Health problem addressed

Couples need protection from sexually transmitted infections (STI) and unintended pregnancy. Women in particular need better protection options since they are more vulnerable to STI/HIV infection and bear the consequences of pregnancy. Many women cannot negotiate safe sex. Female condoms offer alternative protection when men refuse male condom use.

Product description

Product description (350) Woman's condom has a polyurethane pouch, a dissolving capsule made of polyvinyl alcohol, soft foam shapes adhered to the pouch, and an outer ring that keeps the pouch stable and protects the external labia. The device is a single-use device in a foil package. It comes with water-soluble lubricant applied at point of use.

Product functionality

The woman inserts the capsule into her vagina, it dissolves allowing the pouch to unfold. Small foam shapes on the pouch gently cling to the vaginal wall and keep the device from moving during sex. A ring at the open end of the pouch protects the external labia. The device is packaged with water-soluble lubricant applied at point of use.

Developer's claims of product benefits

The Woman's Condom is designed to be easy to handle and insert, stable in the vagina during use, comfortable for both partners, and with good sensation. The slim capsule makes the device easy to insert and holds the pouch discreetly until needed. It comes with lubricant, so the woman can apply the amount of lubricant she and her partner want.

Operating steps

Inserted into the vagina before sex. The Woman's Condom is designed to protect from both pregnancy and STIs. It is removed after sex. It is intended for only one use. The Woman's Condom is packaged unlubricated. User applies lubricant to inside of pouch before sex.

Development stage

The Woman's Condom is at late-stage clinical validation transitioning into early introduction and market development activities. CE Mark approval was granted in December 2010 based on compliance with ISO production standards. A clinical trial was completed in China and a regulatory dossier is under review. Clinical studies underway in the US include a comparative performance and failure mode study and a contraceptive effectiveness study. Production scale-up is underway to increase production and reduce product cost.

Future work and challenges

(1) Develop sustainable supply at a cost that meets price points required by the public sector for large scale procurement. (2) Balance production volume scale-up with private sector market development, as well as social marketing, and public sector programming. (3) Invest in market development, develop alternative distribution networks; invest in promotion/advocacy to effectively reach key market segments. (4) Develop coordinated mechanism for regulatory approvals to increase access. (5) Develop mechanism to aggregate.

Use and maintenance

User: Self-user
Training: Training tools are available from PATH.

Environment of use

Requirements: Female condoms require some coaching and counseling to learn to use comfortably and confidently.

Product specifications

Shelf life: 3 years
Other features: Single-use
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