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**TUBULAR PROTECTIVE DEVICE FOR PROTECTION AGAINST TRANSFER OF INFECTIOUS MATTER
DURING SEXUAL INTERCOURSE**

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(56) Prior Art Documents
US 3102541
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(57) Claim

1. A tubular protective device for protection against a transfer of infectious matter during sexual intercourse comprising:

(a) a flexible, thin-walled tube having a sufficiently large diameter to permit movement of a penis within said tube during coitus, said flexible thin-walled tube having a closed end and an open end, said open end having a means for maintaining said open end in a radially extended condition; and

(b) means at said closed end of said flexible, thin-walled tube, for retaining said closed end in a vagina of a user.

13. A tubular protective device for protection against a transfer of infectious matter during sexual intercourse, said protective device comprising:

(a) a thin-walled, flexible tube having;

(i) a closed end,

(ii) an open end, and

(iii) a first diameter;

(b) a collar-shaped outwardly extending means for

- maintaining said open end in a radially stretched condition, said means having a second diameter wherein said first diameter of said tube is smaller than said second diameter of said means and said first diameter is sufficiently large to permit movement of a penis within said tube during coitus; and
- (c) an outwardly extending ring-shaped means at said closed end of said flexible, thin-walled tube for retaining said closed end in a vagina of a user.

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COMPLETE SPECIFICATION FOR THE INVENTION ENTITLED:

"TUBULAR PROTECTIVE DEVICE FOR PROTECTION AGAINST TRANSFER
OF INFECTIOUS MATTER DURING SEXUAL INTERCOURSE"

The following statement is a full description of this invention,
including the best method of performing it known to us :-

The present invention relates to a tubular protective device or condom-like device for protection against the transfer of infectious matter during sexual intercourse.

Condoms, besides being contraceptives, offer protection during sexual intercourse against the transfer of infectious matter such as bacterial and viral microbes that cause venereal diseases. After the appearance of AIDS great efforts have been made by various health authorities to impel people to increase the use of condoms during sexual intercourse in order to prevent the spread of this fatal disease.

Condoms comprise a thin tubular casing, that is typically manufactured from latex and that has an open end and a closed end. Condoms are drawn over the penis before coitus. The casing has an inner diameter that is



adapted to allow the condom to fit tightly on the penis. At the open end of a condom an elastic, flexible ring or rolled portion of latex is usually provided. This ring portion is the same diameter as the tubular casing of the condom. This elastic ring portion serves primarily to secure the condom on the penis and to prevent leakage of semen from the interior of the condom. Such elastic ring portions contract the open end of a condom onto the penis and do not radially extend the open end of the condom.

It is a generally accepted that the AIDS virus can only be transferred through contact with the carrier's blood or blood plasma. During sexual intercourse such a transfer of the AIDS virus occurs when lesions of the carrier contact the mucous membrane or skin of the carrier's partner. Such a transfer of the AIDS virus is especially likely to occur around the root or base of the penis and the vulva. There is a risk that lesions in these areas can be caused to bleed during sexual intercourse. When using a standard condom, these areas are unprotected or unshielded by the condom and consequently a condom does not offer full protection against the transfer of infectious matter such as the AIDS virus.

Numerous attempts have been made to design a condom or condom-like device that provides effective contraception and/or more protection against the transfer of infectious matter than the standard condom. A sampling of these attempts are described below.

U.S. Patent Number 4,004,591 to Freimark discloses a birth control device. This birth control device is a female condom made of a strong rubber, plastic, or other similar material. This condom has a rigid, ring-like rim that is bent or scalloped. This rim can be a wire. The rim is not adapted to radially extend the open end of this device because this device is a hard molded material and not flexible. The cross-sectional dimensions of this condom are disclosed as being sufficiently large to easily accommodate the average male width with some additional clearance space. The primary function of this device is to prevent unwanted pregnancy. This device is useful in preventing the spread of venereal disease. This device provides no means to prevent an exchange between partners of secreted fluids that may contain venereal disease. Additionally, this birth control device is intended for use by females, but includes no means to secure or maintain the device in the vagina.

U.S. Patent Number 4,630,602 to Strickman et al. discloses a disposable contraceptive cervical barrier. The cervical barrier of this invention is similar to standard diaphragms in size and design. This cervical barrier contains various "cavities for cells" that can hold spermicidal lubricants. These spermicidal lubricants can also be placed in numerous grooves within the body of the cervical barrier. Urethane polymers are used to make the device. The cervical barrier of this invention, unlike a condom, has no tubular side walls to prevent the exchange between partners of secretions that can contain a venereal disease.

U.S. Patent Number 3,536,066 to Ludwig discloses a human birth control appliance. The appliance of this patent protects both partners from any dermic contact. This device is large and awkward to use.

U.S. Design Patent Number 254,808 to Meldahl discloses a design for a male contraceptive. This contraceptive appears to be larger in diameter than the average condom, but this contraceptive has no means at its open end to aid in the prevention of the spread of venereal disease.

The ^{consumer}~~industry~~ is lacking a simple, easy-to-use device that provides protection against the transfer of body fluids between partners during sexual intercourse, especially between the base of the penis and the vulva.



The invention is a tubular protective device for
5 protection against a transfer of infectious matter during
sexual intercourse. The protective device comprises:

- 10 (a) a flexible, thin-walled tube having a
sufficiently large diameter to permit movement
of a penis within said tube during coitus, said
flexible thin-walled tube having a closed end
and an open end, said open end having a means
for maintaining said open end in a radially
extended condition; and
- 15 (b) means at said closed end of said flexible,
thin-walled tube, for retaining said closed end
in a vagina of a user.

The invention also provides a tubular protective
device for protection against a transfer of infectious
matter during sexual intercourse, said protective device
20 comprising:

- (a) a thin-walled, flexible tube having;
 - (i) a closed end,
 - (ii) an open end, and
 - 25 (iii) a first diameter;



- 5 (b) a collar-shaped outwardly extending means for maintaining said open end in a radially stretched condition, said means having a second diameter where said first diameter of said tube is smaller than said second diameter of said means and said first diameter is sufficiently large to permit movement of a penis within said tube during coitus; and
- 10 (c) an outwardly extending ring-shaped means at said closed end of said flexible, thin-walled tube for retaining said closed end in a vagina of a user.

Besides protecting against a transfer of infectious matter, the protective device is a contraceptive and, due



to the presence of the collar-shaped portion of the
5 device, the contraceptive effect is even more efficient
than that obtained with standard condoms because of the
additional protection provided around the vulva.

10 The walls of the tubular device are preferably held
in a relatively immovable state or condition against the
vaginal wall. The means for maintaining the open end of
the device in a radially extended condition may be a
collar covering the vulva which is, also, essentially
immovable with respect to the vulva during coitus.

15 The flexible, thin-walled tube of the invention is



desirably cylindrical in shape. The tube is preferably made from a natural or synthetic polymer material. Desirable polymer materials are members selected from the group consisting of latex, polyethylenes, polyurethanes, and derivatives based upon these polymers. The preferred material is a polyether polyurethane that has a soft, nonadhesive "hand feel". Other polymers or plastics such as polyolefins can be used to manufacture the tube of this device.



The tube of this device can be manufactured by numerous methods that are standard within the industry that fabricates items from polymer materials. The particular method chosen to manufacture the device of this invention varies with the particular polymer material chosen. An acceptable method of manufacturing the device can include curing a polymer material, such as latex, on a mold that has been dipped into a container of heated, liquified polymer material. Other methods can include either vacuum forming or blow molding a sheet of heated polymer material into or onto a mold. Vacuum forming and blow molding are desirable with synthetic polymer materials such as polyurethanes.

The preferred method for manufacturing the device, when it is made of a synthetic polymer such as polyurethane, is to heat seal two layered sheets of the polymer material together to form the desired shape of the device. Heat sealing methods can be undesirable if caution is not exercised during the process. This is because these methods can leave hardened seams that can potentially irritate skin and mucous membrane surfaces. Additionally, the seams are subject to leakage and tearing if the heat sealing method is performed at an undesirably high temperature. Heat sealing methods, however, are desirable because the sheets of polymer

are
material, ~~is~~ not stretched during the manufacturing of
the device and a consistent wall thickness for the
device can be obtained.

The wall thickness of the condom-like device can
vary greatly. Typically, thinner wall thicknesses for
the device allow more sensitivity during coitus. Wall
thicknesses can be varied depending upon the strength of
the polymer material that is chosen for the device.
Preferably, a wall thickness for the device is between
20 and 60 microns (μm) for synthetic materials such as
polyurethanes and 30 to 90 microns for natural materials
such as latex. A wall thickness, regardless of the
material from which the device is manufactured, must
provide a tensile strength of at least 17 MPa when
tested less than 12 months after manufacture and at
least 15 MPa when tested 12 months or more after
manufacture in order to comply with the standards of the
American Society for Testing and Materials.

The internal or inner diameter of the tubular
protective device in its unstretched state is desirably
of a sufficiently large dimension to permit movement of
a penis with respect to the protective device during
sexual intercourse. The ~~invention~~^{device} can have an inner
diameter that causes the condom to be form fitting, but
form fitting condom devices do not permit adequate



sensitivity for the male during sexual intercourse. This is because a form fitting condom moves with the penis and prevents direct contact between the vaginal wall and the glans area during intercourse. This undesirable effect of form fitting condoms discourages their use by many members of the public. A condom-like device having a large inner diameter merely functions as a liner for the vaginal wall. In this situation the device is relatively stationary to the vaginal wall and the glans is in direct contact with the surface against which it is moving. This structural arrangement, wherein the inner diameter of the condom-like device is larger than a penis, provides greater sensitivity for both partners.

Desirably any diameter of the tube below the outwardly extending collar-shaped means for radially stretching the open end or such as an elastic ring is smaller than a second diameter of the means for radially stretching the open end and the first diameter is sufficiently large to permit movement of a penis within the tube during sexual intercourse.

Standards within the industry for condoms, typically, do not define the inner diameter of a condom, but define the acceptable width of the condom when it is laid flat on a surface. A condom having a width of

about 47 millimetres to about 51 millimetres is considered, within the industry, to be form fitting. Contoured or loose fitting condoms have a width of about 50 millimetres to about 54 millimetres. For this invention an acceptable width is at least about 50 millimetres in an unstretched state along the entire length of the tube. A desirable range for the width of the condom-like device of this invention is between about 55 millimetres and about 85 millimetres.

As mentioned, the open end of the protective device has a means for radially extending the open end. This means, e.g. a ring, serves to prevent the open end of the tubular protective device from being pushed into the vagina during sexual intercourse.

The means for extending the open end is desirably a semirigid ring or ring-like member. In the most desirable embodiments of the invention, the ring is manufactured from a suitable plastic as a separate part. The device can be made wherein the means for extending the collar is integrally formed from the same material from which the walls of the device are formed. Such a structure can be formed by rolling the polymer material that forms the walls of the device from the open end of the tube so as to form a ring of material.



This ring of material can be maintained by heating the ring or using an adhesive to maintain the ring and prevent it from unrolling.

The diameter of the means for radially extending the open end is desirably large enough to prevent the exchange of secretions between partners during sexual intercourse. The diameter of the means for radially extending the open end is desirably large enough such that the vulva and the base of the penis are covered by the extended end. The preferred embodiments of the invention have a first diameter for the tube of the device and a second diameter for the means for radially extending, such as an elastic ring wherein the second diameter is larger than the first diameter. Acceptable diameters for the means for radially extending are at least about 50 millimetres and desirably between about 60 and about 75 millimetres. Preferably, the open end of the device is conically shaped and when a tubular protective device having an inner diameter of approximately 50 millimetres is used, the open end, supported by the means for radially stretching, preferably has an inner diameter of approximately 75 millimetres.



Insertion into the vagina of the tubular device of the invention can be done by either the man or the woman. The device can be inserted in the traditional manner by the male partner placing the device over the penis before coitus. The female partner can insert the device with a finger or by means of a insertion probe or applicator.

In order to prevent the tubular protective device from unintentionally slipping out of the vagina once inserted by the female partner has occurred, means for retaining the device in the vagina, ^{is provided, e.g.} ~~such as~~ a circular elastic member or an elastic ring, ~~can be used~~. This member or ring can be connected to the internal or external wall at or near the closed end of the device. After being placed correctly in the vicinity of the uterus, the circular elastic member or an elastic ring is maintained within the vagina in the same manner as a diaphragm.

In order to facilitate insertion of the tubular protective device into the vagina, the closed end of the device can be enclosed by a sheathing which is axially movable relative to the protective device. During the insertion of the protective device into the vagina, the sheathing is moved backwards and, thus it opens for insertion of the closed end of the protective device.



Such a sheathing is not typically present if a means for retaining the device in the vagina such as an elastic ring is present.

Prior to or in connection with the insertion of the tubular protective device, a lubricant is preferably applied to at least the inner side of the device to reduce friction during contact with the penis. If desired, a lubricant can also be applied to the exterior side of the device. Application of a lubricant to the inner side of the tubular protective device can facilitate the insertion of the device into the vagina. Selection of a desirable lubricant can vary greatly. The selection of a lubricant depends in part upon the compatibility of the lubricant with the polymer material used to manufacture the device. Desirable lubricants can include ointments, creams, or water-based mucilages or mucilage-like substances such as cellulose-based lubricants.

The invention will now be described in more detail, by way of example only, with reference to the drawings, in which:

Figure 1 is a three dimensional view of a protective device according to a first embodiment of this invention;

Figure 2 is a three dimensional side view of the protective device of Figure 1;

Figure 3 depicts a second embodiment of protective device according to the invention, in which the ring for the closed end is a separate component;



Figure 4 is a top plan view of a closed end or internal ring for use with the protective device of Figures 1 or 3;

Figure 5 is a three dimensional front view of the protective device of Figure 3 with the closed end or internal ring of Figure 4 inserted therein;

Figure 6 is a three dimensional side view of the protective device of Figure 3 with the closed end or internal ring of Figure 4 inserted therein.

Figure 1 discloses a front view of a thin-walled tubular device 1 having a closed end 2, that is rounded, and a collar 3 that is stretched by an elastic ring 4. At the rounded end 2 of the thin-walled tubular device 1, a second elastic ring 5 is located and held in position by a means for affixing the ring 6. In this figure the means for affixing the ring is a small square of flexible material that is affixed on two of its edges to the thin-walled tubular device 1. In this manner the small square of flexible material is adapted to allow the second elastic ring 5 to pass freely through an open passage between the center of the square of flexible material and the thin-walled tubular device 1 that is covered by the square of flexible material 6. The means for affixing the ring serves to maintain the thin-walled tubular device 1 in the vagina. The thin-walled tubular device of this figure functions as a female condom-like device.



In Figure 1 the tubular element 1 can be enclosed at the closed end by a thin cylindrical sheathing (not shown) which is axially movable in relation to the tubular element 1. However, the tubular protective device does not ordinarily have both a sheathing and a second elastic ring 5 at the same time.

Figure 2 discloses a side view of the thin-walled tubular device 1 of Figure 1. In this figure the structural and spatial arrangement at the closed end 2 of the second ring 5 and the square of flexible material 6 is depicted so as to illustrate the passage through which the second ring 5 is free to move. The second ring 5 in this embodiment is not in a planar position that is parallel to the planar position of the first ring 4. This planar position of the second ring 5 is at an acute angle to the planar position of the first ring 4 in this embodiment because the opening of the uterus is positioned at a similar angle to the vulva.

The diameter of the internal or second ring 5 is typically smaller than the diameter of the first ring 4. The diameter of the second ring 5 can vary to include any size that can adequately retain the closed end 2 in the vagina. In this manner the female condom-like device can be inserted into the vagina and worn for a significant period of time before coitus. Desirable



outer diameters for the second ring 5 are those typically used for diaphragms which are between about 65 millimetres and 80 millimetres.

Figure 4 is a top plan view of the internal of second ring 5 of Figures 1 and 2. In desirable embodiments of the invention the second ring 5 is not attached to the flexible wall of the thin-walled tubular device 1. In such embodiments the thin-walled tubular device of Figure 3 can be provided with, but separately from, the second ring 5. In this manner the invention can be adapted for use either as a male or female condom-like device after its purchase. The thin-walled tubular device 1 can be used as a male condom-like device without a second ring 5. The thin-walled tubular device 1 can be adapted for used as a female condom-like device by inserting the second ring 5 into the closed end 2 of the thin-walled tubular device 1.

Figure 3 discloses a thin-walled tubular device 1 having a closed end 2 that is rounded. At the end of the thin-walled tubular device 1 that is opposite to the closed end 2, the thin-walled tubular device 1 continues into a conically-shaped collar 3 ending in an elastic ring 4. The composition and dimensions of the elastic ring 4 are adapted such that the collar 3 is stretched and maintained in a stretched condition. The flexible material used to form the thin-walled tubular device 1 of this embodiment overlaps or encapsulates the elastic ring 4. The thin-walled tubular device of this figure



functions alone as a male condom-like device.

Figure 5 depicts a front view of the thin-walled tubular device 1 of Figure 3 with the internal or second ring 5 of Figure 4 inserted into the closed end 2. This represents a preferred embodiment of the invention. The second ring 5 is inserted into the closed end 2 by squeezing it to form an oval shape and then inserting the second ring 5 into the thin-walled tubular device 1. When the second ring 5 is released, it regains its circular shape. When the second ring 5 is in place, the thin-walled tubular device 1 can be inserted into the vagina by using the second ring 5 to function in a manner similar to a diaphragm.

Figure 6 depicts a side view of the thin-walled tubular device 1 of Figure 3 with the internal or second ring 5 of Figure 4 inserted into the closed end 2.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A tubular protective device for protection against a transfer of infectious matter during sexual intercourse comprising:

- 5 (a) a flexible, thin-walled tube having a sufficiently large diameter to permit movement of a penis within said tube during coitus, said flexible thin-walled tube having a closed end and an open end, said open end having a means
10 for maintaining said open end in a radially extended condition; and
- (b) means at said closed end of said flexible, thin-walled tube, for retaining said closed end in a vagina of a user.

15 2. The tubular protective device of claim 1, wherein said open end is conically shaped.

3. The tubular protective device according to claim 1 or 2, wherein said flexible, thin-walled tube is a polymer material, said polymer material being selected
20 from the group consisting of latex, polyethylenes, polyurethanes, and derivatives thereof.

4. The tubular protective device according to claim 1, 2 or 3 wherein said means for maintaining said open end in a radially extended condition is an elastic ring
25 integrally connected with said open end.

5. The tubular protective device of any preceding claim, wherein said closed end is enclosed by a sheathing which is axially movable relative to said protective device.

30 6. The tubular protective device of any preceding claim, wherein said means for retaining is an outwardly extending planar ring-shaped means.

7. The tubular protective device of claim 6, wherein said means for retaining is an elastic ring, said elastic
35 ring being removably insertable into said closed end.

8. A tubular protective device according to claim 1, wherein said open end has a collar-shaped, outwardly



extending portion and said means for maintaining said open end in a radially extended condition comprises means for radially stretching said collar-shaped portion having a second diameter larger than said first diameter.

5 9. The tubular protective device of claim 8, wherein said means for radially stretching said open end is an elastic ring.

10 10. The tubular protective device of claim 8 or 9, wherein said means for retaining is an outwardly extending planar ring-shaped means.

11. The tubular protective device of claim 10, wherein said means for retaining is an inner elastic ring, said inner elastic ring being removably insertable into said closed end.

15 12. The tubular protective device of claim 10, further comprising a means for affixing said means for retaining to said flexible, thin-walled tube.

13. A tubular protective device for protection against a transfer of infectious matter during sexual intercourse,
20 said protective device comprising:

(a) a thin-walled, flexible tube having;

- (i) a closed end,
- (ii) an open end, and
- (iii) a first diameter;

25 (b) a collar-shaped outwardly extending means for maintaining said open end in a radially stretched condition, said means having a second diameter wherein said first diameter of said tube is smaller than said second diameter of said means and said first diameter is
30 sufficiently large to permit movement of a penis within said tube during coitus; and

(c) an outwardly extending ring-shaped means at said closed end of said flexible, thin-walled tube for retaining said closed end in a vagina of a user.

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14. The tubular protective device of claim 13, wherein said means for maintaining said open end in a radially stretched condition is an elastic ring.

15. The tubular protective device of claim 14, wherein
5 said outwardly extending planar ring-shaped means is a second elastic ring, said second elastic ring being removably insertable into said closed end.

16. The tubular protective device of claim 15, wherein
10 said second ring is affixed to said flexible, thin-walled tube.

17. A tubular protective device according to claim 13 wherein said ring-shaped means is adapted for radially



stretching said closed end, whereby to retain said closed end in a vagina during coitus.

18. The tubular protective device of claim 16 further comprising a means for affixing said ring-shaped means to said flexible, thin-walled tube.

Dated this 12th day of February, 1992

CHARTEX INTERNATIONAL PLC

By their Patent Attorneys

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FIG. 3

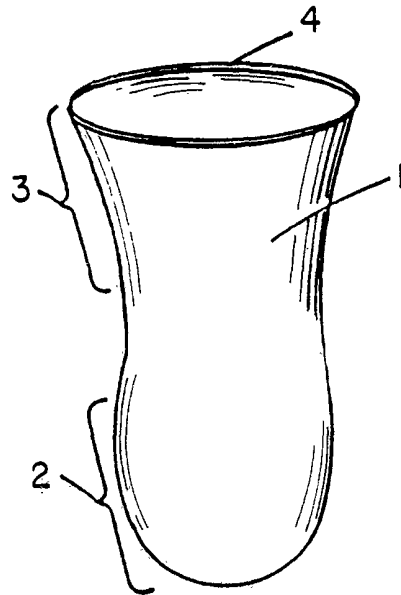


FIG. 1

