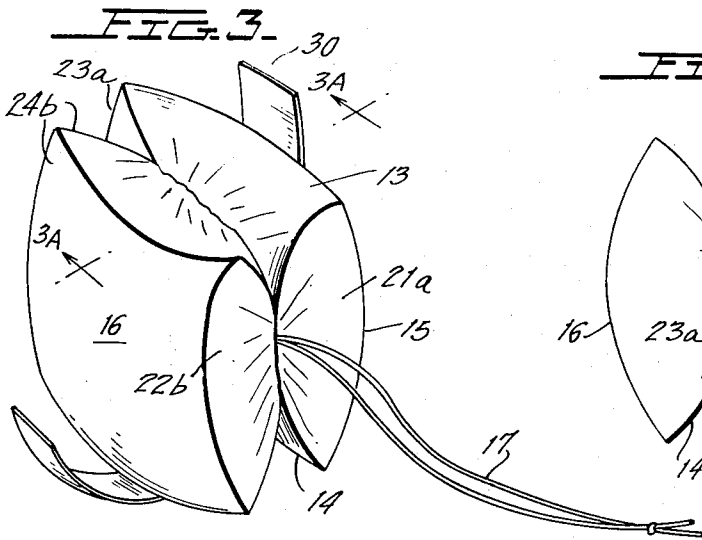
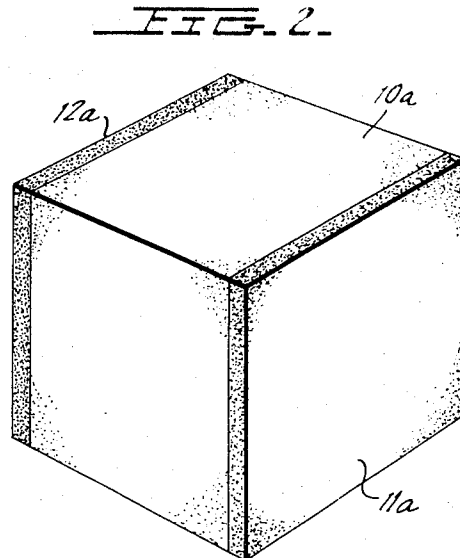
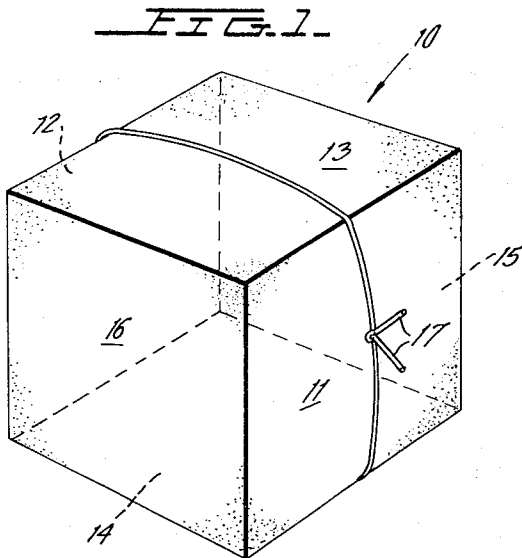
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[57] **ABSTRACT**

A six-way acting vaginal contraceptive having a body of sponge-like resilient compressible absorbent material, the body being initially compressed on one axis by a string and on the other axis by a band to form two bifurcated butterfly ends which in turn form a pair of barriers across the vaginal canal, the inner barrier being adapted to lie against the cervix of the uterus and the edges of the butterfly ends being adapted to block the vaginal fornices. The barrier ends are impregnated with a spermicide and at least one end may be impregnated with a coital lubricant.

**6 Claims, 12 Drawing Figures**





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FIG. 3A.

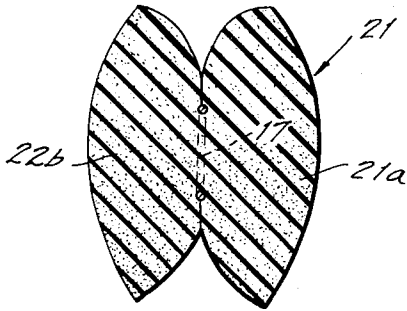


FIG. 4A.

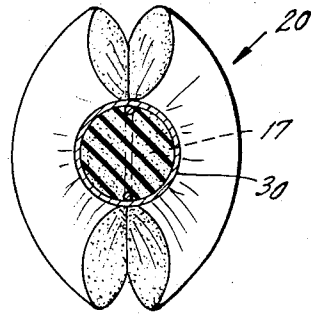


FIG. 6.

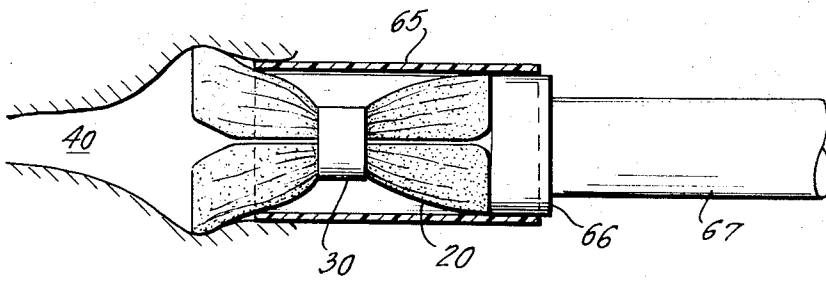
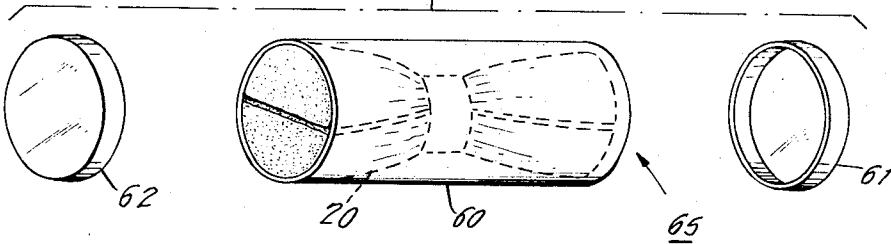


FIG. 7.

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FIG. B.

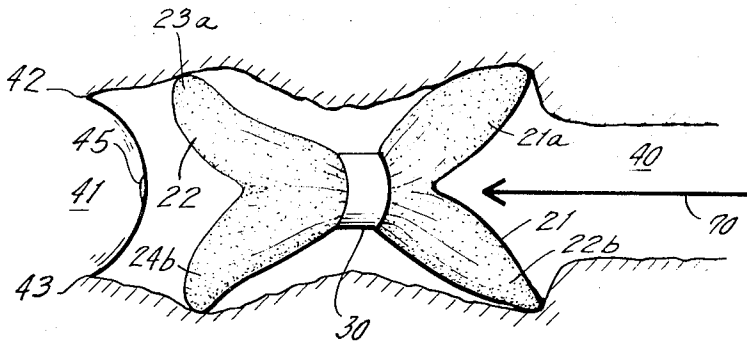


FIG. BA.

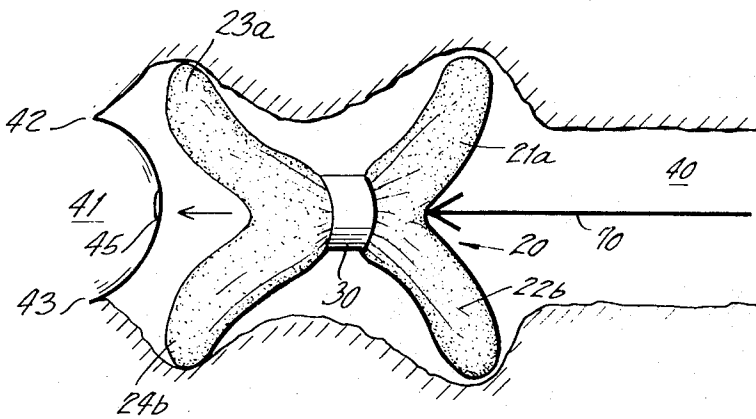
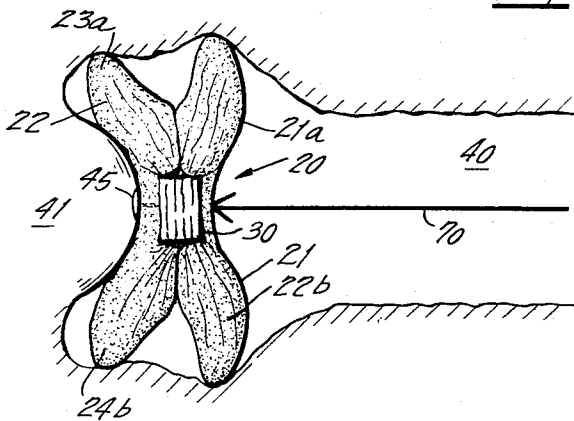


FIG. 9.



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**CONTRACEPTIVE**

The present invention relates to contraceptives and more particularly to an insertable contraceptive device which has a double butterfly construction so arranged as to block the cervix of the uterus (the entry to the uterus) as well as to provide a blocking action for the vaginal fornices thereby preventing the formation of pools of sperm-containing material; because the butterfly construction comprises a similar arrangement at each axial end, it provides a second blocking wall directed toward the entry which blocking wall will form a first barrier to the entry and passage of sperm-carrying material (seminal fluid). The invention contemplates that the insertable double butterfly blocking device will be made of a highly compressible resilient and elastic foam material such as cellular or foam rubber, neoprene, polystyrene and other similar materials which will not be decomposed in the presence of body fluids or vaginal acidity, which will maintain its resiliency, elasticity and cellular condition when inserted and which will also have the capacity to absorb and retain spermicidal and other fluid materials in close proximity to the various body parts including especially the cervix and the vaginal fornices.

Social scientists have been seriously concerned with the over-population problem and the future population explosion. In the United States alone approximately 4,000,000 babies are born annually of which it is estimated that approximately 2,000,000 are unwanted pregnancies. In the six months period between July 1, 1970 and Dec. 31, 1970, 70,000 legal abortions were performed in New York City alone and it has been estimated that about 1,000,000 abortions were performed during the year 1970 in the United States. It has also been estimated that about 600,000 children were born to out-of-wedlock mothers in the same period. These figures do not of course include the 1,000,000 aborted embryos from women who did not desire to have children at that time.

Although there are many and varied contraceptives and contraceptive agents which have been available for many years, those previously in general use have suffered from major defects either in construction, use or application or in their original concept as evidenced by the increasingly large number of unwanted pregnancies despite their utilization. Perforation, improper placement or misuse of barrier type devices are well known. The utilization of contraceptive material without carriers thereof other than the jellies, foams or fluids in which they are contained have resulted in undesired and unwanted pregnancies owing to the fact that the spermicidal material carried thereby is not held for a sufficient length of time in the desired location in relation to the cervical opening. For instance, a pool of sperm-carrying material may form in the posterior or lower fornix and if the spermicidal material is not held in situ for sufficient length of time, which may be several hours, a sperm cell may migrate to the cervical opening and cause a pregnancy.

The present invention contemplates the formation of a double barrier, each of the barriers extending substantially normal to the axis of the passage to the uterus and each of the barriers being formed of a compressible resilient and elastic foamed material having minute passages, channels and cells which may retain spermicidal and other fluids and which will absorb, retain, block and immobilize sperms in the seminal ejaculate.

The double barrier as above pointed out is formed by the butterfly construction in which essentially a large cube of the sponge-like material is girdled by a string passing over four sides approximately midway between the two remaining faces of the cube. The string is pulled tight until the central portion of the cube is completely compressed by the string. This compresses the four walls which the string has traversed toward each other and toward the center of the cube, leaving the two opposite faces uncompressed and bowed with the edges of the opposite faces adjacent the compressed faces forming a butterfly construction. The string is pulled out between the two compressed butterfly faces on one side. Thereafter the structure thus formed is girdled by a tape passing around the two faces which have not been compressed by the string, compressing these two faces and the remaining material toward each other at the center.

This operation now forms the double butterfly construction in which at each end the material of the now compressed cube flares out resiliently, compressibly and elastically into two wings on each side, the edges of which are squeezed toward each other.

In use, the double butterfly structure is inserted with the portion of the butterfly structure, from which the string extends, extending toward the opening while the other butterfly structure extends towards the interior; both are substantially normal to the axis of the unit. The faces on each side of the double butterfly structure may expand to a size larger than any object which may reasonably be inserted into the vaginal passage; the walls of the passage are sufficiently elastic, dilatable and contractible to permit of the entry of the entire structure.

The double barrier thus obtained by the two butterfly structures provides an efficient barrier against the passage of fluid from one side to the other. Further activity and the insertion by the male will force the butterfly structure further into the vaginal canal to form a full block and still further action will position the butterfly so that it lies close against the cervix and the wings thereof extend into the fornices.

The portion of the butterfly contraceptive intended to be adjacent to the cervix uteri is impregnated with a fluidy spermicidal agent. The rear of the contraceptive device directed toward the opening to the body is also impregnated with a spermicidal agent; this area may also be impregnated with an appropriate lubricating material such as a jelly or a material which is a composite lubricant and spermicidal agent.

Therefore in addition to the double barrier which is provided, the sperm material should be killed or immobilized by the spermicidal agent at the face of the first barrier. Should any of the sperm-carrying material penetrate at all toward the area adjacent the cervix as, for instance, should it enter the posterior fornix which is at the lowest point during the operation and form a pool there despite the barrier (which should not occur) the spermicidal material at the face toward the cervix uteri will kill the sperms in that location and any sperm which tends to migrate toward the uterus.

In the event that the material of the initial cube from which the device is formed (owing to its compressibility, resilience and elasticity) should not be sufficiently absorbent then the two opposite faces of the cube which will form the butterfly ends may be provided with a highly absorbent surface laminated or otherwise

secured or integrated with the cube so that an efficient retainer for the spermicidal material and any lubricant that may be used will be provided at the desired location.

In use the entire double butterfly contraceptive is compressed into a tubular container provided with openings at each end which may be covered and airtight during storage. The covers are removed prior to insertion and the double butterfly contraceptive device is pushed through the tube into the vaginal canal and up close to the uterus; an appropriate pushing device or plunger may be provided for this purpose.

The primary object of the present invention therefore is the provision of a highly compressible, elastic, absorbent sponge-like double butterfly type structure which may readily be inserted.

A further object of this invention is the provision of such an insertable member so arranged that it forms an effective double barrier or dam against the penetration of sperm-carrying material.

Still another object of the present invention is the provision of the double barrier so arranged that in use and in action it is forced home to a further complete blocking position where it not only blocks the entry to the uterus but also blocks the fornices.

Still another object of the present invention is the formation of the multifaceted butterfly wings of highly absorbent material to absorb the sperms and their environmental medium.

Still another object of the present invention is the provision of the double blocking structural action in combination with the utilization of the absorbent, resilient, elastic soft material to carry and automatically dispense spermicidal material as well as lubricating material both on insertion and in use.

The foregoing and many other objects of this invention will become apparent in the following description and drawings in which

FIG. 1 is a view in perspective of a spongy cube which is utilized as the first step in the manufacture of the present invention.

FIG. 2 is a view in perspective of an alternate cube structure hereinafter more specifically described.

FIG. 3 is a view in perspective of the cube structure of either FIG. 1 or 2 in which the string has been drawn tight around four faces of the cube to form the butterfly structure.

FIG. 3A is a cross-sectional view taken at line 3a-3a of FIG. 3 looking in the direction of the arrows.

FIG. 4 is a view in perspective of the next stage in the manufacture of the novel contraceptive in which a band has been placed around the structure of FIG. 3 in order to form the double butterfly arrangement.

FIG. 4A is a cross-sectional view taken at line 4a-4a of FIG. 4 looking in the direction of the arrows.

FIG. 5 is a view taken from line 5-5 of FIG. 4 looking in the direction of the arrows.

FIG. 6 is a view showing the novel double butterfly contraceptive encased in an open ended tube, also showing the removable covers.

FIG. 7 is a schematic view showing the manner in which the double butterfly contraceptive may be expelled from the tube into the canal.

FIG. 8 is a schematic view showing the double butterfly contraceptive device initially inserted as a double barrier in the vagina.

FIG. 8A corresponds to FIG. 8 and shows further insertion.

FIG. 9 is a view corresponding to that of FIGS. 8 and 8A showing the location of the double butterfly contraceptive against the uterus and blocking off the fornices as a result of action during use.

Referring now to FIG. 1, there is here shown a cube 10 of absorbent resilient elastic highly compressible material such as sponge or foam rubber, neoprene, polyurethane or other materials which will readily expand elastically on the removal of compressive force and having an appropriate cellular, channel or sponge formation providing capillary means to absorb and hold fluid materials such as the spermicidal agent and lubricating materials hereinabove and hereinafter referred to and to dispense those materials on compression thereof. When the unit is fully compressed from the cube of FIG. 1 into the double butterfly contraceptive 20 of FIG. 4 face 11 of the cube will form the faces 21 and 22 respectively of the double butterfly contraceptive of FIG. 4.

In the event greater absorption and capillary attraction and holding of spermicidal and other fluid material is required at these faces, the initial cube may be formed as shown in FIG. 2 wherein in the basic cube 10A has laminations 11a and 12a of highly absorbent material secured thereto in any suitable manner to provide for maximum absorption and fluid retaining power at these faces.

A string is passed around the sides 11, 12, 13 and 14 of the cube of FIG. 1 or the corresponding sides of the cube of FIG. 2 and drawn tight to produce the intermediate structure shown in FIGS. 3 and 3A. It will thus be seen that the face 11 has been compressed to the face 21 of FIGS. 3 and 3A comprising the butterfly sections 21a and 22b. Similarly the opposite face 12 has been formed into two butterfly sections 23a and 24b (see also FIGS. 4 and 5).

A tape 30 is then passed around the remaining sides 15, 16 as shown in FIGS. 4 and 4A to compress the structure of FIGS. 3 and 3A into the structure of FIGS. 4 and 4A. The adhesive tape 30 compresses the central axis of the contraceptive of FIG. 4 to the greatest possible extent. The adhesive tape 30 is then secured in position so that it will remain forming the completed contraceptive 4 and 4A.

The contraceptive of FIG. 4 may most aptly be described as a double butterfly arrangement having the butterfly elements 23a and 24b at either end. The tail of string 17 passes between the butterfly elements 21a and 22b of end 21 and provides a means for withdrawal and retrieval of the contraceptive if required.

The contraceptive of FIG. 4 is arranged so that the axial distance between surfaces surface of butterfly 21a and 22b on the one hand and the surfaces of butterfly elements 23a and 24b on the other hand is greater than the diameter of the butterfly contraceptive 20. This ensures that insertion will occur in the proper orientation.

In addition, the presence of the withdrawal tail string 17 ensures that insertion into the canal will be in a direction so that the string may later be used for retrieval. Therefore it is intended that in use, the double butterfly contraceptive 20 be first inserted and moved to the position of FIG. 8 adjacent the uterus. The movement to this position, owing to frictional contact with the wall of the canal 40 ensures that the end 23a and 24b of the double butterfly contraceptive 20 will spread to form

a complete barrier. The walls 40 of the canal are sufficiently flexible so that they will follow the contour of the operative face of the barrier formed by sections 23a and 24b as seen in FIG. 5. This will serve to provide a first barrier across the canal 40.

A second barrier is formed by butterfly elements 21a and 22b of the end 21 of the butterfly contraceptive 20 of FIG. 4 and as shown in FIGS. 8 and 9. The outer surface of the butterfly elements 23a and 24b of the double butterfly contraceptive of FIGS. 4 and 8 may be impregnated with a fluid spermicidal agent. Hence any sperms carried by any sperm carrying material which may possibly penetrate the double barrier above described will be subjected to the spermicidal agent. The opposite end 21 of the double butterfly contraceptive of FIGS. 4 and 8 may have its exposed surface impregnated also with a spermicidal agent as well as a lubricating material. Since any sperm carrying material which will be ejected will first strike the barrier formed by end 21 of the double butterfly contraceptive, the sperm therein will be subjected to the spermicidal agent held and released by the elements 21a and 22b of the end 21 and absorbed by them. Should any of the sperm or sperm carrying material penetrate past the first barrier at end 21, it will be subjected to the second barrier at end 22 consisting of the butterfly elements 23a and 24b. Should such sperm or sperm-carrying material nevertheless penetrate beyond this barrier, which is not believed to be possible, the spermicidal agent carried thereat will serve to kill off the sperm cells.

In operation however, owing to the action which occurs either during the insertion of the double butterfly contraceptive 20 and owing to the action that occurs thereafter, the double butterfly contraceptive 20 will be forced toward the uterus 41 as shown in FIG. 8A and on further activity and further pressure, it in such be forced against the uterus and ends 23a and 24b of the butterfly will be forced toward the (anterior) fornix 42 and the (posterior) fornix 43 as seen in FIG. 9. Any sperm-carrying material which may get past the two separate dam structures and lie in a pool in either fornix 42 or 43, depending on the position of the user, will now be trapped on such fornices by the butterfly elements 23a or 24b as the case may be. Since the dam formed by the butterfly elements 23a and 24b is up against the uterus 41 the entry of sperm into the cervical opening 45 of the uterus is blocked mechanically. In addition, any initiation of progress of the sperm or sperm-carrying material from either of the fornices 42 and 43 toward the cervical opening 45 of uterus 41 is also mechanically blocked. Further, any sperm that might tend to migrate from the fornices toward the cervical opening 45 of the uterus 41 must come in contact with surfaces which have delivered but still retain spermicidal material.

There have been many prior attempts to use sponge and spongelike materials particularly in the form of spherical balls, cylinders, or tampons for insertion in order to produce contraceptive action and some of these had previously utilized the spongelike material to carry spermicides. The utilization of such cylinders, balls, or tampons has provided an incomplete damming or blocking action; no assurance could be obtained that the material would also form a dam in or adjacent to the vaginal fornices even though the said material might possibly engage the cervical opening in the uterus.

In addition owing to the tremendous elasticity of the vaginal walls (sufficiently elastic to permit the head of an infant to pass through) any insertion device which is to act as a dam must have a very substantial bulk.

Thus for instance the cube of FIG. 1 with which the process starts for the formation of the novel double butterfly contraceptive is preferably of the order of 3 inches on a side. This large volume and large size will ensure that when the cube has first been compressed by the string to the condition of FIG. 3 and compressed to its final form to form the double butterfly contraceptive 20 of FIG. 4 there will be sufficient volume and sufficient surface area at the opposite ends 21 and 22 of the double butterfly arrangement to form an efficient blocking and absorbing dam at each end and at the same time to retain and dispense sufficient amounts of spermicide and lubricant. Since a 3 inch cube would hardly be psychologically acceptable for insertion, while nevertheless the volume adjacent each opposite end surface is important in order to form a dam of sufficient size and fluid retaining material of sufficient size, the first compression into the shape of FIG. 3 and then the final compression at an axis normal to the first compression into the final butterfly shape of FIG. 4 produces the desired effect. The contraceptive insert first provides two dams in series, the first of which is expected to be sufficient to block and absorb the passage of any sperm-carrying material while at the same time providing additional surfaces to dispense absorbed spermicidal material as well as lubricant.

The flexibility of the ends 23a and 24b of the double butterfly contraceptive 20 of FIG. 4 as shown particularly in FIGS. 8A and 9 provides inherently a flange-like structure which is forced into the fornices to block any migration from any pool formed in either fornix to the uterus and to block and dam the front of the uterus. As will be seen particularly from FIGS. 3A, 4A and 5, the faces 23a and 24b of the end 22 of the double butterfly contraceptive 20 of FIG. 4 as well as the opposite faces, owing to the compression of the large initial cube of foam material are for practical purposes continuous with each other. The seam 50 between the two faces is sufficiently compressed to form a continuous barrier. The indentations at the face at the areas 51 and 52 are sufficiently slight so that the vaginal wall may follow the contour thereof and in fact the vaginal wall may well compress any bulging lateral area of the face to conform to the vaginal wall. Also, as pointed out above, the reverse action may occur in the event that these elements of the contraceptive are not compressed, the vaginal wall will follow their contour.

By this means therefore a complete mechanical block is obtained consisting of essentially two dams across the vaginal wall before the uterine opening. In addition the flexibility of the material permits the fornices to be blocked to prevent migration of any sperm from any pool of sperm-carrying material that may have reached the vaginal fornices. The spermicidal material carried at both faces should be sufficient to immobilize or to kill virtually all of the sperm at the face 21 which is first struck by the sperm-carrying material and to kill off any of the sperm that may migrate past the first barrier. Any possible live sperm that may migrate past the first barrier will be blocked by the second barrier formed by elements 23a and 24b. If not blocked, the spermicidal material at these faces should serve to kill off and immobilize such sperm. The blocking of the fornices by

the edges of elements 23a and 24b at the end 22 of the double butterfly contraceptive 20 will prevent migration of any sperm from any pool that might have been formed in either fornix to the uterus since both the fornices and the uterine opening are both blocked at this point. Further, any sperm that might possibly migrate in this area must come into close contact with the spermicidal material which might not yet have been expressed from these surfaces and be killed thereby. The device functions even if there is shallow penetration or the penetrating instrument is not very long.

By this means therefore a six-way contraceptive action is obtained by a simple mechanical insert: The first method of contraception is that the sperm-carrying material will first be ejected against the surface 21 which comprises the butterfly sections 21a and 22b; this surface 21 should for all practical purposes serve to absorb all of the sperm-carrying material and retain it within that surface. Second, the sperm will be brought into contact with the spermicidal material at the end 21 consisting of the elements 21a and 22b. The sperms should be killed or immobilized by this spermicidal material. Third, a dam is provided by the action of the butterfly elements 21a and 22b to block the passage of sperm-carrying material and sperm past the end 21 of the double butterfly contraceptive 20. Fourth, a second dam is provided by the elements 23a, 24b at the end 22 which should block the passage of sperm-carrying material past this dam. Fifth, in the event any sperm-carrying material should penetrate both dams and come to rest at the fornices, the extension of the ends of elements 23a and 24b into the fornices while the center of the unit bears against the cervical opening 45 of the uterus provides a further blocking action. Sixth, the spermicidal fluid dispensed and retained at the surfaces 23a and 24b will serve to kill any sperm which may possibly have penetrated the spermicidal areas and the dam and which may attempt to migrate from either of the fornices to the cervical opening 45 of the uterus 41.

The device itself provides physically (1) a blocking action (2) an absorptive action for the semen. The chemical impregnation provides (1) a spermicidal action and (2) immobilization of the sperm.

From experience, the first dam and the spermicidal material retained thereby at the end 21 and formed by elements 21a and 22b of the double butterfly contraceptive 20 should be sufficient for full contraception. The utilization of the additional dam 23a formed by the elements 23a and 24b and the action of such additional elements as hereinafter described should by themselves furnish full contraception; nevertheless these additional elements are required only to act with respect to material which may only problematically have gone beyond the first dam at end 21 and might have resisted the spermicidal action at that end. Further, the utilization of spermicidal material at the inner end 22 in connection with the second dam and the action of the second dam provides a final contraceptive action which may in actual practice never have to come into play but is present for the purpose of ensuring complete contraception.

The butterfly contraceptive element 20 prior to insertion if permitted to be fully expanded would at its end 22 have a diameter of the order of from 1 1/2 to 2 inches which, while insertable, presents at least a psychological block to insertion. It should be noted, as

pointed out above, that the vaginal walls have a great amount of flexibility, can be dilated to an unexpected extent so that the vaginal walls will have no problem accommodating themselves comfortably to the insertion of a unit having a cross section of this diameter. Since the foam resilient elastic material of which the unit is made is very soft, the resilient and elastic vaginal walls and the resilient and elastic unit will cooperate to reduce the diameter of the unit when it is inserted and to ensure complete blockage. The length of the butterfly contraceptive, uncompressed, is of the order of 2 1/4 inches. However, when the unit is inserted as shown in FIG. 8, or driven home as shown in FIG. 9, the length of the unit is determined almost entirely by the width of the tape 30. I have found that since the tape is of the order of 1/2 inch in width, the unit once inserted and in use may actually have an axial dimension of well under 1 inch (close to that of the width of the type which may itself wrinkle and collapse to a smaller width in use) owing to the flexibility, compressibility, resilience and softness of the foam material.

However, in order to remove any possible psychological barrier to the insertion of a device which appears to be so large, I have provided a capsule type of container 60 as seen in FIG. 6, having two removable covers 61 and 62. The capsule is preferably about 2 1/2 inches long axially and slightly under 1 inch in diameter and is sized so that it may be inserted as shown in FIG. 7 into the opening 65 of the vaginal canal. The contraceptive may then be pushed completely into the canal by the finger or by an appropriate plunger 66 having a handle 67 of sufficient length to ensure complete insertion of the double butterfly contraceptive 20.

The materials used whether foam rubber, polyurethane, neoprene or other cellular or spongelike materials may be made sufficiently soft so that they can be readily compressed into the capsule 60 and readily expelled therefrom. In addition the lubricant at the end 21 of the double butterfly contraceptive will facilitate the movement of the contraceptive 20 out of the capsule as it will also facilitate the movement thereof further into the canal to the positions of FIGS. 8 and 9. In use the additional force which occurs, as indicated at 70 of FIG. 9, will drive the double butterfly contraceptive 20 to a final full blocking position.

Even if it is driven only to the position of FIG. 8A, full blocking and absorptive action will occur and the spermicidal and immobilizing chemical will be available to perform its function.

The string 17 shown in FIG. 4 and tucked into the vagina will be available for removal of the unit at any desired time. It should be kept in mind that since the blocking action is present at all times while the contraceptive is in position and the spermicidal action is present as long as the unit retains any spermicide and the canal and all parts within are bathed by the spermicidal action there is no need for immediate removal of the contraceptive unit and it may be left in for a substantial period of time. This string will however permit removal at any time.

In the foregoing the invention has been described only in connection with preferred illustrative embodiments thereof. Since many variations and modification of this invention will be apparent to those skilled in the art, it is preferred to be bound not by the specific disclosure herein contained but only by the appended claims.



The embodiments of the invention in which an exclusive privilege or property is claimed are defined as follows:

- 1. A contraceptive having a flexible, compressible elastic, resilient sponge-like body and comprising:
  - a band located substantially centrally of said body;
  - and compressing said body at said band;
  - said body flaring on each side of said central band, said body being additionally compressed at an axis substantially normal to that of said band;
  - the flaring portions of said body on each side of said band being thereby bifurcated to form a butterfly arrangement;
  - a string; said string effecting said additional compression;
  - an end of said string passing between said bifurcated portion of the body on one side and extending beyond the boundary of the body.
- 2. The contraceptive of claim 1 in which at least one end is impregnated with a spermicide.
- 3. The contraceptive of claim 1 wherein the original body prior to the placement of the string and band thereon is substantially cubic in shape, the edge of said cube having a dimension of the order of 3 inches.
- 4. A contraceptive having a flexible, compressible

- elastic, resilient sponge-like body and comprising:
  - a band located substantially centrally of said body;
  - and compressing said body at said band;
  - said body flaring on each side of said central band;
  - at least one end of said body being impregnated with a spermicide.
- 5. A contraceptive having a flexible, compressible elastic, resilient sponge-like body and comprising:
  - a band located substantially centrally of said body;
  - and compressing said body at said band;
  - said body flaring on each side of said central band, at least one end of said body being impregnated with a lubricant.
- 6. A contraceptive device having a flexible compressible sponge-like body and comprising a pair of flaring ends and a section of lesser cross-sectional dimension between the flaring ends,
  - and a string surrounding said portion having a lesser cross-sectional dimension;
  - said string having an extension beyond said sponge-like body,
  - one of said flaring ends being impregnated with a spermicide and the other of said flaring ends being impregnated with a lubricant.

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