

Adapted from West of Scotland Protocol

Diaphragm Guideline

This guideline covers diaphragms only. For information on female condoms please refer to the Condoms protocol.

What's New:

Women using a diaphragm or cap should be aware that there is little evidence that these methods reduce the risk of HIV/STI transfer or the development of CIN.

Added informative video on how to insert Caya® Diaphragm:
<https://www.youtube.com/watch?v=-reMvb4SAvs>

Devices:

Diaphragm

- Inserted into the vagina to lie diagonally across the cervix, vaginal vault and much of the anterior vaginal wall.
- Available in latex or silicone in different sizes from 55-95mm (in 5mm increments)
Which can be:
 - Flat spring (most commonly used)
 - Coiled spring (some women find it more comfortable as softer)
 - Arching (may be required if the position of the cervix makes other types easy to fit)
- Also available the Caya® a contoured, silicone single size diaphragm is designed to fit a broad range of women. **It is stocked in Sandyford and should be fitted for women in the first instance.**
 - It costs £22.59 (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%). Caya®Gel is also available. It is a contraceptive gel which is being promoted for use with Caya®, other diaphragms, caps and condoms. It is based on lactic acid (not from nonoxynol-9).
- Used with spermicide (nonoxynol-9, GYGEL)

Cervical caps

These are not stocked at Sandyford.

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Effectiveness in preventing pregnancy and the transmission of STIs and BBV

Percentage of women experiencing an unintended pregnancy within the first year of use of barrier contraceptive methods in the USA

Device	Failure Rate	
	Typical use	Perfect use
Diaphragms (with spermicide cream or jelly)	12%	6% (range 4.3 to 8.4%)
Male condom	18%	2%
Female condom	21%	5%

In a study in the UK comparing the contraceptive cap to the diaphragm it was found to be less effective at preventing pregnancy. The unadjusted typical use probability of pregnancy at 6 months use was 13.5% for contraceptive cap users compared to 7.9% for diaphragm users. When used consistently, correctly and with spermicide, diaphragms and cervical caps are estimated to be between 92-96% effective at preventing pregnancy.

User Acceptability

Variable and discontinuation rates can be high.

Advantages

- No serious side effects
- Their use is under the woman's control
- They need to be inserted prior to intercourse and retained for 6 hours afterwards

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 diaphragm or cervical cap by a trained health professional

Medical Eligibility for Diaphragm and Cervical Cap Use

Women wishing to use this method and who have no contraindications to its use (see UKMEC <https://www.fsrh.org/documents/ukmec-2016>) Updated September 2019.

There are no conditions which represent unacceptable health risk if diaphragms or caps are used (WHOMEK 4). There are some medical conditions for which the theoretical or proven risks usually outweigh the advantages of using the method (WHOMEK 3).

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Not suitable:

- first 6 weeks post-partum - diaphragms and caps
- Cervical Intraepithelial Neoplasia (CIN) or cervical neoplasia and women with markedly distorted cervical anatomy - caps
- Certain cases of prolapse - diaphragm

Nonoxynol-9 is not considered to be teratogenic. Its use in lactating women has not been studied.

Spermicide should no longer be applied to the lower surface of the diaphragm (apply to the upper surface and leading rim)

Diaphragms and cervical caps with the concurrent use of spermicide present a physical and chemical barrier to prevent sperm reaching the cervix.

Side Effects

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.

The risk of Toxic Shock Syndrome in menstruating women using diaphragms and caps may be increased. They should not be used during menstruation and should not be left in situ longer than is recommended by the manufacturer.

Drug Interactions

Oil based lubricants (such as baby oil, petroleum jelly) and oil based vaginal creams and pessaries can damage latex and may increase the risk of failure. Non-oil based lubricants are recommended. Silicone diaphragms and caps are unaffected by oil-based lubricants. The manufacturer of Caya advise the use of water based lubricants.

Type and Choice of diaphragms and caps

Latex and Silicone Diaphragms

- Caya® silicone single size diaphragm. **It is stocked in Sandyford and should be fitted for women in the first instance.**
- Reflexions® flat spring diaphragm range, manufactured by Williams Medical, has been discontinued in the UK since 2015.

Silicone Cervical caps

- Femcap® is currently the only cap available in the UK. It is made in 22, 26 and 30mm sizes.
- Women with poor muscle tone or prolapse may find that a cap fits better than a diaphragm.

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Assessment of Client Suitability

History

- Clinical history taking and examination allow an assessment of medical eligibility for diaphragm use.
- Diaphragms are not suitable for women less than 6 weeks post-partum.
- There is no evidence that nonoxynol-9 is teratogenic. Its use in lactation has not been studied. Consider medical eligibility as above.

Examination

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

Fitting of Diaphragm (excluding Caya)

- 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.

Instructions to clients for Diaphragm Use

- Clients need to read the manufacturer's instructions that come with the diaphragm.
- With clean hands **two strips** of spermicide about **2cm long** should be applied to the **upper side of the diaphragm**. A little spermicide on the leading rim can make inserting easier.
- A diaphragm 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**.
- More spermicide will need to be applied (as a pessary or as cream using an applicator) **if sex is to take place and > 3hrs has lapsed** since diaphragm was inserted or if sex is **repeated** whilst method in place.
- The diaphragm must be **left in place for at least 6 hours after the last episode of sex** but do not leave it longer than the recommended time (see individual manufacturer's instructions). In general for latex diaphragms the **maximum time is 30hrs**.
- 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 a bath.
- Wash the diaphragm in warm water with mild, unperfumed soap and allow to air dry. Store in its container in a cool dry place.
- Regularly check the diaphragm for tears, holes or cracks.

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Caya® Diaphragm

- After the first use, each Caya® diaphragm should not be used for a period longer than 2 years.
- 4 mls of spermicide (a teaspoonful) should be placed into the silicone membrane (and some gel spread around the external rim) prior to inserting into the vagina and reapplied if in situ for more than 2 hours before intercourse
- The Caya® diaphragm has to remain in the vagina for 6 hours after intercourse
- The Caya® diaphragm should not be worn for longer than 24 hours continuously. The CEU advice is if there has been intercourse in the last 6 hours, Caya® 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.
- If repeated consecutive intercourse is planned, the Caya® diaphragm can remain in position, but additional contraceptive gel with the aid of an applicator should be applied
- The manufacturer of the Caya® diaphragm report it is safe to use during menstruation (the CEU Clinical Effectiveness Unit consider menstruation a contraindication to diaphragm use)
- The use of water-based lubricants (e.g. Sylk) has no influence on the use and safety of the Caya diaphragm.
- Patients' should be advised to watch the following video on how to insert Caya® diaphragm: <https://www.youtube.com/watch?v=-reMvb4SAvs>

Documentation

- The client's record should be completed or updated as required.
- Name of chaperone (if present) should be recorded.
- Name and size of the diaphragm or cap provided
- Written method information given to patient
- Permission should be sought as to whether the client's GP can be notified.

Follow up visits

Diaphragms should not be relied upon for contraception until the client has returned and demonstrated confidence in its use.

Clients should be asked to return with the diaphragm in situ. The woman should be examined to ensure she has been able to insert it correctly.

Also ensure the woman 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

Discuss the potential need for emergency contraception. This may be indicated in the following situations (not exhaustive list):

- Diaphragm or cap is dislodged or removed within 6 hrs of sex
- Diaphragm or cap is has been left in for longer than 3 hrs before sex and no additional spermicide applied.

Discuss the advance provision of oral emergency contraception.

Advise the client to regularly check the diaphragm for any signs of damage or perishing.

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Advise the client to contact Sandyford:

- 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
- if there are signs of damage or perishing of the diaphragm. (There is currently not recommendation for frequency of follow up/replacement of diaphragms)

References

Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit FSRH Guidance (August 2012, updated October 2015) Barrier Methods for Contraception and STI Prevention <http://www.fsrh.org/pdfs/CEUGuidanceBarrierMethodsAug12.pdf> [accessed December 2021]

Faculty of Sexual and Reproductive Health Care New Product Review from the Clinical Effectiveness Unit One size contraceptive diaphragm (Caya®) <http://www.fsrh.org/pdfs/NewProductReviewCaya.pdf> [accessed December 2021]

<http://www.caya.eu/en/> [accessed December 2021]