

WOS DIAPHRAGMS AND CAPS GUIDELINE

What's New

Gygel (nonoxyl-9 spermicide) has been discontinued

Introduction

Caps and diaphragms create a physical barrier to sperm and hold spermicide close to the cervical os. Sperm do not survive in the vagina for more than 6 hours

Efficacy

Percentage of women experiencing an unintended pregnancy within the first year of use of barrier contraceptive methods¹

Device	Annual Failure Rate	
	Typical use	Perfect use
Diaphragms (with spermicide cream or jelly) excluding Caya®*	12%	6% (range 4.3 to 8.4%)
Caya® (pregnancy rates from 6 months of use with spermicidal gel extrapolated to give estimated probability of pregnancy at 12 months)	17.8%	13.7%
Femcap®*	13%	7.7-11.2% ⁵
Male condom*	18%	2%
Internal condom*	21%	5%

*in the USA

Choice of device:

Diaphragm

- Devices inserted into the vagina to lie diagonally across the cervix and vaginal vault and much of the anterior vaginal wall.
- All currently available products are made of silicone
- Singa® is a dome shaped silicone diaphragm with a nylon spring (sizes 55-95mm (in 5mm increments)
- Caya® is a one size silicone contraceptive device with a polymer spring designed to fit 80% of women with a flexible rim, grip dimples and a removal dome.

Cap

A cap fits onto the cervix to create a barrier to sperm trying to enter the cervix FemCap which is silicone, is the only currently available cervical cap.

There are 3 sizes:

22mm: for clients who have never been pregnant

26mm: for clients who have been pregnant but not delivered vaginally

30mm: for clients with at least one vaginal delivery

Spermicide

Diaphragms and Caps should be used with spermicide .Nonoxyl-9 spermicides are no longer recommended as they can cause vaginal irritation increasing the risk of STI acquisition. Current spermicidal gels products are acid buffering gels, which are thought to have similar efficacy and better tolerability. The manufacturer of Caya® advises use with an acid buffering lubricant, Caya® Gel which contains lactic acid, sodium lactate, cellulose and sorbic acid which acts by reducing the motility of sperm cells (the acidic gel creates a hostile environment inside the vagina) and creating an additional physical barrier in front of the cervix (cellulose is a gel forming agent). Other brands are available such as Contragel (contains Water Lactic Acid Sodium Lactate (dairy-free) Methyl Cellulose Sorbic Acid Vanillum) ⁸

Spermicides are class IIa medical devices

NB VCF contraceptive film is a nonoxynol-9 containing product from the USA that can be bought on line in the UK

User Acceptability

Variable and discontinuation rates can be high. Advantages

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- non hormonal
- no serious side effects
- use is under the user's control
- silicone is suitable for clients or sexual partners with latex allergy or latex sensitivity
- only need to be inserted prior to intercourse and retained for 6 hours afterwards
- Caya® and Femcap® are available to purchase over the counter or on line. They come with illustrated fitting instructions.

Perceived disadvantages:

- messiness
- problems with insertion / removal
- irritation from spermicide
- lack of sexual spontaneity
- patients should initially be assessed for type and correct size of Singa diaphragm by a trained health professional. Size may need changed after pregnancy
- No good evidence of protection against HIV/STI or CIN. As only the cervix is covered by these methods, they do not prevent exposure of the vaginal mucosa to semen or exposure of the penis to cervico-vaginal secretions.

Drug Interactions

Silicone diaphragms/caps are unaffected by oil-based lubricants but the manufacturer of Caya® and Singa advises only water based lubricants should be used

Assessment Of Client Suitability

In this context the history should include: relevant social and sexual history (to assess risk of sexually transmitted infections – STIs), the importance attached to avoiding pregnancy and willingness to insert the device.

Prolapse, small or absent retropubic recess The diaphragm may not fit adequately with a prolapse or small /absent retropubic recess but a cap is suitable. Caya's manufacturer states Caya cannot be used with severe pelvic floor or uterine descent.

Caya's manufacturer does not recommend its use in people who previously used a diaphragm size of 85mm and larger, or 60mm and smaller.

Acute frequent bladder infections. Diaphragm use has been linked to urinary tract infection. A diaphragm should be chosen that will ensure a correct fit but which does not put undue pressure on or obstruct the urethra.

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Toxic Shock Syndrome . The CEU Clinical Effectiveness Unit consider menstruation a contraindication to diaphragm use. The manufacturer of the Caya® diaphragm report it is safe to use during menstruation

Postpartum use Manufacturer advice re earliest post-partum fitting;
Caya, Singa: 6 weeks; Femcap: 10 weeks

There is no evidence that nonoxynol-9 is teratogenic. Its use in lactation has not been studied.

Examination

Pelvic examination is required to identify the appropriate size and type of Singa diaphragm

Caya is one-size. Femcap size is based on parity

Clients may wish help ensuring they have fitted the device correctly

Fitting of Singa® Diaphragm

- Diaphragms should initially be fitted by a competent health professional
- Diaphragms should be positioned so that the rim fits comfortably and not too loosely or tightly into the vaginal fornices. Ideally the anterior rim should sit in the groove behind the pubic bone.
- Clients need to be competent at removing the diaphragm before they leave the clinic
- Clients should also be given the opportunity to insert the device themselves at the clinic
- The method cannot be relied upon for contraception until the client has returned and demonstrated confidence in its use

Advice to clients on Diaphragm and Cap Use

- Clients need to read the manufacturer's instructions that come with the device

Spermicide use

Singa: two strips of spermicide ~2cm long to upperside of the diaphragm. A little spermicide on the leading rim can make inserting easier.

Caya: 4 mls of spermicide (a teaspoonful) into the silicone membrane and some

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spread around the external rim, prior to inserting into the vagina

Femcap: ¼ teaspoon spermicide in the bowl, and ½ teaspoon in the groove, then spread all over the cap except where the thumb and finger will be holding it for insertion.

Apply more spermicide (as a pessary or as cream using an applicator) if sex is to take place > 3hrs (caya – 2 hours) since device was inserted or if sex is repeated whilst method in place

Timing of insertion

Singa/Caya can be inserted at any time with spermicide before sex and must remain in place for at least 6 hours after the last episode of sex.

Femcap should be placed at least 15 minutes before sexual arousal.

Timing of removal

A diaphragm/cap must be left in place for at least 6 hours after the last episode of sex but not left longer than the recommended time:

Singa & Caya 24 hours

Femcap: 48 hours

The CEU advise that a device can be kept in until at least six hours has passed even if this means it will be in place for more than 24 hours.

Care of diaphragms and caps

- wash the device after use in warm water with mild, unperfumed soap and dry with a soft clean cloth
- Store device in its container in a cool dry place.
- Advise regularly checking the diaphragm/cap for signs of damage or perishing

Emergency Contraception may be indicated in the following situations

- Diaphragm or cap is dislodged or removed within 6 hours of sex
- Diaphragm has been left in for longer than 3 hours before sex and no additional spermicide applied
- Discuss the advance provision of oral emergency contraception

Documentation

- The client's record should be completed or updated on NaSH.

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- Name and size of the diaphragm provided
- Written method information given to patient
- Permission should be sought as to whether the client's GP can be notified.
- After insertion the client must always check that the cervix is covered and if not the diaphragm should be removed and an attempt made at reinsertion

Water can wash away spermicide so if bathing after insertion, opt for a shower rather than bath.

Follow up visits

- Diaphragms/caps should not be relied upon for contraception until the client is confident about use.
- Caya and Femcap are intended to be used without clinical assessment so follow up is client led

Clients using Singa must return for a check

Clients being followed up should be asked to return with the diaphragm/cap in situ. The client should be examined to ensure they have been able to insert it correctly.

Also ensure the client is:

- comfortable using the method including during intercourse and be able to check the position before and after intercourse to recognise if it is correctly positioned
- is tolerant to the use of spermicide

Advise the client to return:

- if they have any problem with the use of their diaphragm (such as discomfort with use, pain, vaginal discharge or urinary tract infection)
- if their weight alters by 3kg or more
- after full term delivery
- after any unplanned pregnancy regardless of outcome to assess possible reasons for method failure
- after vaginal surgery

Replacement of device

- Singa® diaphragm should not be used for longer than 2 years
- Caya® diaphragm should not be used for longer than 2 years.

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- Femcap should be replaced every year
- Replace sooner if signs of deterioration, cracks or holes

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