



Faculty of Sexual & Reproductive Healthcare

New Product Review from the Clinical Effectiveness Unit One size contraceptive diaphragm (Caya®)

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Product summary

Description

- Silicone contraceptive diaphragm
- Contoured with a flexible rim, grip dimples and a removal dome
- Designed to fit most women (approximately 80%)

Mechanism of action

- Barrier method covering the cervix to prevent sperm from reaching the cervical canal
- Manufacturer advises use with an acid buffering lubricant

Efficacy

- Very limited efficacy data available
- Pregnancy rates from 6 months of use with spermicidal gel extrapolated to give an estimated cumulative probability of pregnancy at 12 months of 17.8% and 13.7% with typical and perfect use respectively

Benefits

- Non-hormonal
- Suitable for women or sexual partners with latex allergy or latex sensitivity
- Available to purchase over the counter or online

Administration

- Spermicide should be added to the silicone membrane prior to use and reapplied if in situ for more than 2 hours before intercourse.
- Should stay in situ for at least 6 hours after sexual intercourse but not more than 24 hours continuously

Duration of use

- Each diaphragm can be used as per the manufacturer's instructions, for up to two years after the first use

Disadvantages and contraindications

- Does not protect against HIV and other sexually transmitted infections
- With typical use, barrier methods are less effective than long-acting reversible contraceptives
- Not advised if less than 6 weeks postpartum or if previously used a diaphragm size of 85 mm or larger, or 60 mm or smaller

Cost

- £20.54 (source Durbin: <http://www.durbin.co.uk>). Online prices for personal purchase £30-40

Background

Diaphragms are non-hormonal barrier methods of contraception that protect women against pregnancy by preventing sperm reaching the cervix. A single size contraceptive cap, FemCap, has been available since 2004, but until recently diaphragm products have been made in a range of sizes and designs. As a result women may have been required to try several types of diaphragm during the fitting process.^[1]

What is the Caya® diaphragm?

The Caya® diaphragm is a new barrier contraceptive which comes in one size. Input from women, their partners and providers helped to inform the design of the diaphragm that was originally referred to as the SILCS diaphragm. It is a contoured silicone diaphragm that has a number of features such as a flexible rim, grip dimples to help with insertion and a removal dome to assist removal. A direction arrow on the diaphragm helps guide insertion and should point towards the body when inserting.

A single diaphragm costs £20.54 (costs for women buying online may vary) and is provided in its own case, with illustrated fitting instructions and a user DVD. The diaphragm is designed to fit most women (c.80%).

Figure 1: Image of Caya diaphragm*

Removal dome plus directional arrow for insertion

Flexible rim for stability and to guide insertion

Grip dimples to assist insertion

Cervical cup designed to fit a range of different sized cervixes.

* Reproduced with permission from Kessel Marketing

How should it be used?

The manufacturer has produced instructions on how to use the Caya diaphragm <http://www.caya.eu/assets/downloads-2/anleitung-caya-multilanguage.pdf>. It is advised that approximately 4ml (teaspoon) of an acid buffering lubricant be added to the upper surface of the diaphragm before use. If the diaphragm is inserted more than 2 hours before sex, additional contraceptive gel should be reapplied.

Women should use the grip dimples to squeeze together the rim of the diaphragm for insertion. The diaphragm should be inserted into the vagina and gently pushed along the posterior vaginal wall until the cervix sits inside the diaphragm, with the edge of the removal dome sitting behind the upper part of the pubic bone.

According to the manufacturer's advice, following intercourse, it should remain in situ for at least six hours but should not be kept in situ for longer than 24 hours continuously. However, if there has been sexual intercourse in the last 6 hours, the CEU advises that the diaphragm can be kept in situ more than 24 hours (until at least 6 hours have passed).

A removal dome has been incorporated into the diaphragm to assist removal by providing a site for women to hook their finger under or over.

Following use, the diaphragm should be washed with warm water and non-perfumed soap and left to air dry before placing back in its storage case.

Women are advised to practise inserting and removing the device a couple of times prior to use.

Figure 2: Caya diaphragm using grip dimples to squeeze for insertion[†]



[†] Reproduced with permission from Kessel Marketing

Effectiveness

The effectiveness of the SILCS diaphragm at preventing sperm penetration of mid-cycle cervical mucus was examined in a postcoital crossover study^[2]. A baseline cycle and one test cycle was completed by 14 couples; 8 couples completed three test cycles in addition to a baseline cycle. Two SILCS diaphragms were used during the study; one with a metal spring and one with a polymer spring (Caya®). The diaphragms were tested with use of nonoxinol-9 (N-9) and with a lubricant: following a baseline assessment cycle, women were randomised to receive either N-9 or the lubricant first. The average number of progressively motile sperm per high power field was reduced to 0 with use of a SILCS diaphragm with N-9 compared to 0.5 with lubricant, from a baseline measure of 12.5^[2].

In a multicentre study^[3] designed to estimate the risk of pregnancy associated with the SILCS diaphragm, women were followed up for at least 190 days and six menstrual cycles. Follow-up data was available for 94% of the 450 couples who were randomised to either use the SILCS diaphragm (polymer spring) with either N-9 (150 couples) or with an acid buffering gel (300 couples). A total of 35 pregnancies occurred giving a reported 6-month Kaplan Meier cumulative typical pregnancy probability for both groups combined of 10.4% (95% CI 6.9%-14%). Extrapolated to 12 months, the failure rate was estimated to be 17.8% with typical use and 13.7% with perfect use. The data were presented in a conference abstract^[3]. The CEU is not aware of any further contraceptive efficacy studies.

Size and fit

Among 40 women, the cervix was found to be covered in 39 of those women who were initially assessed with the SILCS diaphragm (metal spring prototype). However, in 10% of women (n=4) the shape of the device was distorted, and in 18% (n=7) there were palpable gaps around the rim^[2]. Amongst the nine women who were additionally fitted with a polymer spring diaphragm, more women following fitting with a SILCS polymer spring experienced palpable gaps compared with the SILCS metal spring. Nine women, who failed screening with the metal spring SILCS diaphragm, were asked to undergo additional fitting with the polymer spring device; improvements were observed in terms of fitting. Postcoital results showed that in the majority of women, the device covered the cervix. However, gaps were observed in 19% and 13% of the cycles for the metal spring and polymer spring groups respectively^[2].

To assess the in vivo fit of the SILCS (polymer spring) diaphragm, a pilot study was undertaken using magnetic resonance imaging in six women within different body mass index categories^[4]. For each category (<25, 25-30 or >30) there were 2 women - one of whom was nulliparous and one of whom was multiparous. The diaphragm was found to cover the cervix in all women and simulated sexual intercourse for a period of 2 minutes did not appear to affect the position of the diaphragm. The study was limited by the small number of women included. The study included a teaching element prior to attending for imaging, which may have helped ensure appropriate placement and therefore may need to be considered for any women requesting this diaphragm.

Correct placement of the SILCS diaphragm (polymer spring) was found to be more difficult on the first insertion attempt compared to first insertion of an Ortho ALL- FLEX diaphragm^[5].

Materials from the company report that 80% of participants achieve a good fit on first insertion and that this increases to 98% with additional coaching^[6].

Acceptability

In a small comparative study^[5] of twenty couples randomly assigned to either use the Ortho ALL-FLEX diaphragm or the SILCS diaphragm (polymer spring). Following instruction on its use, practice and assessment of correct insertion, placement and removal, couple evaluation was undertaken. Questionnaires administered after first use and then after a fourth use were used to assess experience. Couples then used the alternative device for the same number of episodes of intercourse and similarly completed questionnaires. There appeared to be little difference between the devices in terms of awareness of the device and device sensation^[5]. Compared to the SILCS diaphragm, men appeared more likely to report their awareness of the Ortho diaphragm as bothersome (13% vs. 25%) and a slightly higher proportion of men, reported pain or discomfort. No p-values were noted. When asked at the end of the study to express their overall preference, men and women appeared to prefer the SILCS diaphragm^[5].

In a small non-randomised, non-blinded, multi-site pilot study of 41 couples from South Africa and Thailand, 80% of women and 60% of men reported good comfort and sensation with use of the product. During sex, men reported awareness of the SILCS diaphragm in 62% of uses. However generally this did not appear to affect their sexual experience. The study findings were again limited by the small sample size and selection bias.

Benefits

A potential advantage of this method is that it is non-hormonal which may be preferable to some women. As it is made of silicone, the Caya diaphragm is suitable for women with a latex allergy or latex sensitivity.

Disadvantages

A potential limitation of the device is that with typical use its effectiveness is less than other methods, which are not as dependent on the user. Even with perfect use, the efficacy rates are lower than most other methods of contraception. Caya is available over the counter provision meaning that it does not necessarily require fitting by a health professional. In Germany, where the Caya diaphragm is available and provided over the counter, a study designed to explore preliminary consumer and provider experience reported that of the 121 who responded, 70% of women did not visit a healthcare provider to correct the position or fit of the diaphragm.

Contraindications

Listed contraindications to use include women who have previously used a diaphragm size of 85mm and larger or 60mm and smaller. As per the United

Kingdom Medical Eligibility Criteria for Contraceptive Use (UKMEC)^[7] and the manufacturer's instructions, it is not advised that women use diaphragms prior to six weeks postpartum. UKMEC would also suggest that in women who have a history of toxic shock syndrome the theoretical or proven risks of using a diaphragm are considered to outweigh the advantages of using this method (UKMEC 3). The diaphragm cannot be used in certain cases of prolapse.

Cost

The Caya diaphragm costs £20.54 compared with other diaphragms listed in the British National Formulary^[8] which cost between £6-9.

What does the Caya diaphragm add to the range of contraceptives already available?

The Caya diaphragm provides women with further contraceptive choice. There is insufficient evidence to compare efficacy with other barrier methods.

From the limited data, it appears to be well accepted and relatively easy to use. It is designed with several features to help aid insertion and removal and the cervical cup is said to fit a wide range of cervixes. The main benefit would be that it can be offered without fitting. However, the single size will not be suitable for all women and some women may still require assistance from a health professional to ensure correct fitting prior to use. It is not clear from the product information or scientific literature how a woman would recognise that the Caya diaphragm is the wrong size, incorrectly fitted or how frequently this is unrecognised when a woman chooses to fit a Caya diaphragm without the assistance of a healthcare provider.

Reference List

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