

#### Instruction manual

Contraceptive diaphragm Natural, safe, hormone-free

### Manual de instrucciones

Diafragma para la anticoncepción Natural, seguro, sin hormonas



# Caya<sup>®</sup> Contoured diaphragm

### EN – english

#### Instruction manual

## Read the instructions for use before using the Caya® diaphragm.

Your Caya<sup>®</sup> diaphragm is a safe and easy-to-use contraceptive method. It is recommended to use the diaphragm with a contraceptive gel. The shape of the Caya<sup>®</sup> diaphragm is designed to fit the female anatomy. One size is sufficient and fits most women.

#### Your Caya® diaphragm looks like this:



- Silicone membrane: is placed over the cervix and prevents entry of the sperm cells into the uterus.
- Grip dimples: to facilitate vaginal insertion.
- Flexible rim: to ensure correct position.
- **Removal dome:** on the front of the diaphragm to facilitate removal from the vagina.

## What is the position of the Caya® diaphragm in the vagina?

When inserted correctly, the diaphragm covers the cervix and is positioned in the upper part of the vagina, between the pubic bone and the vaginal walls.



During and after sexual intercourse, the Caya® diaphragm prevents sperm cells from entering through the cervix into the uterus. This in turn prevents unwanted pregnancies.

NOTE: It is recommended to use the diaphragm with a contraceptive gel.

Practice inserting the Caya® diaphragm on your own a few times before using it for the first time during intercourse.

#### Before using Caya® the first time:

- Take your time
- Read the instruction manual carefully
- If possible, watch the animation on the internet at www.caya.us.com



 Find the cervix – it feels like the tip of your nose.



• Also find your pubic bone (in the vagina).

#### How do I insert the Caya® diaphragm:

NOTE: Insert the Caya® diaphragm before intercourse.

Check your Caya<sup>®</sup> diaphragm before you use it every time to make sure it is still ok.

- Remove the Caya<sup>®</sup> diaphragm from the case. Before first use, the Caya<sup>®</sup> diaphragm should be washed with soap and water, rinsed and then dried with a soft clean cloth.
- Before inserting the Caya<sup>®</sup> diaphragm prior to intercourse, place 4 ml (about a teaspoon) of contraceptive gel into the silicone membrane.



Spreading the gel around the rim facilitates insertion into the vagina.



Before inserting it into the vagina, fold the Caya® diaphragm using the grip dimples.

NOTE: If you have inserted the diaphragm more than 2 hours before sex, you need to add more contraceptive gel.

 Choose a position which is comfortable for you – kneeling down, lying down or standing with one leg elevated.



 Hold the Caya<sup>®</sup> diaphragm with one hand. Place the thumb and index finger on the grip dimples along the rim. The arrow has to point towards your body.



 Using your free hand, spread the labia. Push Caya® deeply along the posterior vaginal wall, towards your back, until the cervix rests inside the cup.



6. Use a finger to verify that the cervix is covered by the membrane of the Caya<sup>®</sup> diaphragm. Can you feel the cervix through the cup? If yes, then it is in the correct position.



If you cannot feel the cervix or the Caya®: Remove the diaphragm and try inserting it again.

The edge of the removal dome should be located securely and safely behind the upper part of the pubic bone.



If you have verified both of the above and the Caya<sup>®</sup> diaphragm is in the correct position, safe contraception is ensured. You are now ready for intercourse.

7. After intercourse, the Caya<sup>®</sup> diaphragm must remain in the vagina for <u>at least 6 hours</u>.

NOTE: The Caya<sup>®</sup> diaphragm should never be left in the vagina for longer than 24 hours without interruption. Wearing it for longer, uninterrupted periods can promote bacterial growth in the vagina. These bacteria could lead to Toxic Shock Syndrome.

In the event of repeated intercourse, or if the Caya® diaphragm was inserted longer than 2 hours before intercourse, insert additional contraceptive gel deep into the vagina without removing the diaphragm.

 To remove the diaphragm, insert one finger into the vagina and pull out the Caya<sup>®</sup> diaphragm using the removal dome.



#### Instructions for cleaning and care:

After use, the diaphragm should be carefully washed with soap and water, rinsed and then dried with a soft clean cloth. The diaphragm should not be heated in order to dry it. Synthetic detergents or organic solvents should not be used. Each time the Caya® diaphragm is used and washed, it should be examined carefully to ensure that there are no pin-holes or thin spots and that the spring is fully enclosed by silicone rubber.



The Caya® diaphragm is reusable.

With appropriate care, it is expected the Caya® diaphragm should last for a period of two years of average use. If any indication of wear are observed, the diaphragm should be replaced immediately. Therefore, please note the date of first use on the case of the Caya® diaphragm. Silicone oil based lubricants have deleterious effect on products made of silicone rubber. Please use a water based contraceptive gel. The Caya® diaphragm should be stored in its case when not in use. NOTE: After treatment of a vaginal infection, the Caya® diaphragm should be replaced with a new one.

#### About Caya®:

Use: The Caya® contoured diaphragm is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception. It is recommended for use with a contraceptive gel.

The shape and safety of the Caya® diaphragm were developed in an intensive research process lasting several years in the USA and in worldwide studies.

- The Caya<sup>®</sup> diaphragm is a birth control method a woman puts in her vagina before she has sex.
- Caya® covers the cervix (the opening to the uterus). The Caya® diaphragm used with a contraceptive gel helps block sperm and helps keep the woman from getting pregnant.
- One size fits most women.
- Wait to remove Caya<sup>®</sup> at least six hours after intercourse.
- Never leave in the vagina for longer than 24 hours without interruption.

NOTE: Always keep the Caya® diaphragm in the original case and out of the reach of children.

#### Information

Toll free phone 1-800-850-1657 www.caya.us.com

#### More Information:

- About 14 out of 100 women might get pregnant in one year, if they use Caya<sup>®</sup> the right way every time they have sex.
- About 18 out of 100 might get pregnant in a year, if they do not use Caya<sup>®</sup> the right way every time they had sex.
- If you are not sure that Caya® is a good method for you, talk with your doctor.
- You should replace Caya® every two years.

#### Warnings – Do not use Caya® if you:

- Are within the first 6 weeks after delivery/birth.
- Previously used a traditional diaphragm of size 60 mm or smaller, or size 85 mm and larger.
- In case of a severely prolapsed pelvic floor/cervix.



NOTE: Never use the Caya<sup>®</sup> diaphragm with lubricant gels containing silicone oil.

NOTE: Intended for personal use only – not to share with others.

#### Caya<sup>®</sup> does not prevent STIs or HIV/AIDS:

- Caya<sup>®</sup> does not offer protection against sexually transmitted infections.
- You should use a condom along with Caya<sup>®</sup> to help protect yourself from these diseases.

## Talk to your healthcare provider, if:

- You have difficulty getting the Caya<sup>®</sup> diaphragm to fit in your body comfortably.
- You use treatments for vaginal infections.
- You frequently suffer from urinary tract infections.
- You have had lower abdominal/vaginal surgery.
- You have ever had a Toxic Shock Syndrome.

## Stop using Caya<sup>®</sup> and talk to your healthcare provider, if:

- You or your partner get burning, itching, a rash, or other irritation of the vagina or penis.
- You or your partner have difficult or painful urination.

#### Please consult your healthcare provider for any other medical questions.

NOTE: If you have forgotten to use the Caya® diaphragm and have had unprotected sexual intercourse, please consider Emergency Contraception to prevent pregnancy. Take Emergency Contraception within 72 hours of unprotected intercourse.

#### Material:

Silicone (LSR), Polyamid 66 (PA66)

#### Contents:

- One Caya® vaginal diaphragm
- Instructions for use
- Storage case

#### FAQs

## How effective is the Caya<sup>®</sup> diaphragm?

No contraceptive method can guarantee 100 % safety from unwanted pregnancy. The Caya® diaphragm is just as safe as the traditional diaphragm. The more often you use the Caya® diaphragm, the more confident you will become in using this contraceptive method and the more safety this method will offer you.

#### How can I positively influence safety when using the Caya<sup>®</sup> diaphragm?

Regular use of the Caya® diaphragm and the use of a contraceptive gel are important measures for ensuring contraceptive effectiveness. In addition, the diaphragm should always be inserted before and not during intercourse.

## How do I know that Caya<sup>®</sup> is inserted correctly and fits?

Use your longest finger (usually the middle finger) to verify the correct position of the diaphragm: check whether the cup covers cervix and the removal dome is located securely behind your pubic bone. If this is the case you are well protected.

## For how long can I use the Caya® diaphragm?

After the first use, the Caya® diaphragm can be used for 2 years before replacement.

#### Why does the Caya® diaphragm have to remain in the vagina for 6 hours after intercourse?

Leaving Caya® in place for 6 hours will help ensure that sperm are inactivated by the contraceptive gel that you used with the Caya® diaphragm. This will help prevent unwanted pregnancy.

#### What should I do if I forget to remove Caya® after 24 hours have passed?

Remove Caya® and contact your healthcare provider regarding the long insertion period to see if an examination is necessary.

#### Why should Caya® not be worn for longer than 24 hours without interruption?

Wearing the Caya® diaphragm for longer than 24 hours without interruption can promote bacterial growth inside the vagina. These bacteria can lead to Toxic Shock Syndrome (very rare).

#### Can I have repeated consecutive intercourse with the Caya<sup>®</sup> diaphragm?

Yes, your Caya® will remain in position, but you will have to apply additional contraceptive gel with the aid of an applicator. Applicators for contraceptive gel can be purchased in the pharmacy.

#### Can the Caya<sup>®</sup> diaphragm also be used as a menstrual cup?

The Caya® diaphragm is intended to be used for contraception. It is not intended for collection of menstrual blood.

#### What should I do if I have or suspect I have a vaginal infection?

Please visit your healthcare provider for treatment in case of a vaginal infection (e. g. fungus). Please use condoms during treatment and NOT a diaphragm. Upon completion of the treatment you should purchase and use a new Caya<sup>®</sup> diaphragm for your own safety.

## Could my partner feel the Caya® diaphragm?

This is highly unlikely. However, in rare cases, your partner may feel the rim of the diaphragm.

## Does the Caya<sup>®</sup> diaphragm influence my sexual desire?

No, the Caya<sup>®</sup> diaphragm has no influence on your libido as it contains no hormones.

#### What should I do if Caya<sup>®</sup> causes pain during intercourse?

First verify the correct position of Caya® using a finger. If the Caya® diaphragm continues to cause pain, please visit your doctor.

## What should I do if Caya<sup>®</sup> accidentally comes out during intercourse?

Re-insert Caya® again after applying some more contraceptive gel. If the diaphragm comes out after your partner has ejaculated or if you do not feel safe, visit your healthcare provider to discuss whether you may need an Emergency Contraception.

#### What do I have to consider when using the Caya<sup>®</sup> diaphragm?

The only habit that requires changing is that one always uses the Caya® diaphragm when it is needed – during intercourse. The more often Caya® is used, the more confident one becomes in handling the diaphragm.

#### Can Caya<sup>®</sup> break or tear?

This is very rare. However, if you do notice that your Caya® is damaged in some way after intercourse, please visit your healthcare provider immediately (within 72 hours) to discuss the possibility of emergency contraception.

#### Can I use additional lubricants with Caya®?

Yes, but <u>only</u> water-soluble lubricants. It is important to understand that silicone oil lubricants can damage your Caya<sup>®</sup> diaphragm. Please note: if using a contraceptive gel as recommended, it is important to understand that the compatibility or effect of any lubricant on the efficacy (effectiveness) of a contraceptive gel is unknown.

#### Can I use the Caya® diaphragm in combination with condoms that are coated with silicone oil?

Yes, the Caya<sup>®</sup> diaphragm can be used with condoms that are coated with silicone oil. The small amount of silicone oil does not damage the Caya<sup>®</sup> diaphragm.

## Medintim

### \*\*\*

KESSEL medintim GmbH Kelsterbacher Str. 28 64546 Mörfelden-Walldorf Germany

www.medintim.com

Made in Germany

**C E** 0483



Distributor:

HPSRx Enterprises Inc 1640 Roanoke Blvd Salem, VA 24153 Toll Free Phone 1-800-850-1657 www.hpsrx.com

US patent # 5,771,900



Once opened, can be used for 24 months Una vez abierto el envase utilizar en los 24 meses siguientes



Temperature restriction Limitación de la temperatura



Read instructions for use Consulte las instrucciones de uso

LATEX

Sin látex

Phthalate-free Sin ftalatos

I atoy-froo

Do not use if package is damaged No usar si el envase está dañado



Protect from moisture/ Keep dry (store in a dry place) Proteger de la humedad/el agua



Waste Desechos



Manufacturing date Fecha de fabricación



Batch number Denominación/número de lote



Expiry date Fecha de caducidad



Medical device Dispositivo médico

#### www.caya.us.com