

FEMALE CONDOM WITH ADHERING SHIELD AND METHOD OF MANUFACTURE

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TECHNICAL FIELD

The objective of the present invention is related to sexual barriers for prevention of fertilizing spermatozoa and sexually transmitted diseases (STD) during sexual intercourse. Particularly it relates to the protection of both the internal and external genitalia of either sexual partner to prevent exchange of body fluid by a thin flexible walled female condom with an extended shield. It is yet another object of the present invention to provide a device that is cheaper to produce and easier to use than the prior art.

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BACKGROUND ART

The need to create a good barrier contraceptive and anti- infective device has never been greater. The world population is constantly on the rise, so are the unplanned and unwanted pregnancies. STD, especially AIDS, are widespread in many parts of the world. Many attempts at the barrier methods have been made to counter this trend, some to certain success, but none has been able to be truly effective in both contraception and disease prevention.

The problems with the familiar condom are well known. It depends on the rigidity of the unreliable penis to stay in place. Furthermore it only covers the body of the penis and not the base, therefore unable to prevent diseases, such as herpes and warts, through the external genital, anal or oral contact. In addition, it depends on the male partner's willingness to use it. It is also not user friendly. Unrolling it in dim lighting often ends up in the wrong direction, and its strangulating pressure decreases the tactile sensation of the penis.

Female condoms thus provide viable alternatives to male condoms.

US Patent No. 5094250 (Figure 1a) to Hessel describes a thin wall tubular device with a closed end and an open end. It has an inner ring at the closed end positioned at the cervix and an outer ring at the open end positioned at the introitus. The device only partially shields the external genitalia and it does not seal up the introitus. Therefore it does not prevent infections through direct contact of external genitalia or the exchange of body fluid. Furthermore, it is more expensive to produce than a regular condom.

To address the above issues of preventing exchange of body fluid and shielding the external genitalia to achieve better contraception and disease prevention during coitus, US Patent No. 5269320 (Figure 1b) to Hunnicutt describes a rubber female condom with an extended shield at the open end. The shield covers the external genitalia, pudendum, and is secured in place by an adhesive. The shield may be formed as part of a panty or men's brief. The tubular portion is provided in a compacted, folded state, and together with the shield portion, it is covered by releasing paper on both sides.

US Patent No. 4898184 (Figure 1c) to Skurkovich et al describes a similar female condom made of rubber latex, but with greater shield area held in place by weak adhesive or straps around the genitalia.

US Patent No. 5515862 (Figure 1d) to Artsi describes yet another similar female condom with an even larger shield that is sealingly attached to or integrally formed with the open end, said shield having six well defined regions which together form a continuous, seamless surface surrounding the open end, the surface having a continuous outer edge. An adhesive is applied close to, and around the entirety of the outer edge beyond the pubic hairline to resist seepage of fluid during coitus. The tubular portion is provided in the folded manner like a concertina, as seen in the invention of Hunnicutt.

All the three aforementioned female condoms with the adhering shield are made of a thin soft water-impermeable material, for instance rubber latex or other biologically acceptable plastic films, such as polyurethane, polyethylene, polypropylene, polyester, nylon, polyvinyl chloride, bioplastics, nitrile and others. As the shield portion has a plane which is

perpendicular or at an angle to the tubular portion, the constructions of these female condoms are complicated, let alone the difficulty in the application of adhesive onto the flimsy shield, as the tubular portion is situated at the centre of the shield. If rubber latex is used as described in the construction in the aforementioned prior art of Fig. 1b and 1c, a complex molding process and adhesive application will be needed, so the cost of production will be high. On the other hand, if a thin flexible membranous film is used, one would not be able to create a "continuous, seamless surface" for the shield as described by Artsi, and membranous film will be difficult to handle due to its flimsiness. For example, to fold the thin membranous tubular portion into a concertina as described by Artsi would be technically difficult.

There is therefore a need for female condoms with adhering shield that can be manufactured at a low cost and can be easy to handle, while providing a secured barrier for both internal and external genitalia to effectively prevent unplanned pregnancies and transmission of STD during coitus.

SUMMARY OF THE INVENTION

In accordance with the present invention there is provided a prophylactic device that is to be worn by a person to prevent the transmission of STD and sperm during sexual intercourse. The device is a female condom which comprises two layers of flexible, thin membranous films, such as such as rubber, polyurethane, polyethylene, polypropylene, polyester, nylon, polyvinyl chloride, bioplastics, nitrile, silicone and others, sealed together in an omega or similar shape. The sealing can be performed by using heat, chemical, mechanical, light, electrical or other source of energy. The seam that forms the base of the omega shape has two elongated flanges which at separation from one another, form the shield portion of the female condom, while the tubular space thus created by the omega shape becomes the female condom consisting of a closed end and an open end. The diameter of the said open end is constructed to be sufficiently large to permit insertion and movement of a penis, while the length of the said tubular space is sufficiently long enough to accommodate the entire penis. The said shield portion is constructed to be sufficiently large to seal the entire external genitalia to prevent seepage of fluid from female genitalia. It can be enlarged to cover more area of the lower part of the body to prevent direct dermal contacts between the external genitalia of the user and her partner.

In all the different embodiments mentioned herewith, the said omega shape's tubular portion can be replaced by other similar shapes, such as a narrow bell shape or a rectangular shape or a combination of these.

Another feature of the present invention is the application of adhesive to the external surface of the shield portion together with releasing paper or plastic sheet. Another feature of the present invention is that the adhesive can be applied partially or wholly on both the tubular and shield portions. Anything that keeps the membranous shield portion in place can be used as "adhesive". It can range from static electricity to industrial glue such as poly-isobutylenes, polysiloxanes and polyacrylate; weak adhesive such as hydrogel, or non-adhesives such as petroleum jelly, lanolin, ointment, cream, lotion, grease, honey and syrup etc. The advantage of the later would be the ability of adjustment of the shield portion after deploying the female condom and painless removal of the shield from the hairy skin. It also allows easy removal of the flimsy female condom without breaking it, thus avoiding the possible spillage of seminal content in the vagina.

Another feature of the present invention is the adhesive could be medicated with spermicides and/or other anti-septics. It may also be enriched with health supplements such as vitamins or minerals.

Another feature of the present invention is the pre-treatment of the internal and/or external lining of the said tubular portion to be textured with ridges, studs, nubs and so on to enhance the sexual stimulation, to reduce the electrostatic field or to reduce the luminal size of the vagina, especially in multi-parous women.

In another embodiment of the present invention the said shield (and tubular portion) can

be designed to be in various shapes, sizes, colours, opacity, textures, added pictures, wordings and logos to improve protection, aesthetic look and sexual appeal.

Another feature of the present invention is that the sizes and shape of the tubular and shield portion can be made according to: (1) different body build of the users, and (2) the preferred area of coverage for the external genitalia and the lower part of the body.

Another feature of the present invention is the size and shape of the anterior and posterior part of the shield can be the same or different to suit individual preferences.

In another embodiment of the present invention the female condom can be lubricated, perfumed and/ or flavoured to make it "look good, smell good, taste good and feel good".

In another embodiment, the tubular portion of the present invention can be inverted to turn it into a male condom.

In another embodiment, the omega shape sealing of the thin membranous films is performed longitudinally, resulting in the two parts of the shield being opened up side way instead of being anterior-posteriorly.

Another embodiment is having two, instead of one, omega shape sealing of the thin membranous films longitudinally to create two tubular portions enabling both vaginal and anal intercourses for both female and male users.

In yet another embodiment, the tubular portion is folded longitudinally into one or multiple folds before sealing. The resulting tubular portion will then have a greater circumference for a given width, thereby giving less strain to the open end of the female condom.

In yet another embodiment, both layers of thin membranous films are transversely folded into double layers (for example, 5 to 25mm) at the closed end of the tubular portion before sealing. The resulting closed end of the tubular portion will then have a wider diameter than the open end at opening up, therefore allowing a more secured placement of the ring pessary at the closed end, which is used to anchor the female condom in the vagina.

In yet another embodiment of the present invention, the female condom is made up of sealing of more than two pieces of thin membranous films each making up a part of both the tubular and shield portions. In yet another embodiment, the releasing paper/plastic sheet is textured to allow it to be easily identified by touching.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

- Fig.1a: Female condom according to Hessel;
- Fig. 1b: Female condom according to Hunnicutt;
- Fig. 1c: Female condom according to Skurkovich;
- Fig. 1d: Female condom according to Artsi;
- Fig. 2: Brief schematic plan of the manufacturing process of the current invention;
- Fig. 3a: Female condom in perspective view right before deployment;
- Fig. 3b: Perspective view of the female condom with the shield portion opened up ready for deployment;
- Fig. 4a: Perspective view of the female condom when the releasing sheets are partially peeled off;
- Fig. 4b: Perspective view of the female condom properly deployed onto the genitalia of the female user;
- Fig. 5a: Perspective view of the insertion of middle finger into the tubular portion of the female condom;
- Fig. 5b: Perspective front views of Fig. 5a as the releasing sheets are being removed;
- Fig 5c: Perspective back view of Fig. 5b;
- Fig. 6a: Front view of the female condom;
- Fig. 6b: Perspective view of female condom after being deployed;

Fig. 6c: Perspective view of the female user in standing position after deployment of female condom;

Fig. 7a-c: Drawings depicting the alternative shape of the shield portion with respect to Fig. 6a-c.

5 Fig. 8a-b: More drawings as in Fig. 7a-c;

Fig. 9: A fig leaf design for the shield portion as in Fig. 6c;

Fig. 10: As in Fig. 6c, a minimalist design for the shield portion covering the introitus only;

10 Fig. 11a: Perspective view of the female condom where the tubular portion is folded longitudinally;

Fig. 11b: Perspective view of the female user after deployment of the device in Fig. 11a;

Fig. 12a: Perspective view of the female condom without the releasing paper/sheets attached;

15 Fig. 12b: Perspective view of the female condom as Fig. 12a with the tubular portion being inverted, turning it into a male condom;

Fig. 12c-d: perspective view of the deployment of the male condom as in Fig. 12b onto a male user;

Fig. 13a: Perspective view of the female condom with an unequal length of the shield portions anterior and posteriorly.

20 Fig. 13b: Perspective view of the female condom after deployment of the condom in Fig. 13a on a female user.

Fig. 14a: Perspective view of the female condom where the omega shaped sealing runs longitudinally;

25 Fig. 14b: Perspective view of the female user after deployment of the female condom as in Fig. 14a;

Fig. 15a: Perspective view of the female condom with double omega shaped healing sealing running longitudinally;

Fig. 15b: Perspective view of the female condom in Fig. 15a after deployment on a female user;

30 Fig. 15c: Perspective view of the female condom in Fig. 15a, where one tubular portion has been inverted to become male condom, at deployment on a male user;

Fig. 16a: side view of the tubular portion with folded ends of Fig. 16b;

Fig. 16b: Front view of the female condom with the folded closed end, with vaginal ring pessary in the shield portion of the female condom;

35 Fig. 16c: Perspective view of Fig. 16b with the ring pessary placed perpendicularly to the tubular portion.

Fig. 17: Perspective view of the female condom made up of multiple pieces of thin membranous films sealed together, each thin membranous film forming part of both the tubular and the shield portions.

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DESCRIPTION OF THE PREFERRED EMBODIMENTS

45 The present invention is of female condom with an extended adhering shield portion to protect the external genitalia and to prevent the transmission of the sperms and STD during sexual intercourse.

The principle and the operation of the present invention could be understood with reference to the above drawings with the following description.

50 A brief schematic plan of the construction of the preferred embodiment of the present invention is laid down in Fig. 2. It explains how the preferred embodiment could be produced at an efficient and low cost manner, and at the same time shading light on how it is deployed. The double layer thin flexible thermoplastic films 1 would roll out onto the manufacturing table, much like the production of the supermarket plastic bags. Here it is heat sealed into omega or similar shape in quick successive stamping 3. One of the "adhesive" mentioned above 4 is partially or wholly applied to the portion of the membranous films 5 below the seam at the base of the omega shapes 2. Non absorbing releasing paper or plastic sheet 6 is

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then applied onto the entire width of the membranous films. The product is rolled over 7 to have the adhesive and the releasing sheet applied on the external surface of the opposing membranous film in the same manner 8. An alternative method is to approaching the opposing surface from opposite direction simultaneously, thus allowing simultaneous application of adhesive and releasing paper for both surfaces. Yet another method is to apply the adhesive onto the releasing paper before attaching it to the membranous film. Now that the double layer sealed membranous films with the adhesive applied is completely covered with releasing sheet on both sides, it is cut 9 into the final product 10 by using techniques such as stamp or roller cutting.

The cutting edges for the tubular portion are set to be near the seam, while the said lower portions that would make up the shield portion 11 would be cut in a straight or a curve line perpendicular or at an angle to the seam at the base of omega shape 2.

The membranous films may be pre-treated before sealing as aforementioned, such as being painted with pictures or wordings, or textured. Thus the shape of the shield 11 could be constructed to vary according to the type of pre-treatment. In order to ease the deployment of the condom, supporting/ backing sheet can be attached to the inside of the shield portion prior to sealing. Likewise, the releasing paper/ plastic sheet can be textured to facilitate its removal by touch.

Other manufacturing processes may be made within the scope and the spirit of the present invention. Examples of such variation may include the 'adhesive' being applied partially or wholly to either or both the tubular and the shield portion of the female condom, the application of the adhesive and the releasing sheet after the membranous films are cut, or using other methods of sealing, such as laser welding or dielectric bonding etc, on the membranous films.

In anticipation of sexual activity, the female partner 16 would open up the two parts of the shield 11 that hinges at the sealed seam at the base of the omega shape 2 as shown in Fig. 3a and 3b. She would then insert a lubricated middle finger 17 or an introducer/applicator into the said tubular open end 13 all the way up to the said closed end 14 (Fig. 5a). With that the exterior of the tubular portion is lubricated and inserted into the vagina 15 (Fig. 4a). While the said covered middle finger 17 is still inside the vagina, the palm and four other extended fingers of the same hand would press the shield portion 11 against the skin of external genitalia, and the anterior releasing paper or sheet 6 would be peeled off slowly with the other hand (Fig. 5b). The posterior releasing paper or sheet 6 would then be peeled off in the same manner. To facilitate easy recognition by touch, the releasing paper may be textured. Once the said shield 11 is securely adhered to the external genitalia (Fig. 4b), the said middle finger is removed from the tubular portion, which is to remain inside the vagina. Though not essential, a semi rigid ring 27 (Fig. 16b and c) or any anchoring device may be inserted and placed at the said closed end 14 of the tubular portion to further secure the tubular portion in the vagina. The backing/ supporting sheets, if present, are then duly peeled off from the shield portion.

After the sexual activity, the shield 11 would be peeled off from the external genitalia followed by removal of the tubular portion 12 from the vagina and discarded.

Fig. 6a-c shows the preferred embodiment without the releasing sheet being attached. As aforementioned, it comprises two thin flexible membranous films sealed 18 in omega or similar shape with the seam at the base of the omega shape 2 comprising extended shield portion 11. The elongated omega shape portion would become the tubular portion 12 of the female condom. By deploying the female condom onto the female user 16 described above, the open end 13 would be ready for coitus (Fig. 6b). While the external genitalia are completely covered by the female condom, the anus may or may not be covered by the shield, all depending on the preferences of the user. It would then be just a matter of extending the posterior shield portion 23 during construction of the female condom if anus is to be covered.

Fig. 6c shows the female user 16 in standing position. As illustrated, the female condom is more secured, comfortable and aesthetically pleasing compared to Hessel's female condom discussed above, where the outer ring would be dangling outside the introitus in standing position.

Fig. 7a-c shows an embodiment with a different shape for the shield portion. Instead of a rectangular shape, it has cut edges 19 resembling an inverted heart shape. On deployment it resembles a heart sitting at the pubic region.

Fig. 8a shows another embodiment where the cut edges 19 is at an angle to the base of the omega shape 2. It gives the pubic region greater coverage 11 (Fig. 8b). Fig. 9 shows another embodiment with fig leaf shape shield portion 11, whereas Fig. 10 reveals a minimalist embodiment with hardly any pubic region being covered by the shield 11.

Fig. 11 shows another embodiment with longitudinal folds 20 at the tubular portion 12 of the female condom. The folds increase the capacity of the tubular portion at a given width, thereby putting less strain at the open end of the tubular portion during coitus.

Fig. 12a-d describes how the present invention can be converted into a male condom by simply inverting the tubular end 12 inside out. The releasing sheets are not shown in Fig. 12a and b. In Fig. 12c, the releasing sheets are partially peeled while the open end 13 is donned onto the penis with the help of lubricant. The shield portion 11 is adhered to the pubic and scrotal region as shown. In this way man can equally be in control and be protected by the present invention.

As discussed above, the posterior shield portion 23 could be made to leave out the anus by just having a shorter shield 23 than the anterior shield 22 as shown in Fig 13a-b. The dimension of the anterior and posterior part of the shield can be constructed according to the users' preferences.

In another embodiment the sealing of the two membranous films layers is done longitudinally, in this case the shield would be opened up sideways (Fig. 14a-b) with the seam at the base of the omega shape 2 running longitudinally. This embodiment allows the addition of an extra omega shape tubular region 24 for insertion into the anus 25 to enable safe anal sex (Fig. 15a-b). In case of male user, both the penis and anus can be protected in the same way (Fig. 15c).

Fig. 16 shows another embodiment specifically invented for the placement of a ring pessary 27 for anchoring the closed end of the tubular portion to the vagina. Both layers of membranous films at the rectangular closed end 14 is folded (for example, 5 to 25mm) transversely 26 unto itself (Fig. 16a) before they are sealed as shown in Fig. 16b. The ring should have a diameter that is slightly smaller than the width of the tubular portion when it is lied flat. Because of the folding 26, the space at the closed end 14 is increased, thus allowing perpendicular placement of the ring pessary with in the closed end. This eliminates the problem of the ring pessary not staying at the closed end of the tubular portion during deployment of the female condom and during coitus.

In another embodiment, the female condom can be made up of multiple membranous film sealed together to provide both the tubular and shield portions (Fig. 17) It has the advantage of putting less strain on the open end of the tubular portion during coitus, though the production process could be more complicated.

The present invention, at proper application, should completely seal off both the internal and the external genitalia of the female partner to prevent the exchange of genital fluid of both partners during coitus. And since it completely seals off the genitalia, it could conceal off unpleasant vaginal discharge, bleeding or odour. Also because of this, it has the potential for being use in different occasions such as in the bath, shower, swimming pool, sea, beach, and situations such as oral and anal sex without worrying about soiling and contamination. Depending on the opacity of the shield being constructed, it can also be used to cover up unsightly pubic hair, scars, anatomical deformity and pigmentations. It is also convenient to use, as it can be donned any time before sexual contact and removed any time after that. Furthermore, unlike regular condom, it can be used regardless of the varying degree of rigidity of the penis during sexual contact.

Due to the present invention's unique design, manufacturing process and the ease of donning, the thinnest possible membranous films could be employed to construct it. It is therefore able to provide better tactile and thermal sensitivity than the prior art.

The claims

My claims are:

- 5 1. A female condom comprises
 - a. two layers of flexible, thin wall membranous films sealed together in an omega or similar shape
 - b. the seam that forms the base of the omega shape has two elongated flanges which at separation from one another will become the shield portion of the female condom,
 - 10 while the tubular space thus created by the omega shape will become the female condom consisting of a closed end and an open end.
 - c. the diameter of the said open end is sufficiently large to permit insertion and movement of a penis, while the length of the said tubular space is sufficiently long enough to accommodate the entire penis.
 - 15 d. the said shield portion is sufficiently large to completely seal the external genitalia to prevent seepage of fluid from female genitalia.
 - e. The application of adhesive to the external surface of the shield together with releasing paper/sheets with or without the backing paper/sheets.
- 20 2. A condom as in claim 1, the said omega shape's tubular portion is replaced by other substantially elongated shapes, such as a narrow bell shape or a rectangular shape.
3. A condom as in claim 1, the said shield portion is sufficiently large enough to cover enough external genitalia to prevent direct dermal contacts between the external genitalia of the user and her partner.
4. A condom as in claim 1, the adhesive is hydrogel.
- 25 5. A condom as in claim 1, the adhesive is an ointment base.
6. A condom as in claim 1, the adhesive is medicated or enriched with health supplements and minerals.
7. A condom as in claim 1, wherein the adhesive is applied partially or wholly onto the tubular and /or shield portions with the releasing sheets.
- 30 8. A condom as in claim 1, the internal and /or the external lining of the tubular portion is/are pre-treated to be textured with ridges, studs and nubs.
9. A condom as in claim 1, the shield portion is designed to be in various shapes, sizes, colours, opacity, textures, added pictures, wordings and logos.
10. A condom as in claim 1, wherein the condom is lubricated, perfumed and/ or flavoured.
- 35 11. A condom as in claim 1, wherein the sizes of the tubular and shield portions for the external genitalia and the lower part of the body are made according to different body build and the preferred area of coverage of the users.
12. A condom as in claim 1, wherein the size and shape of the anterior and posterior parts of the shield are constructed to suit users' preferences.
- 40 13. A condom as in claim 1, wherein the tubular portion of the present invention is inverted to turn it into a male condom.
14. A condom as in claim 1, wherein the omega shape sealing of the membranous films is performed longitudinally, results in the two halves of the shield portion being opened up side way instead of being anterior-posteriorly.
- 45 15. A condom as in claim 1, wherein there are two omega shape sealing of membranous films to create two tubular portions to allow both vaginal and anal intercourses for both female and male users.
16. A condom as in claim 1, where in the tubular portion is folded longitudinally into one or multiple folds before sealing. The resulting tubular portion thus has a greater circumference for a given width.
- 50 17. A condom as in claim 1, wherein both layers of membranous films at the closed end of the tubular portion is transversely folded into double or multiple layers of typically, but not limited to, 5 to 25mm length before the heart sealing.

18. A condom as in claim 1, wherein the condom is made up of sealing of more than two pieces of membranous films, each making up a part of both the tubular and shield portions.

19. A condom as in claim 1, wherein the steps of manufacturing are:

- 5 a) Sealing of double layer membranous films with or without the pretreatment of backing paper/sheet
- b) Application of adhesive and releasing paper /plastic sheet on one membranous film
- c) Simultaneous or followed by application of adhesive and releasing paper or plastic sheet on the other membranous film
- 10 d) Cutting the membranous films into final product.

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