DIAPHRAGMS AND CERVICAL CAPS

What’s new

Caya® a single size contraceptive barrier designed to fit a broad range of women, is now available for use in the United Kingdom.

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%). 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).

What’s New and Main Changes

This 2012 protocol replaces the 2011 Diaphragms, Cervical Caps and Contraceptive Vaginal Sponges Protocol. Contraceptive vaginal sponges are no longer available in the UK.

Failure rates are reported are now based on those presented in the new 2012 FSRH Clinical Effectiveness Unit Guideline on Barriers Methods for Contraception and STI (Sexually Transmitted Infection) Prevention

The cap is no longer advised for use in women with Cervical Intraepithelial Neoplasia (CIN), cervical neoplasia or markedly distorted cervical anatomy. The diaphragm cannot be used in certain cases of prolapse (see Medical Eligibility Criteria)

There are some changes to the types and choice of diaphragms and caps, see section ‘The Type and Choice of Diaphragms and Silicone Caps’

Diaphragms and caps are not suitable for use in the first 6 weeks post partum.

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.

**Devices:**

**Diaphragm**
- Latex rubber or silicone devices inserted into the vagina to lie diagonally across the cervix, vaginal vault and much of the anterior vaginal wall.
- Used with spermicide (nonoxynol-9, GYGEL)

**Cervical caps**
- Silicone devices that are inserted into the vagina to cover the cervix.
- Held in place by suction.
- Used with spermicide (nonoxynol-9, GYGEL)

**EFFECTIVENESS IN PREVENTING PREGNANCY AND THE TRANSMISSION OF STIs AND BLOOD BORNE VIRUSES**

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Failure Rate</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Typical use</td>
</tr>
<tr>
<td>Diaphragms (with spermicide cream or jelly)</td>
<td>12%</td>
</tr>
<tr>
<td>Male condom</td>
<td>18%</td>
</tr>
<tr>
<td>Female condom</td>
<td>21%</td>
</tr>
</tbody>
</table>

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.

There is little evidence that diaphragms and caps reduce the transmission of HIV and STI transmission.

BARRIER METHODS OF CONTRACEPTION CEG DECEMBER 2015
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

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>UKMEC category</th>
<th>Additional Comments</th>
</tr>
</thead>
</table>

BARRIER METHODS OF CONTRACEPTION CEG DECEMBER 2015
<table>
<thead>
<tr>
<th>High risk of HIV/AIDS</th>
<th>3</th>
<th>Little is known about the effectiveness of diaphragms in preventing the sexual acquisition of HIV. It is recommended that they are used with spermicide and the main spermicide available in the U.K. is nonoxynol-9. Epithelial disruption in the vagina and rectum has identified with nonoxynol-9 use in humans and animal models. Repeated and high dose use of nonoxynol-9 is associated with increased risk of genital lesions which may increase the risk of HIV acquisition. An alternative spermicide is available to buy in the UK does not contain nonoxynol-9. However the UKMEC recommendation for women at high risk remains unchanged. There are currently no clinical data relating to this product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV infected (with or without the use of antiretroviral therapy)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>AIDS (using antiretrovirals)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>History of Toxic Shock Syndrome (TSS)</td>
<td>3</td>
<td>The risk of TSS in non menstrual women using diaphragms and caps and sponges is increased</td>
</tr>
<tr>
<td>Sensitivity to latex proteins in client or sexual partner</td>
<td>3</td>
<td><strong>Silicone</strong> diaphragms, silicone cervical caps and polyurethane sponges can be used by women who themselves, or whose partners, have sensitivity to latex proteins</td>
</tr>
</tbody>
</table>

The cap should not be used in women with Cervical Intraepithelial Neoplasia (CIN) or cervical neoplasia and is not appropriate for women with markedly distorted cervical anatomy.

The diaphragm cannot be used in certain cases of prolapse.
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.

Type and Choice of diaphragms and caps

Latex and Silicone Diaphragms
- Available in different sizes from 55-95mm (in 5mm increments).
- Flat spring diaphragms tend to be the most commonly used. Some women find a coil spring diaphragm more comfortable because it is softer. Arching diaphragms may be required if the position of the cervix makes the other types more difficult to fit.

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.

Assessment Of Client Suitability

History

Clinical history taking and examination allow an assessment of medical eligibility for diaphragm and cap use.

Diaphragms and caps 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.
West of Scotland Protocol Approved September 2012

Examination

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

Fitting of Diaphragm and Cervical caps

- Diaphragms and caps 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 or cap 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 manufacturers 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 anytime 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 that the recommended time (see individual manufactures instructions). In general for latex diagrams 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.
West of Scotland Protocol

- 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

Instructions for Cervical Silicone Cap Use

- Clients need to read the manufacturers instructions that come with their cap
- With clean hands one third of the cap should be filled with spermicide. Spermicide should not be put around the rim as this can stop the cap from staying in place (some caps have a groove between the dome and rim for spermicide)
- A cap 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 the cap was inserted or if sex is repeated whilst method in place
- The cap 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 manufactures instructions). The silicone cap can remain in situ for up to 48hrs.
- After insertion the client must always check that the cervix is covered and if not the cap 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 cap in warm water with mild, unperfumed soap and allow to air dry. Store in its container in a cool dry place
- Regularly check the cap for tears, holes or cracks

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 and caps 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 or cervical cap 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 or cap for any signs of damage or perishing

Advise the client to return:

- if they have any problem with the use of their diaphragm or cap (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 or cap. (There is currently not recommendation for frequency of follow up/replacement of cap/diaphragms)
References
Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit FSRH Guidance (August 2012) Barrier Methods for Contraception and STI Prevention [accessed 5th September 2012]
