

Singa[®]
Diaphragm

Guidelines for healthcare professionals



Medintim

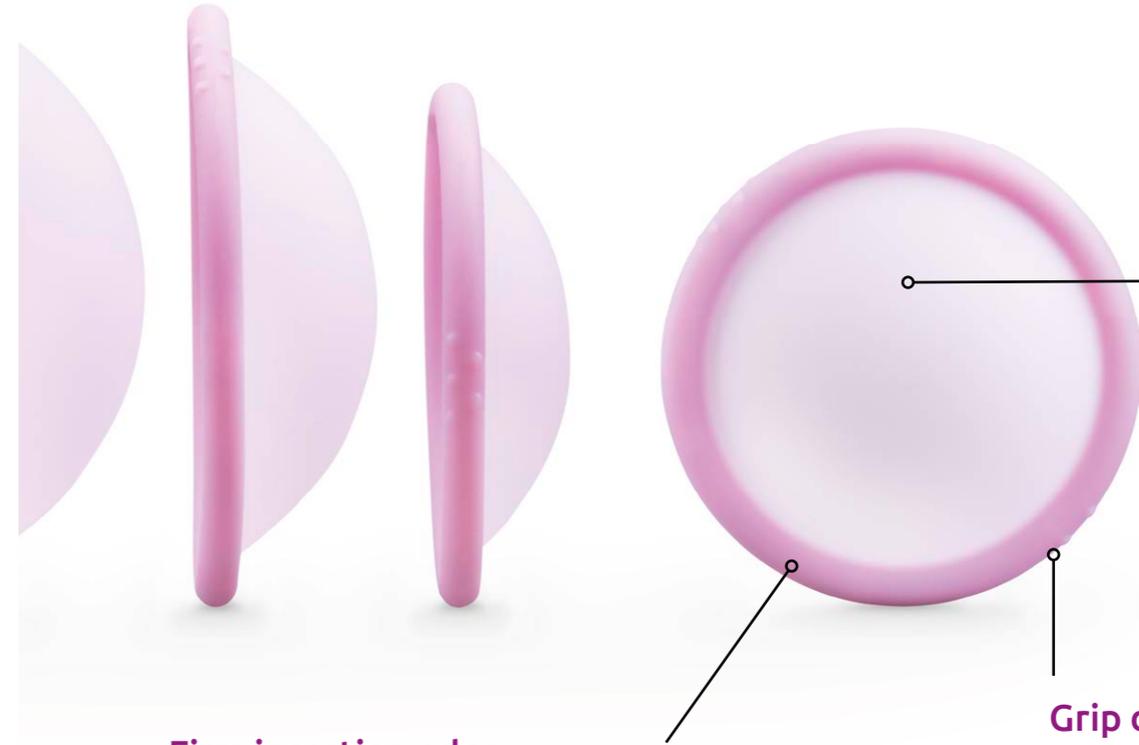
Product features and specifications

- elastic body: medical-grade silicone
- traditional, round shape with polymer spring
- available sizes: 60 mm, 65 mm, 70 mm, 75 mm, 80 mm, 85 mm and 90 mm outer diameter
- box for safe storage



Labelling

- shows product name and size of the diaphragm



Firm insertion edge

- folds compactly for easy insertion
- stable shape during insertion
- supports cervical cup in posterior fornix

Cervical cup

- sized to fit a range of cervical positions
- surrounds the cervix

Grip dimples (nubs)

- cue for where to hold and squeeze the diaphragm
- provides enhanced grip when slippery

Singa® diaphragm – traditional shape in different sizes

The Singa® is a traditional round diaphragm in seven different sizes from 60 – 90 mm diameter. The innovative Caya® contoured diaphragm already covers most sizes and needs of female users.

However, there are women for whom the Caya® contoured diaphragm is not suitable. These are women:

- who need a diaphragm with a diameter smaller than 65 mm.
- who need a larger diaphragm with a diameter of 85 mm or 90 mm,

for example after multiple vaginal deliveries.

- who need a slightly firmer tension of the spring.

All these users of a diaphragm usually need a fitting exam of the correct individual size. Therefore, healthcare providers should be able to check the correct fit. Determining the size of a contraceptive diaphragm is usually not included in the clinical training and education of healthcare providers. This guideline attempts to close this gap.

Pregnancy probabilities for the Singa® diaphragm

- There are few older studies on traditional round diaphragms and their contraceptive effectiveness.
- The most recent studies on contraceptive diaphragms were conducted with the Caya® contoured diaphragm.¹ The Caya® is comparable in its safety and effectiveness to traditional round diaphragms.

- Pregnancy probabilities for 12 months of optimal (correct and consistent) use and typical use of the diaphragm are²:

optimal use	typical use
5* – 6**	17**

¹ Schwartz JL, Weiner DH, Lai JJ, et al. Contraceptive efficacy, safety, fit, and acceptability of a single-size diaphragm developed with end-user input. *Obstet Gynecol.* 2015 Apr;125(4):895-903.

² Barnhart KT, Rosenberg MJ, MacKay HT, et al. Contraceptive efficacy of a novel spermicidal microbicide used with a diaphragm. *Obstet Gynecol.* 2007 Oct;110(3):577-586.

* Diaphragm used together with buffering gel. Mechanism of action comparable to Caya® diaphragm gel.

** Diaphragm used together with Gynol II®

Who can use the Singa® diaphragm?

Nearly all women can use a Singa® diaphragm safely and effectively.

It is particularly appropriate for women who:

- want a user-initiated non-hormonal contraceptive method.
- cannot use hormonal contraception for medical reasons (e.g., risk of thrombosis).
- cannot (or do not want to) use an intrauterine device.
- want a method that can be used while breastfeeding.
- are at least six weeks post childbirth or six weeks after a second trimester abortion or miscarriage.
- have a latex allergy (e.g., cannot use latex male condoms).
- want an eco-friendly and economical method of contraception.
- prefer a method that extends the time between two pregnancies (so-called “spacing”)

The Singa® diaphragm may be particularly appropriate for women:

- whose partner will not use male condoms as a barrier method.
- who want a user-initiated birth control method that does not affect fertility and does not interfere with menstrual bleeding.
- who are concerned about potential side effects or health consequences of other contraceptive methods.
- who use a natural family planning method (e.g., symptothermal method) and prefer to use the diaphragm rather than abstaining during their fertile days.
- who use a non-hormonal method of contraception while breastfeeding.
- who do not want to use a long acting method.

Absolute contraindications

The Singa® diaphragm cannot be used if a woman:

- is within the first six weeks after childbirth (a medical check-up is recommended).
- is within the first six weeks after a second trimester abortion or miscarriage.
- has a small or absent pubic recess (notch).
- has poor or absent pelvic floor muscle tone.
- has a pronounced cystocele (bladder prolapse), uterine prolapse or rectocele.
- has an acute urinary tract infection.
- has an acute infection of the genital organs and/or minor pelvis.
- has a history of toxic shock syndrome (TSS) (very rare).
- has a known allergy to sorbic acid/sorbate (component of the Caya® Gel) (very rare).

Relative contraindications

The Singa® diaphragm may not be appropriate if a woman:

- is not comfortable or able to insert, confirm fit and remove the diaphragm (includes psychological, somatic or physical difficulties).
- has no basic understanding of her female anatomy (labia, introitus vaginae, cervix, pubic bone).
- is at risk of HIV infection or has acquired HIV (Singa® diaphragm does not protect against HIV).
- has a history of recurring urinary tract infections.
- has retroversion or retroflexion of the uterus (seldom).

Instructions for medical staff

Medical history:

- Take a brief patient history to rule out any contraindications (see above).

Counsel the woman about how the Singa® diaphragm works and how to use it:

The Singa® diaphragm is a contraceptive barrier device inserted into the vagina before sexual intercourse to reduce the risk of unwanted pregnancy.

It covers the cervix to prevent sperm from entering the uterus. It must be worn during and at least 6 hours after sexual intercourse. Then it is removed and washed.

- The Singa® diaphragm must be used in combination with a diaphragm gel (e.g., Caya® Gel).

- Each time after inserting the Singa® diaphragm, the woman should check that her cervix is covered by the silicone membrane.
- If she is not confident the diaphragm is covering her cervix, she should remove the Singa® and try again.
- Sometimes standing with one leg raised makes insertion easier or squatting down can bring the cervix closer to the introitus vaginae.
- The woman should continue wearing the Singa® diaphragm for at least six hours after sexual intercourse.
- Removing the diaphragm before six hours may reduce the effectiveness.
- The woman should not wear the diaphragm for more than 24 hours without removing it.

- Wearing the diaphragm for longer than 24 hours may increase the growth of bacteria that could lead to Toxic Shock Syndrome (TSS) – a rare but serious illness.

Diaphragm users should be aware of the symptoms of TSS:

- sudden onset of high fever (39°C or more)
 - nausea, vomiting and/or diarrhoea
 - dizziness; skin rash (similar to a sunburn)
 - weakness, fatigue, muscle and/or joint pain
 - red eyes
 - sore throat
-
- If a woman experiences these symptoms, she should remove the diaphragm and contact her healthcare provider immediately.

- If the woman has repeated acts of sexual intercourse, additional diaphragm gel can be inserted into the vagina using an applicator (do not remove the diaphragm).
- After use, wash the Singa® diaphragm with water and a mild soap. It can be dried using a cloth or air dried. For intensive cleaning purposes, it can also be rinsed off with boiling water (in general not necessary).
- Each time the woman uses the Singa® diaphragm, she should check to ensure no tears or holes are found. If a defect is found, replace the Singa® diaphragm.
- The Singa® diaphragm can be used for up to two years; beyond that, it should be replaced.

How to determine that the Singa[®] diaphragm is correctly inserted



1.

Give the woman an opportunity to empty her bladder and bowel before the fitting exam.

Have her wash hands afterwards since she will also insert, check fit, and remove the Singa® during this fitting.

You can use a Singa® diaphragm clinic sample for that.

This will be sent to you free of charge on request by the manufacturer or one of its distributors.

The Singa® diaphragms for fitting are sealed and single-packed. They have a hole in the membrane and must be disposed of after fitting.

Important:

Please do not give a sample diaphragm with hole to the woman.

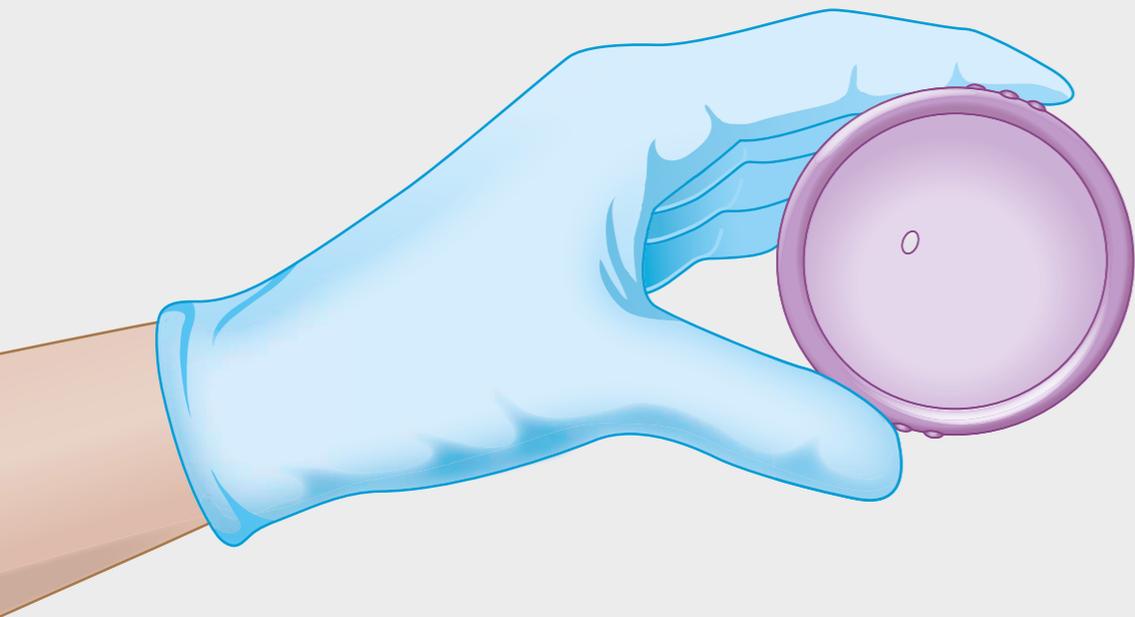
Before fitting, wash the diaphragm with water and soap.



2.

Carry out a preliminary gynaecological examination on your patient.

Palpate the patient's cervix and retropubic recess. Check for any anatomical changes, e.g., pronounced uterine prolapse, cystocele (see above: absolute contraindications).



Insertion
of the Singa®
diaphragm

3.1

Hold the Singa® diaphragm between your thumb and index finger at the grip dimples on the side of the diaphragm. Show the woman how to hold the diaphragm correctly.

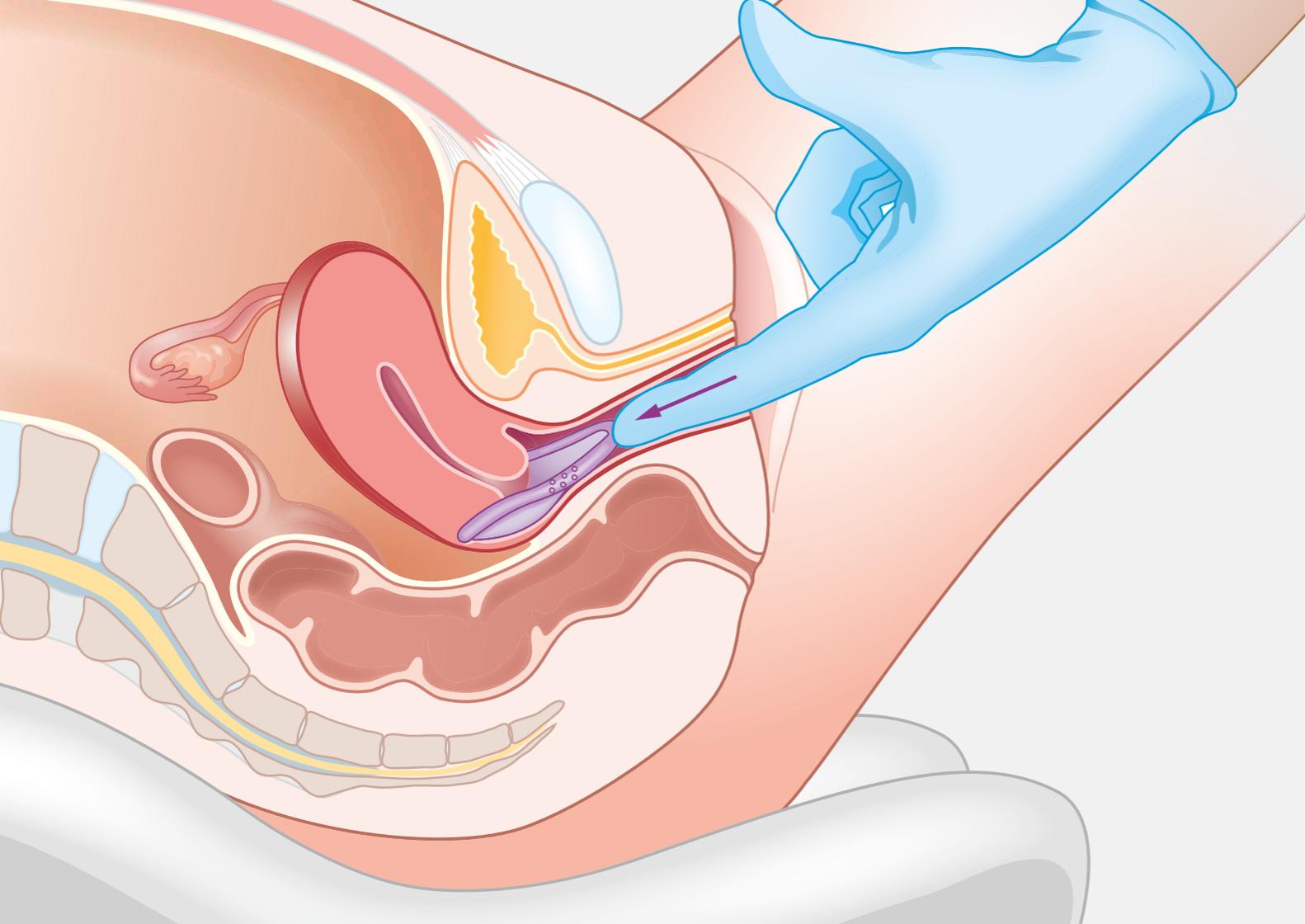


3.2

Squeeze the sides of the Singa[®] diaphragm together as shown in the illustration. Now apply some diaphragm gel into the two resulting membrane indentations.

Approx. 4 ml of gel is sufficient (equivalent to approx. one teaspoon). Extra gel may be applied to the leading edge of the diaphragm to help with insertion.

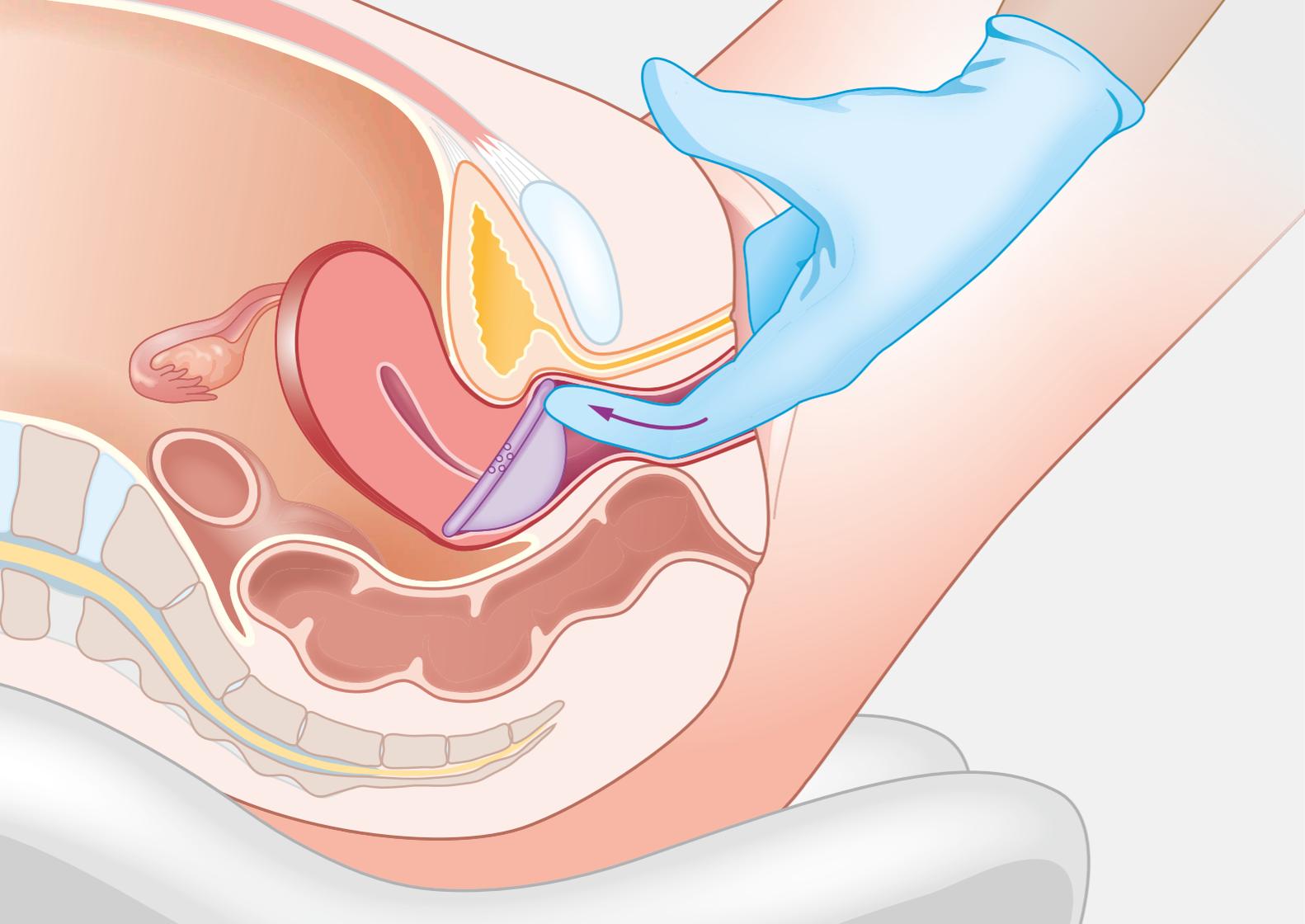
Show your patient the correct way to apply the gel.



3.3

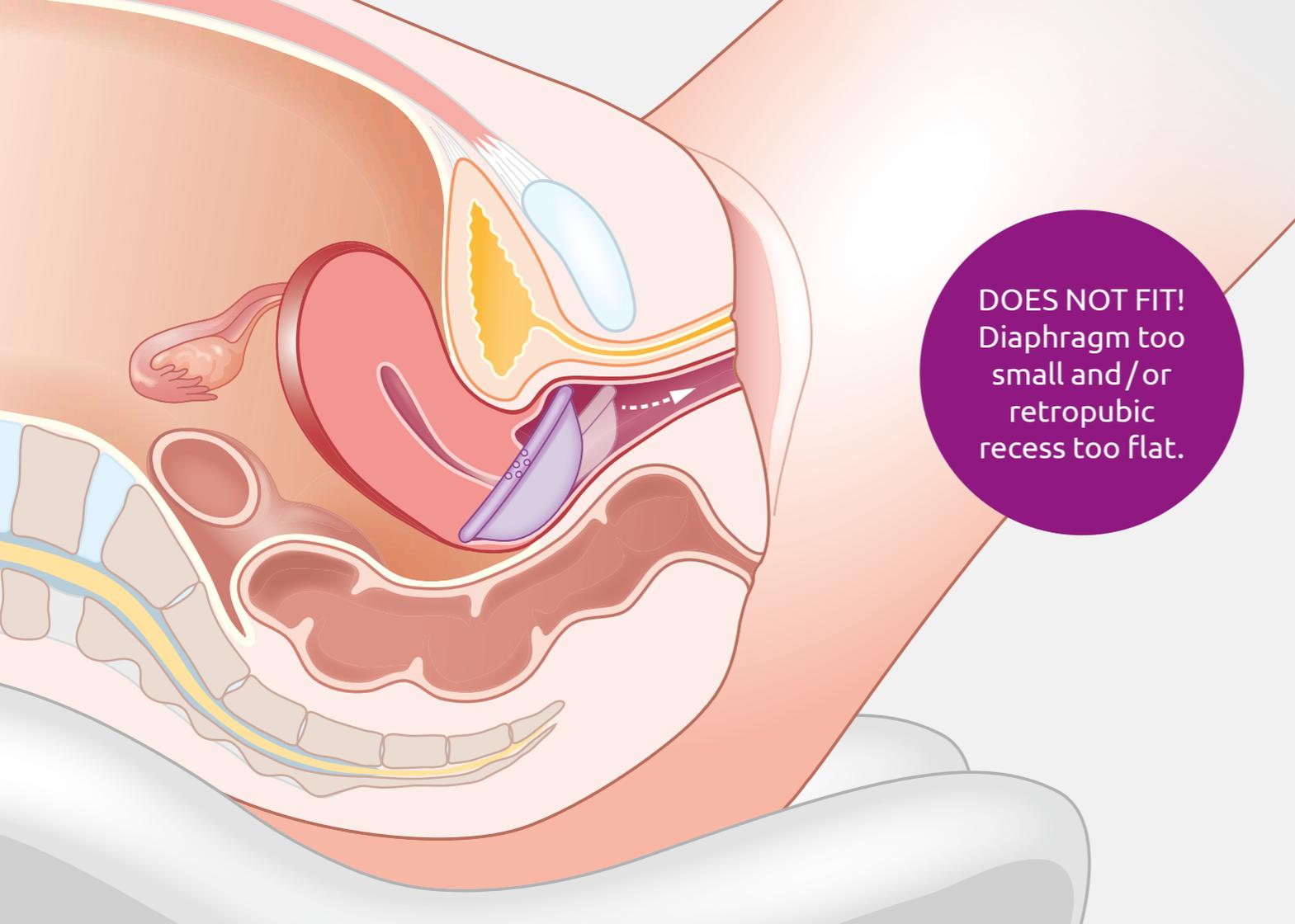
With one hand holding the Singa® in the folded position, open the labia with the other hand. While keeping the Singa® folded, insert the diaphragm as deeply as possible. Push down so the diaphragm slides along the posterior vaginal wall toward the tail bone.

You will need to shift your hand position as the diaphragm is inserted, so eventually your finger will push on the anterior edge of the Singa® as you push it into place. The cervical cup should be covering the cervix.



3.4

Now push the anterior edge up behind the pubic bone / pubic notch.



DOES NOT FIT!
Diaphragm too small and/or retropubic recess too flat.

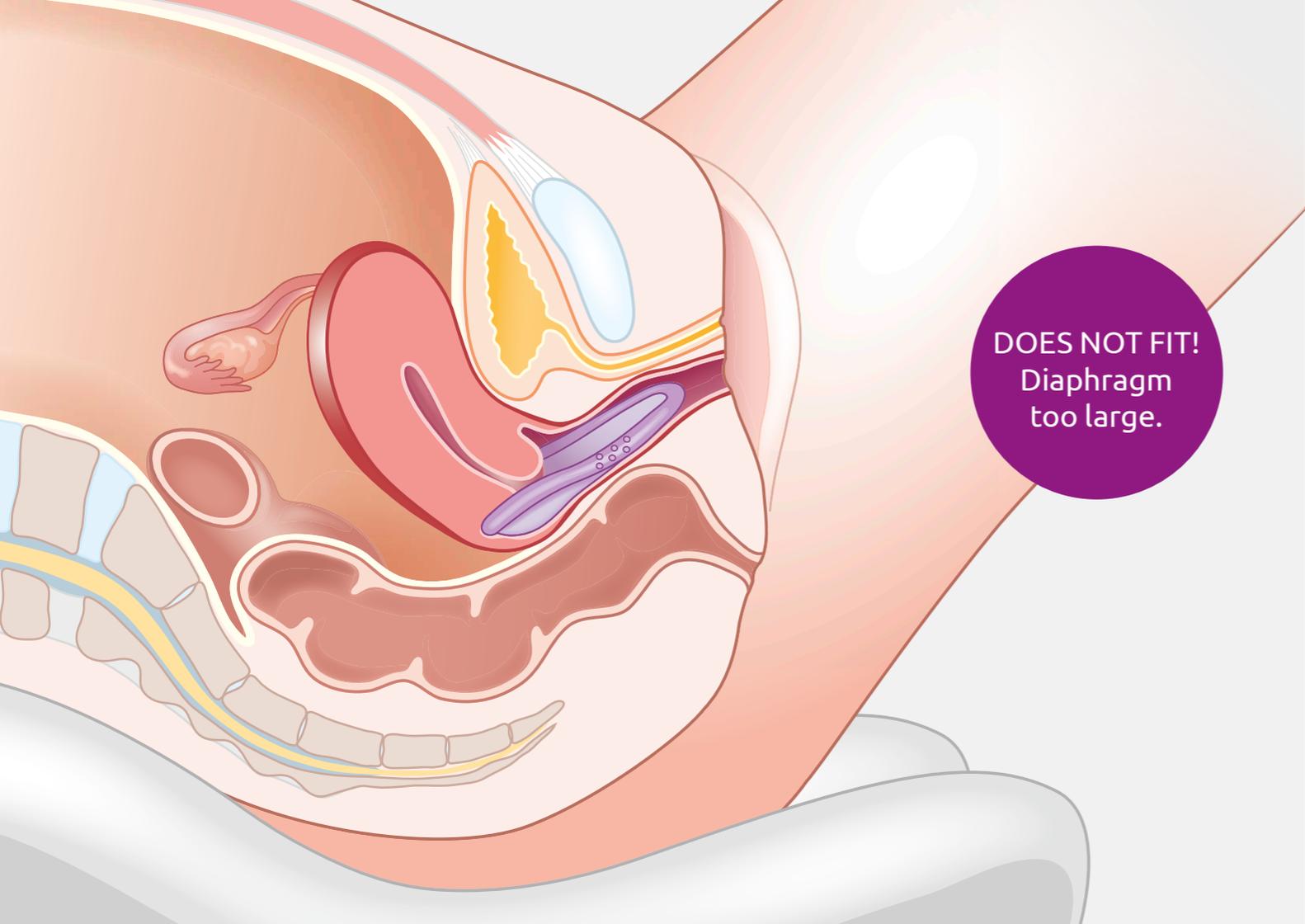
4.1

The Singa[®] diaphragm should lie diagonally between the posterior fornix and the pubic notch (or recess). The cervix should be covered by the cervical cup.

If the diaphragm is too small, the membrane of the diaphragm may not cover the cervix even after the Singa[®] is fully inserted.

If the pubic notch is too flat or shallow, the anterior edge of the diaphragm may not stay secure along the anterior vaginal wall.

If the size tried is too small, try inserting the next larger size until you find the right size for the woman.



DOES NOT FIT!
Diaphragm
too large.

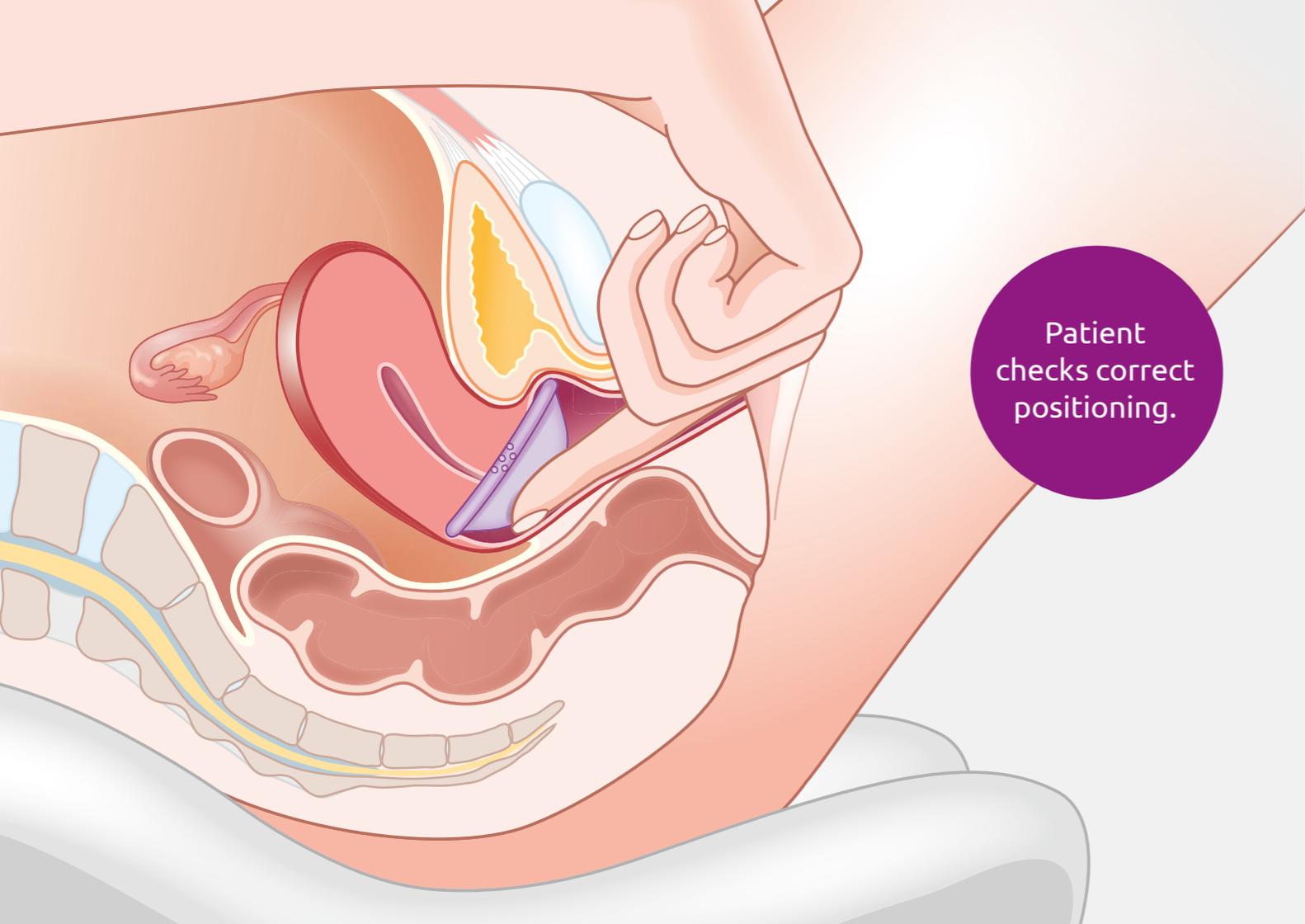
4.2

If the Singa® diaphragm is too large, it will not be able to be inserted comfortably. The woman will feel the anterior edge of the diaphragm at the introitus. The fit will not be secure and it could slip out.

Ask the woman to stand up and move around to get the Singa® situated. If the woman experiences uncomfort-

able pressure on the urethra or rectum or feels the Singa® is uncomfortable, the device may be too large for her.

If the size tried is too large, try inserting the next smaller size until you find the right size for the woman.



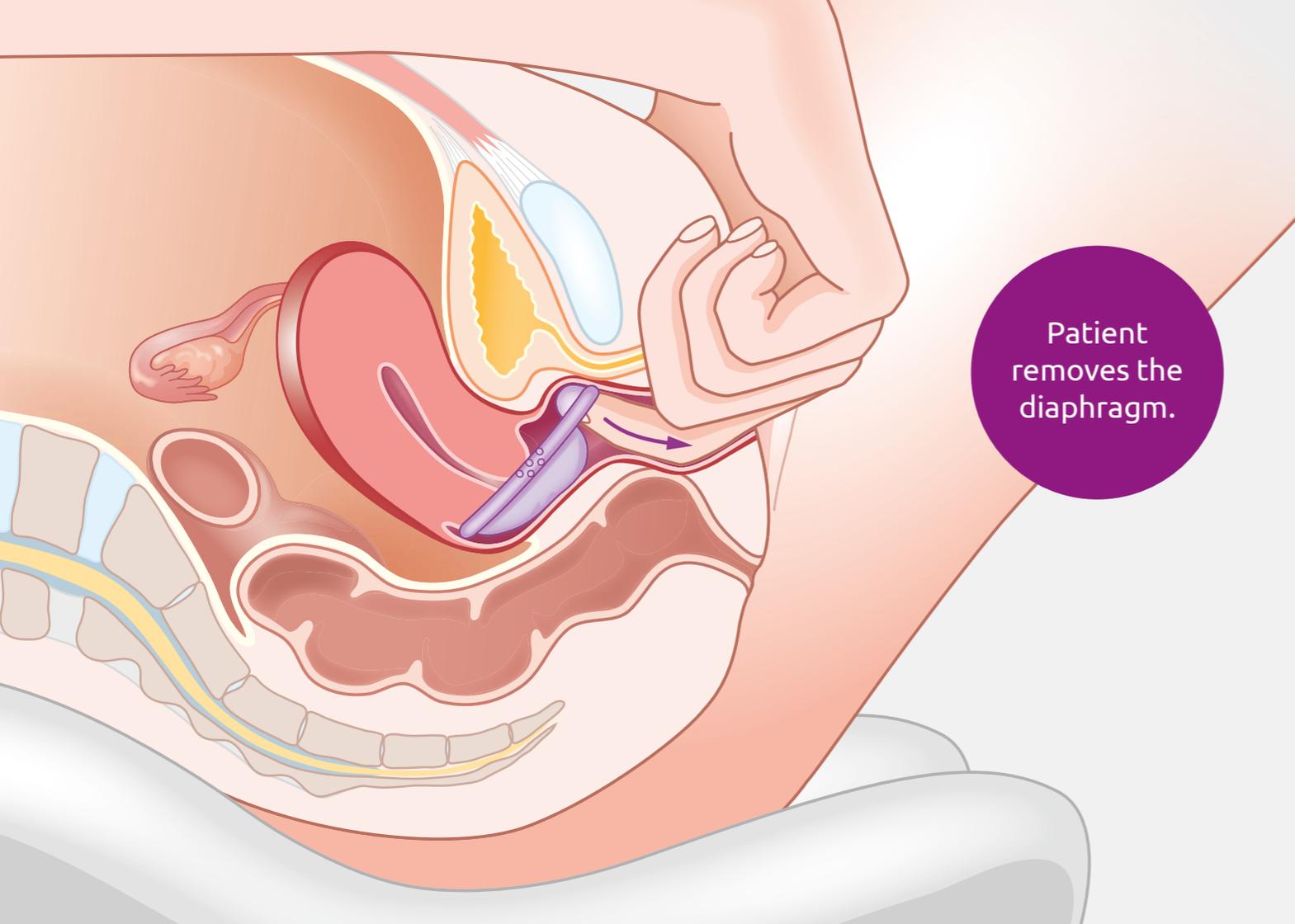
Patient
checks correct
positioning.

5.

Have the woman check fit and placement of the Singa®.

Once she has done this, have her remove the Singa® and practice inserting, confirming fit and removing on her own.

If she has difficulty using one position, counsel her to try a different position.

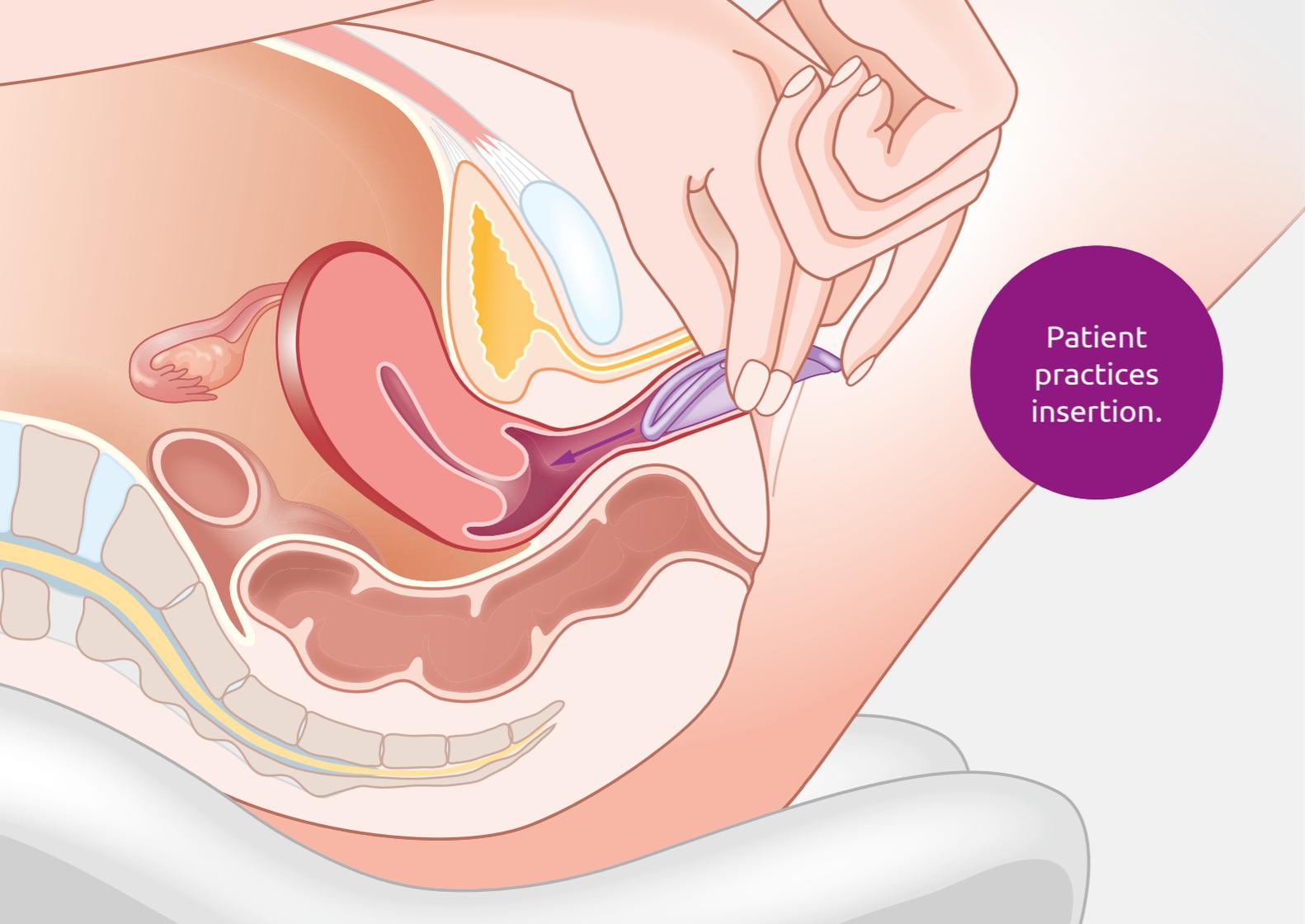


6.

The woman should feel the rim of the Singa® diaphragm.

Once she has put her finger over the rim, she pulls down and out to remove the diaphragm.

If she has difficulty removing the diaphragm, encourage her to try a different position (e.g., squatting or one foot on a stool to open the pelvis and bring the cervix closer to the introitus).



Patient practices insertion.

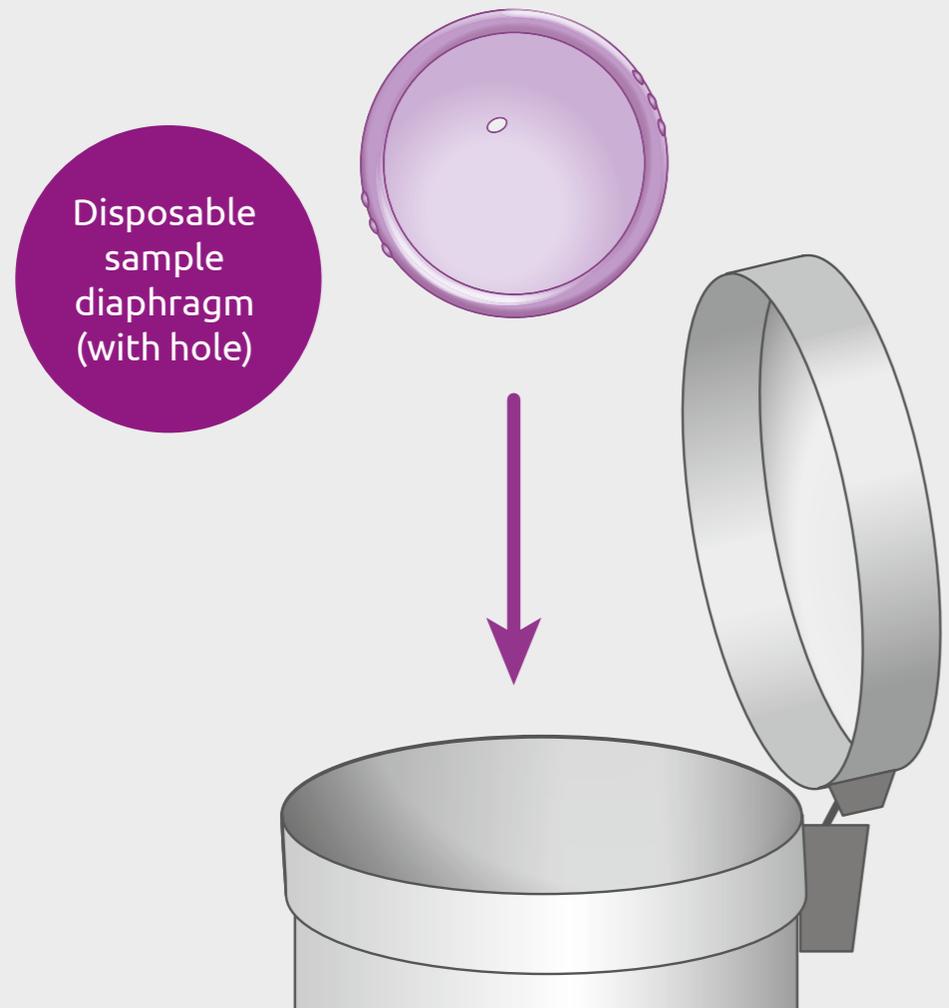
7.

The woman should practice handling, inserting and checking correct placement of the Singa® on her own. Then she should practice removal. You should encourage the woman to use what ever insertion position is most comfortable and easy for her.

The woman should walk around for a few moments after inserting the Singa® (the Singa® will settle more firmly into position as the woman moves).

The woman should use what ever position is most comfortable/easy for removal of the diaphragm. If she has difficulty with that, squatting and “bearing down” as if having a bowel movement will move the cervix closer to the introitus and may help.

Before the woman leaves the clinic, you should be sure that she can insert, check position and remove the diaphragm.



8.

After ensuring the woman understands how to insert, check fit and remove the Singa®, dispose of the Singa® sample diaphragm (with a hole). This sample diaphragm is intended for single-person use and must not be given to the patient. Finally, ask your patient to wash her hands thoroughly again.

Depending on protocol at your clinic you can encourage the woman to return two weeks later – wearing the diaphragm – to have the fit and correct placement checked after she has practiced at home.

The woman should be encouraged to contact her healthcare provider if she has any questions or concerns about using the Singa® diaphragm.

9. Final instructions

Counsel the woman to practice insertion, wearing, and removal several times before using it during intercourse.

Providers also may recommend to come back about two weeks later wearing the diaphragm, so the provider can check and confirm fit again.

This depends on the clinic protocol and also on the provider and client

confidence about fit of the Singa[®] diaphragm. The woman should be encouraged to contact her healthcare provider at any time if she has questions or concerns.

If she thinks the diaphragm may have been dislodged during sexual intercourse or that she may not have been protected, she should contact her provider for Emergency Contraception (“the morning-after-pill”).

Where to get the Singa[®] diaphragm

- The Singa[®] diaphragm is a medical device freely available. In most countries Singa[®] is an over-the-counter-product. In a few countries (France and USA) diaphragms are only available by prescription.
- Reminder: The Singa[®] diaphragm is recommended to be used in combination with a diaphragm gel (e.g., Caya[®] Gel, if it is available or other type of diaphragm gel available in your market).

Medintim