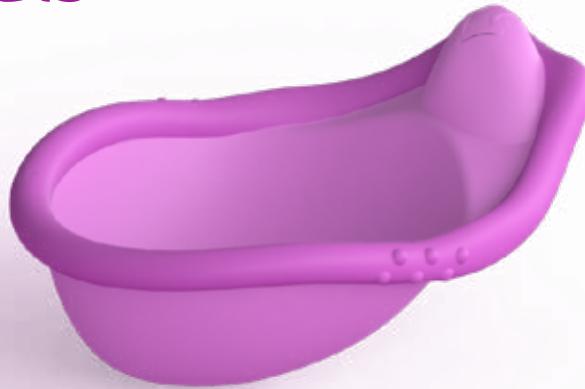


Caya[®]

Guidelines for healthcare professionals



Medintim

Pregnancy probabilities for the Caya® contoured diaphragm

- In clinical studies, the Caya® diaphragm has been shown to provide contraceptive protection similar to the traditional, sized diaphragms.¹
- 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®

The Caya® contoured diaphragm is an innovative single-size design that fits most women.

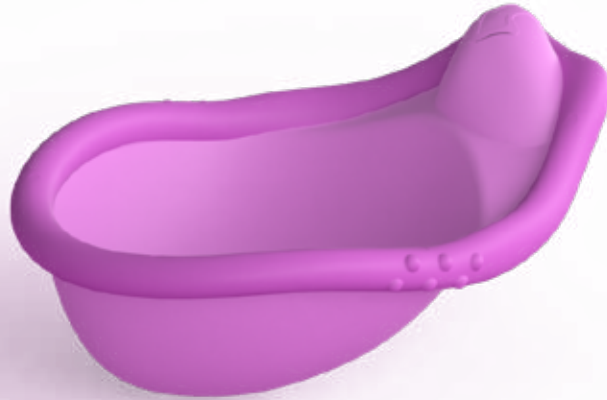
In the contraceptive effectiveness study that led to regulatory approval, more than 75% of women were able to insert, correctly position, and remove the device on the first attempt after reading the instructions. With coaching from the provider and up to three attempts, almost all women (94%) could insert, correctly position, and remove the device.

When clinicians assessed fit, they determined that Caya could fit almost all the women in the study (97.6%).¹

Although most women will not need a fitting exam for the Caya® diaphragm, healthcare professionals will want to know how to assess correct fit in case women have difficulty confirming fit of the diaphragm themselves. For women who have problems determining the correct fit themselves or need assistance due to their individual anatomy, this guideline might be helpful.

Product features and specifications

- elastic body: medical-grade silicone
- core: contoured, one-piece polymer spring
- overall length: 75 mm
- overall width: 67 mm



removal dome

- enables easy hooking for removal
- enhanced insertion and positioning in anterior pubic bone

firm insertion edge

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

cervical cup

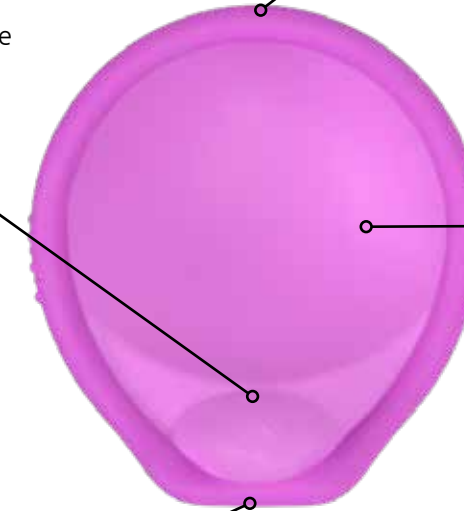
- sized to fit a range of cervical positions
- surrounds the cervix

grip dimples (nubs)

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

relief arch

- avoids excessive pressure on urethra



Who can use the Caya® diaphragm

Nearly all women can use a Caya® 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 child-birth, or 6 weeks after a second trimester abortion or miscarriage.
- have a latex allergy (e.g., cannot use latex male condoms).
- have given birth and are planning another child.
- want an eco-friendly and economical method of contraception.

The Caya® 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 which 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 lactational amenorrhea as postnatal contraception and want additional protection.
- who do not want to use a long acting method.

Absolute contraindications

The Caya® diaphragm cannot be used if a woman:

- has previously used a small (60 mm) or large (85 mm, 90 mm) traditional sized diaphragm.
- 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 (very rare).

Relative contraindications

The Caya® 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 (Caya® diaphragm does not protect against HIV).
- has history of recurring urinary tract infections.
- has retroversion or retroflexion of the uterus (seldom).

Instructions for providers

Medical history

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

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

The Caya® diaphragm is a contraceptive barrier device inserted into the vagina before sex to reduce the risk of unwanted pregnancy. It covers the cervix to prevent sperm from entering the uterus. It must be worn during sex, and at least 6 hours after sex. Then it is removed and washed.

- The Caya® diaphragm must be used in combination with a contraceptive gel
- The Caya® diaphragm can be inserted anytime before sex begins.
- Each time after inserting the Caya® diaphragm, the woman should check that her cervix is covered by the diaphragm dome.
- If she is not confident the diaphragm is covering her cervix, she should remove the Caya® and try again. Sometimes standing with one leg raised makes insertion easier, or squatting down can bring the cervix closer to the introits vaginae.

- The woman should continue wearing the Caya® diaphragm for at least six hours after sex. 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 diarrhea
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 contraceptive gel should be inserted into the vagina using the applicator (do not remove the diaphragm).
- After use, wash the Caya® diaphragm using 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 Caya® diaphragm, she should check to ensure no tears or holes are found. If a defect is found, replace the Caya® diaphragm.
- The Caya® diaphragm can be used for up to two years; beyond that, it should be replaced.
- Let women know more information is available at www.caya.us.com (video and detailed instructions etc.).

How to determine that the Caya® diaphragm is correctly inserted



1.

Give the woman an opportunity to empty her bladder and bowel before the fit exam. Have her wash hands afterward since she will also insert, check fit, and remove the Caya during this fitting.

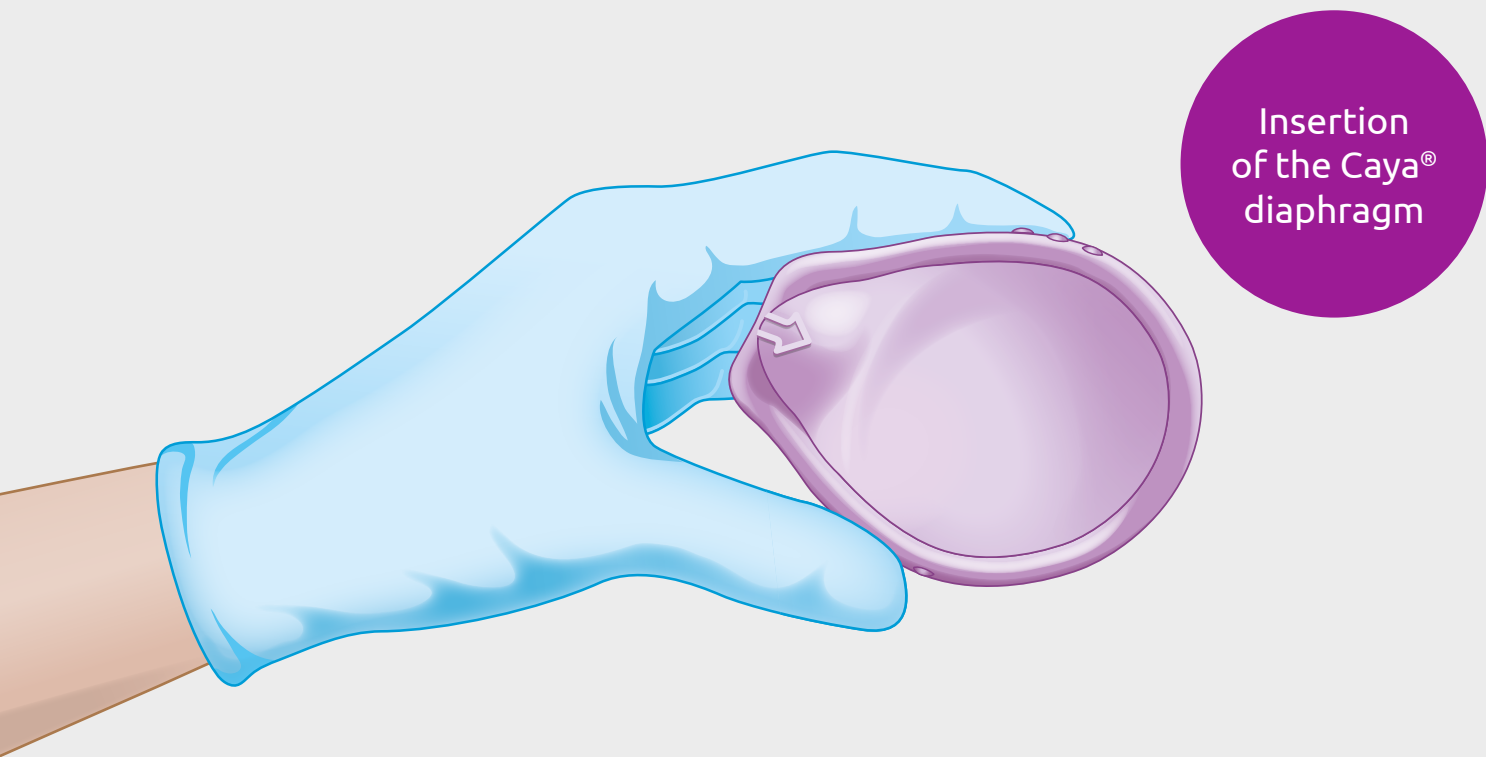
You can use either a clinic sample Caya diaphragm (sealed package, intended for single-client, clinic-use only) or the woman's own Caya® diaphragm if she has brought this. Wash the diaphragm with water and soap.



2.

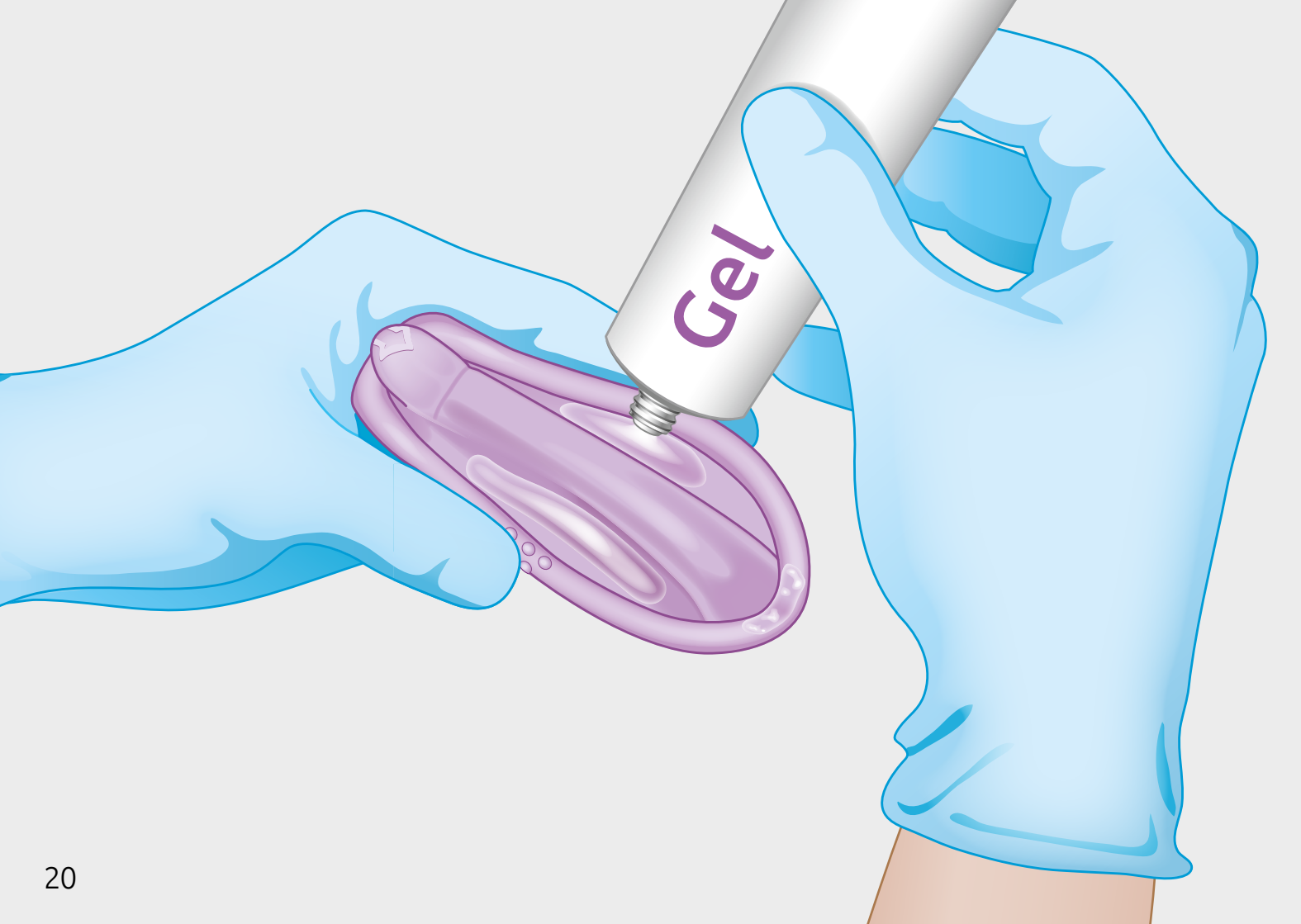
Carry out a preliminary gynecological examination on your patient.

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



3.1

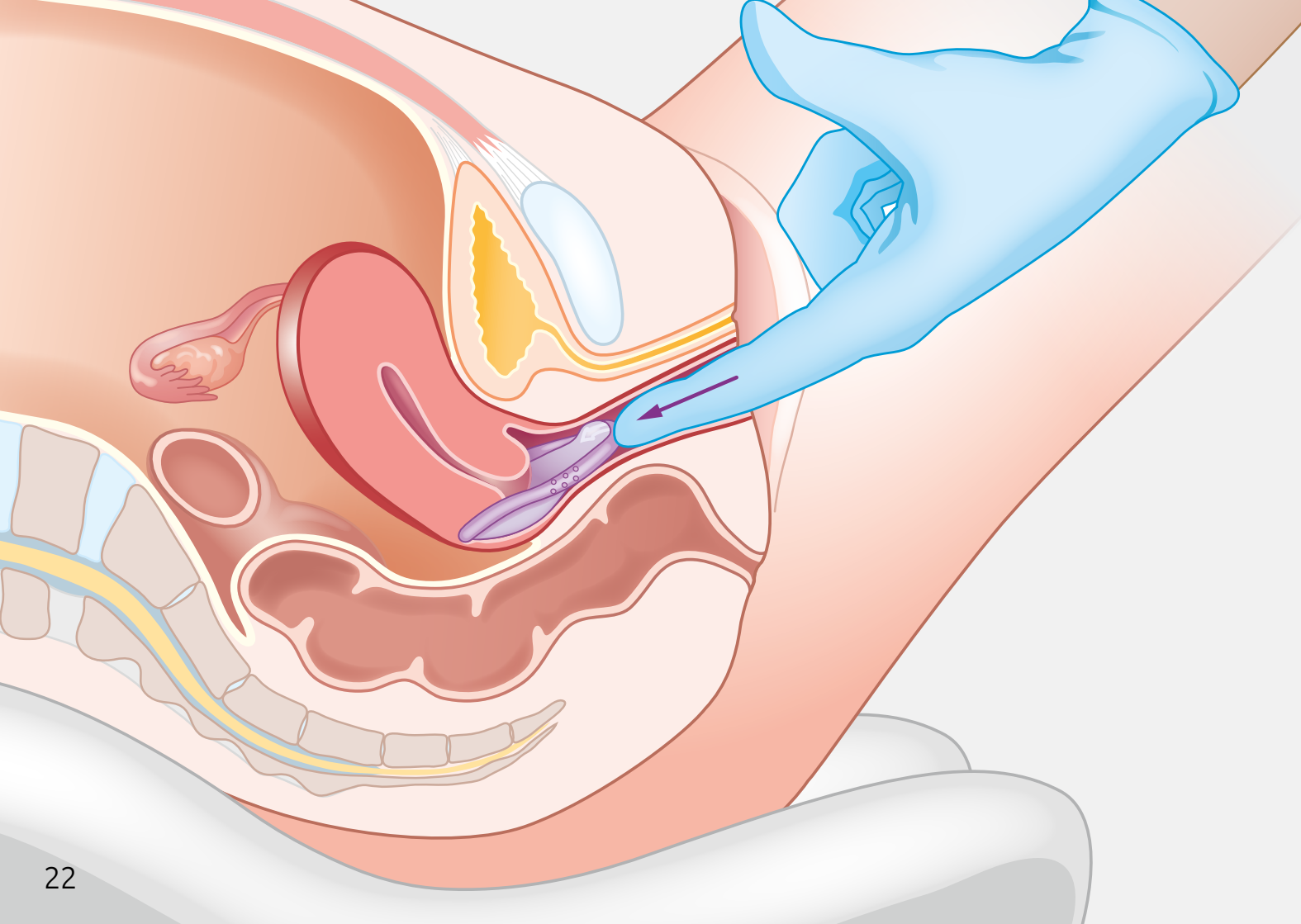
Hold the Caya® diaphragm between your thumb and index finger on the grip dimples on the side of the diaphragm. The arrow on top of the removal dome must be pointing in the direction of the cervix. Show your patient how to hold the diaphragm correctly.



3.2

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

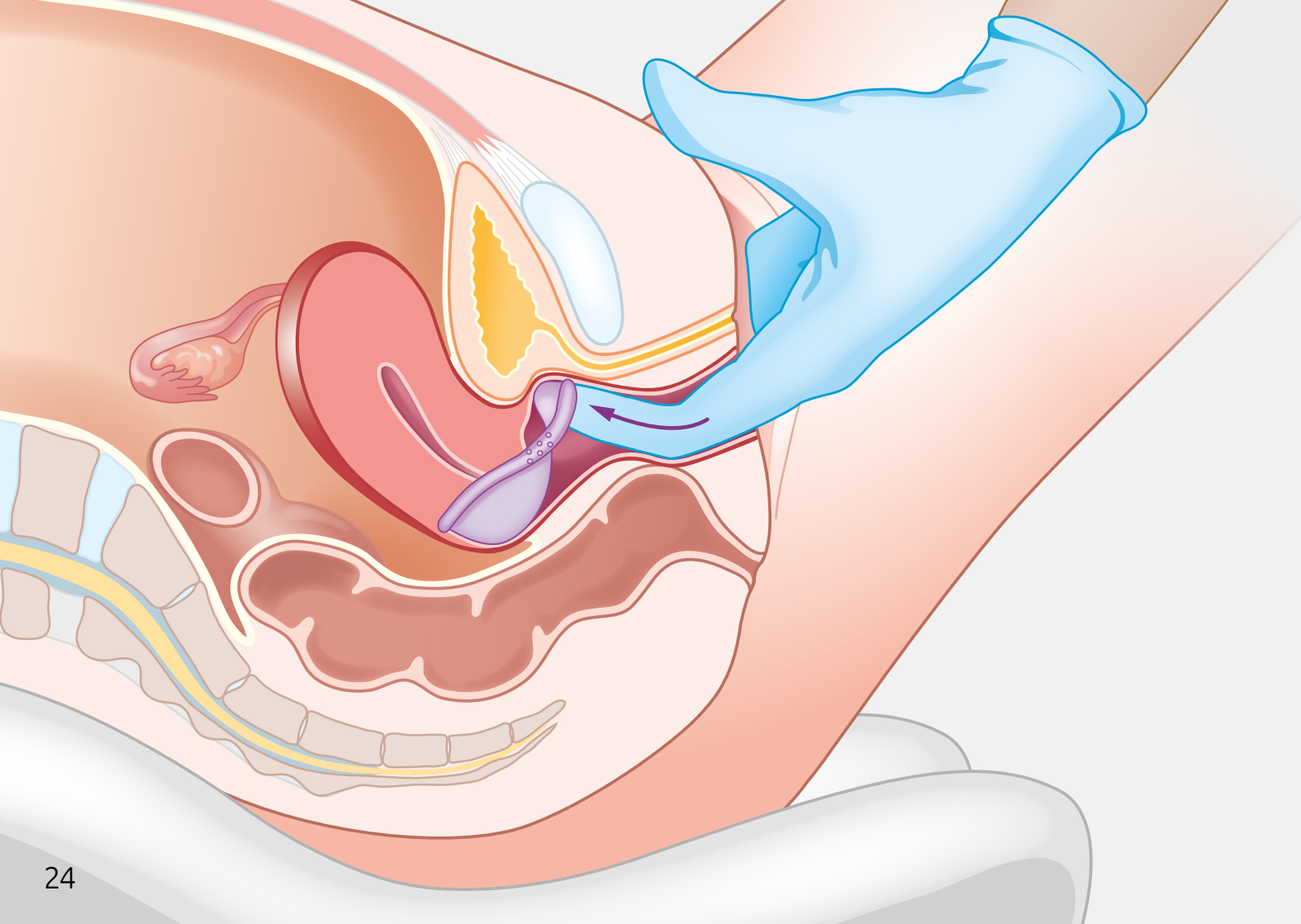
4 ml of gel is sufficient (equivalent to approx. one teaspoon). Extra gel may be applied to the leading edge of the diaphragm to help with insertion. Show your patient the correct way to apply the gel.



3.3

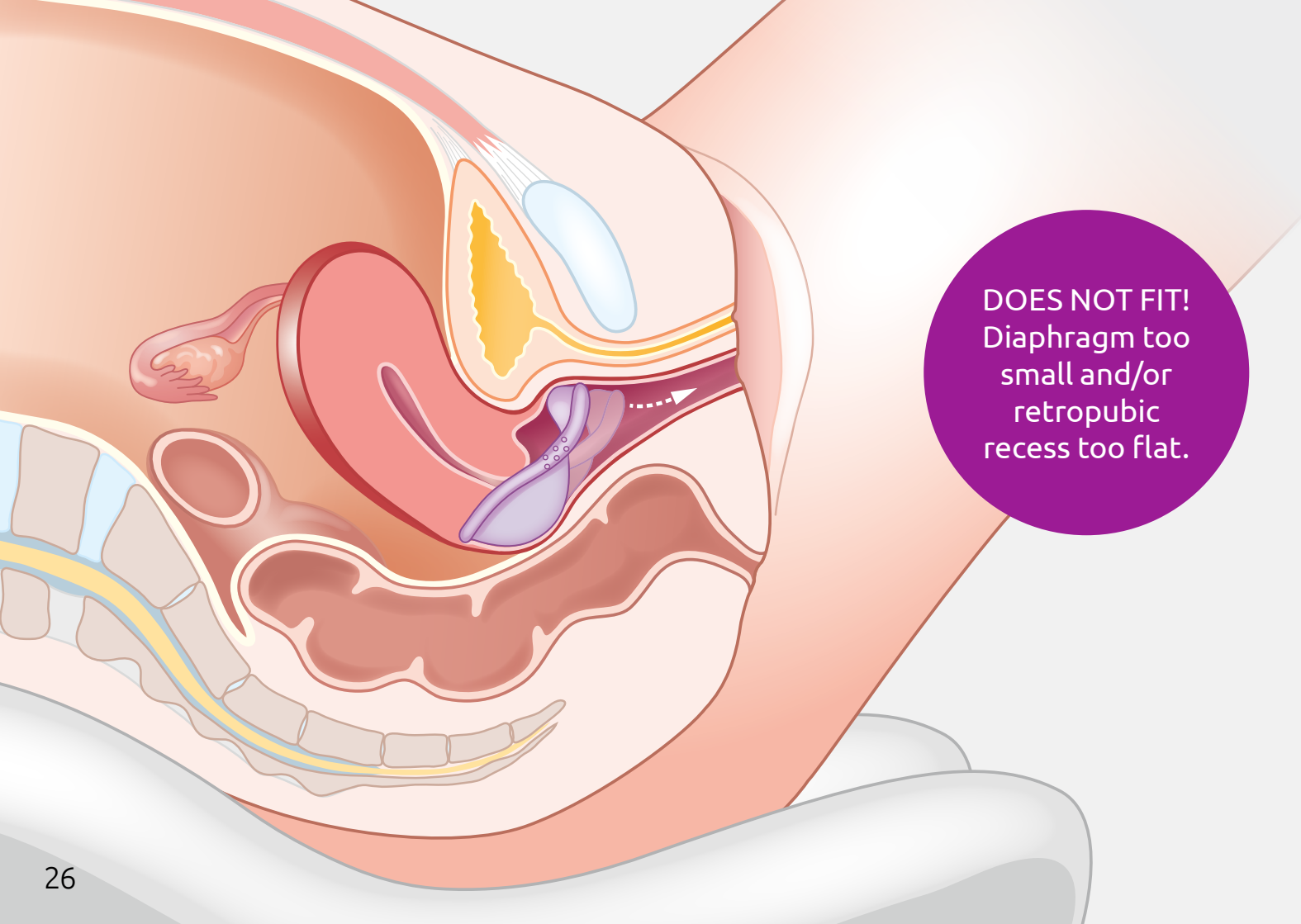
With one hand holding the Caya® in the folded position, open the labia with the other hand. While keeping the Caya® folded, insert the diaphragm as deeply as possible. Push down so the diaphragm slides along the posterior vaginal wall toward the

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 Caya® as you push it into place. The cervical cup should be covering the cervix.



3.4

Now push the anterior edge (where the removal dome is located) up behind the pubic bone/pubic notch.



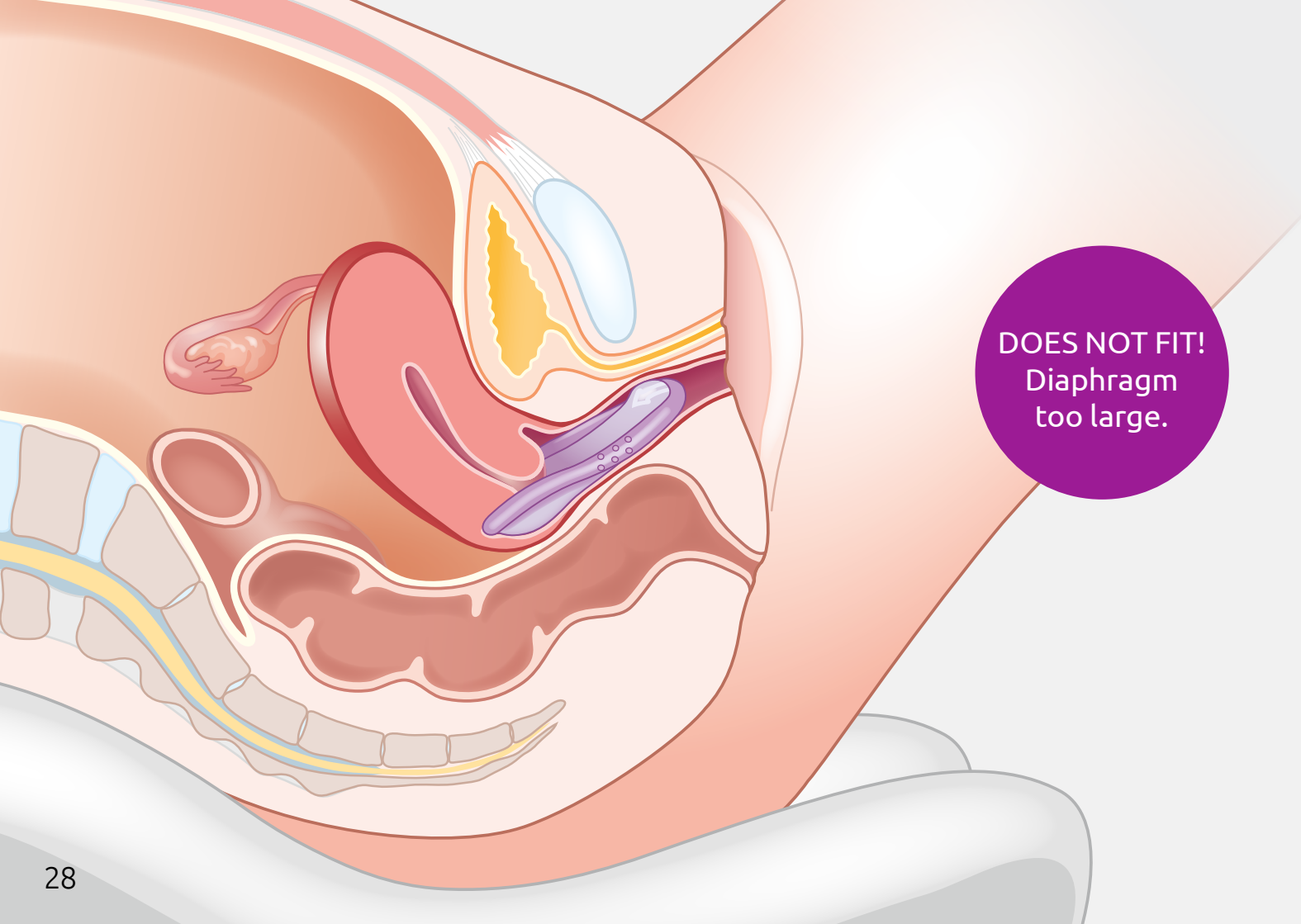
4.1

The Caya® 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 Caya is fully inserted.

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

If the Caya is too small, suggest trying a traditional diaphragm sized 85 mm or larger.

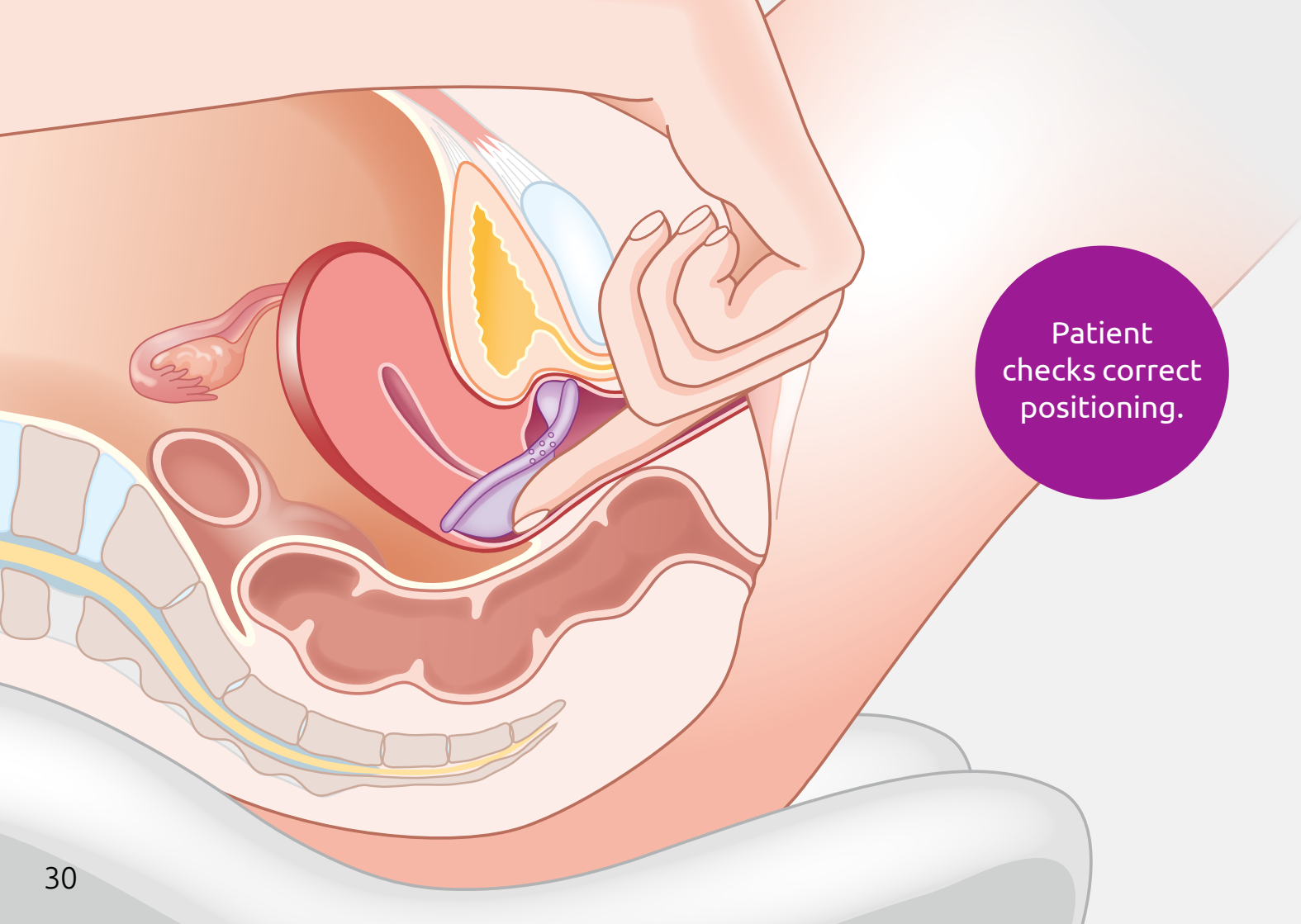


4.2

If the Caya® 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 Caya® situated.

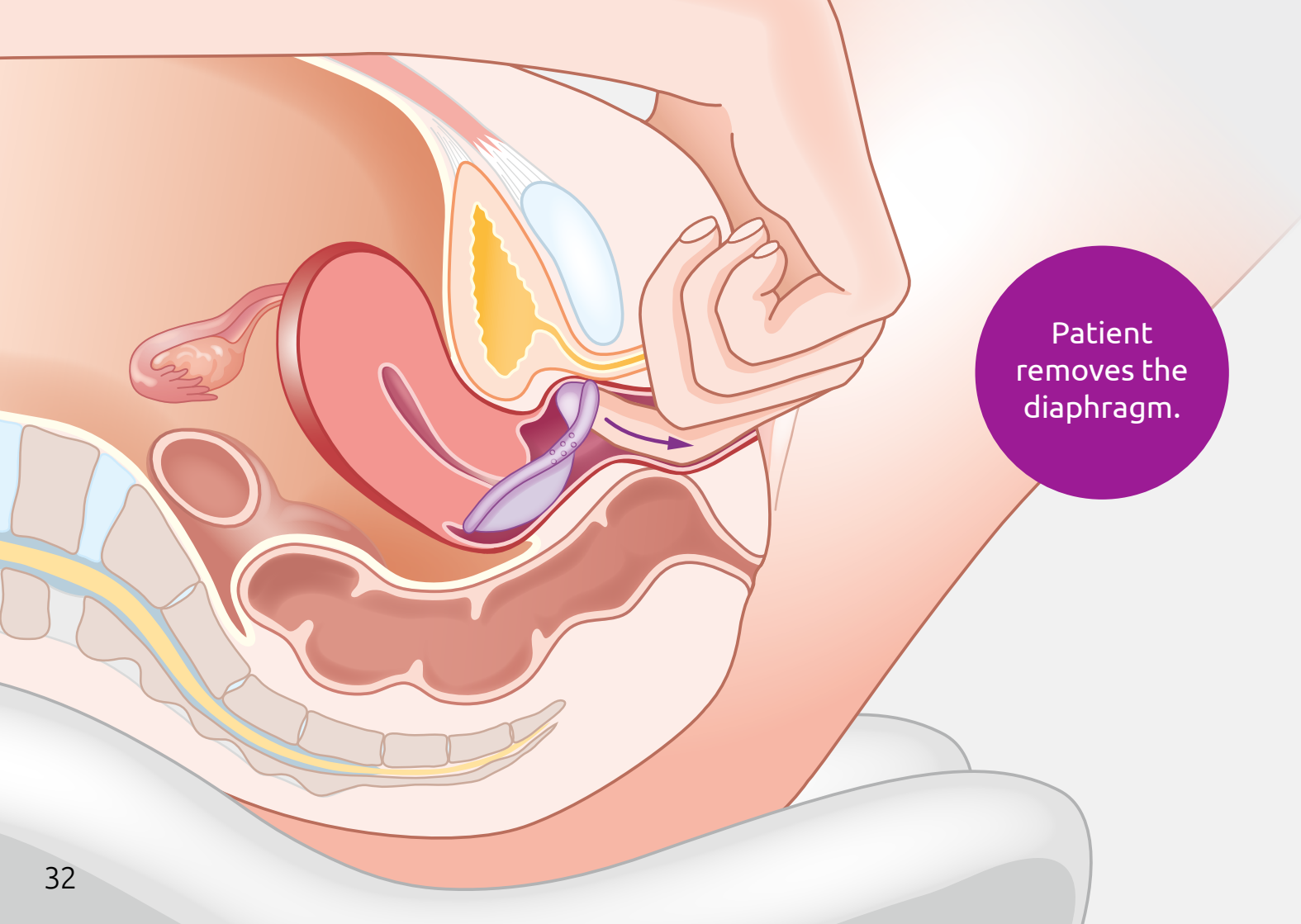
If the woman experiences uncomfortable pressure on the urethra or rectum, or feels the Caya is uncomfortable, the device may be too large for her. In this case, a traditional diaphragm sized 60 mm may fit her better.



5.

Have the client check fit and placement of the Caya®. Once she has done this, have her remove the Caya® and practice inserting, confirming fit, and removing on her own.

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

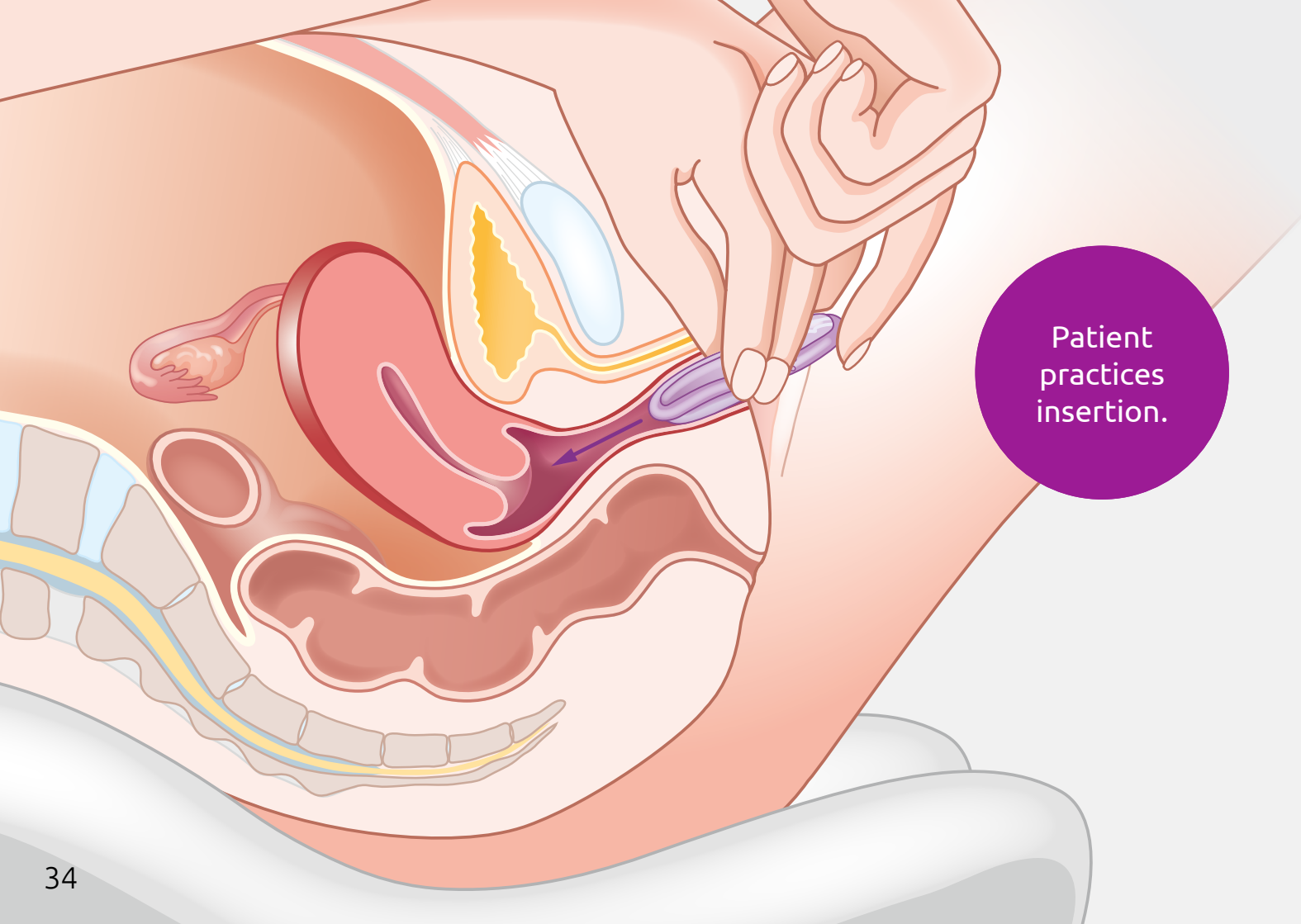


6.

The woman should feel for the removal dome at the front end of the Caya® diaphragm. Using her finger she will hook the diaphragm rim through the removal dome. The dome can be used either by the underside or by slipping the finger over the spring and pushing down on the removal dome.

Once she has her finger in the removal dome, 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 positions open the pelvis and bring the cervix closer to the introitus).

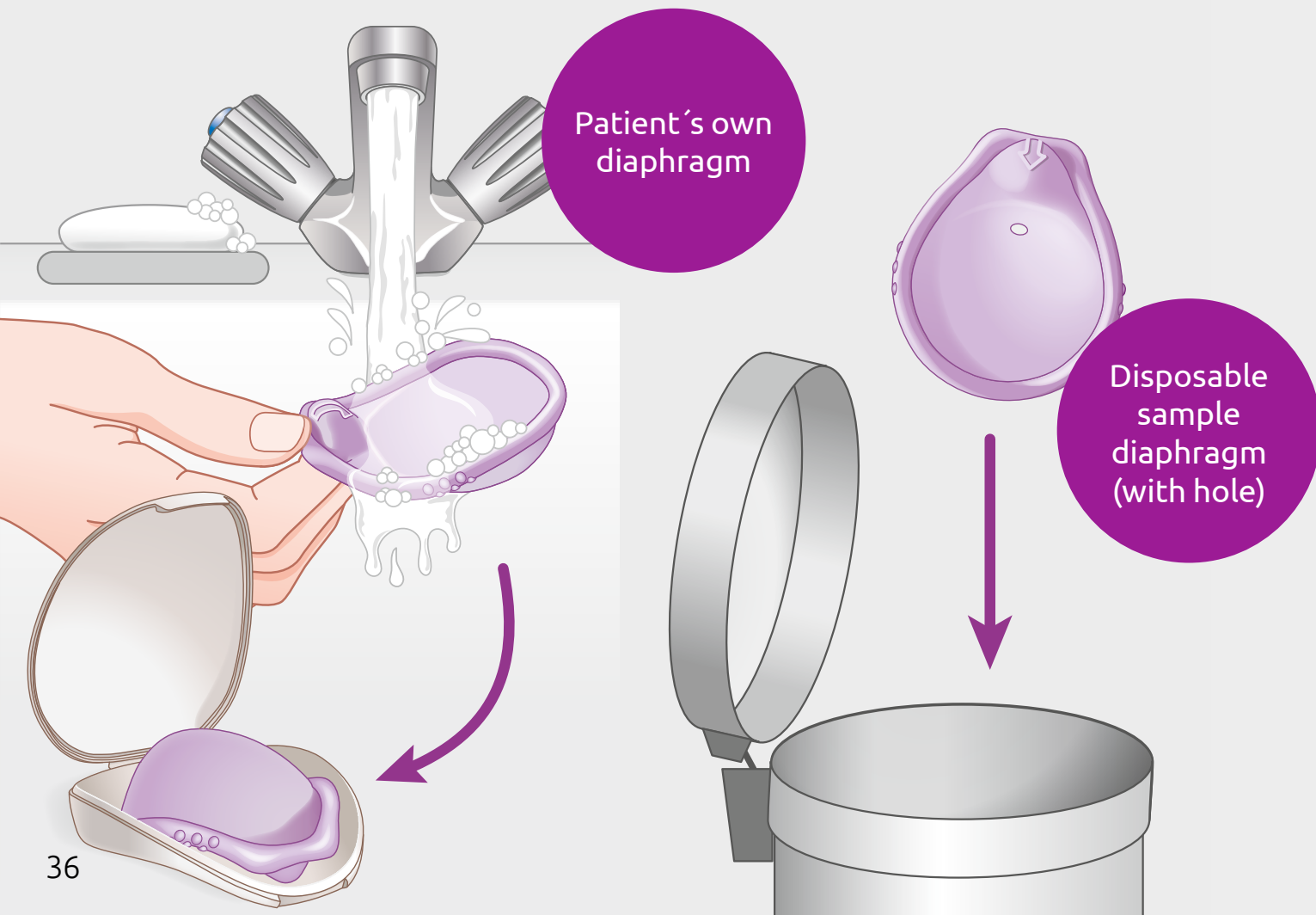


7.

The woman should practice handling, inserting and checking correct placement of the Caya on her own. Then practice removal. The provider 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 Caya (the Caya 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, 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 comfortable that the woman can insert, check position and remove the diaphragm.



8.

After ensuring the woman understands how to insert, check fit and remove the Caya®, dispose of the Caya® sample diaphragm (with a hole). This sample diaphragm is intended for single-person use and must not be given to the patient.

If using the patient's Caya® diaphragm, have her clean it under running water with a mild soap, dry and put back in its case.

Finally, ask your patient to again wash her hands thoroughly. Depending on protocol at your clinic you can encourage the woman to return a week later – wearing the diaphragm – to have the fit and correct placement checked after she has practiced at home. The woman (patient) should be encouraged to contact her health-care provider if she has any questions or concerns about using the Caya® diaphragm.

9. Final instructions

Counsel the woman to practice insertion, wearing, and removal several times before using it during intercourse. Providers also may recommend the woman 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 Caya diaphragm.

Women 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 sex or that she may not have been protected, she should contact her provider for Emergency Contraception (“the morning-after-pill”).

Where to get the Caya® diaphragm

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

Medintim