

Caya[®]

*contoured
contraceptive
diaphragm*



Hormone-free.
Safe.
Easy to use.





TABLE OF CONTENTS

Another Option of Birth Control.....	2
Contraception... Her Way!.....	3
Product Description.....	4
Insertion Guide.....	5
Caya® Survey.....	6-8
Caya® Frequently Asked Questions	9
Gynecological Exam & Contraindications for Caya®.....	10
How To Order Caya®.....	11
Retail Pharmacy List.....	12
Mail Order Pharmacy Form.....	13
Caya® History	14

ANOTHER OPTION OF BIRTH CONTROL

Why should you prescribe the Caya® for your patient?

- Caya® is a one-size-fits-most contoured diaphragm that is designed to fit the woman's shape.
- When a non-hormonal contraceptive is medically required (e.g., increased risk of thrombosis, cardiovascular disease, hypertension, congenital severe lipid metabolic disorders, acute pancreatitis, impaired glucose tolerance)
- For patients who desire a non-hormonal birth control
- When a patient has a latex allergy
- If a patient desires a backup method for birth control (e.g., missed a pill)
- When a patient is between pregnancies
- If using in combination with other methods (e.g., condoms)
- For lactating mothers who wish to not use a hormonal birth control method
- In cases where a patient is having infrequent intercourse
- Caya® is a perfect option for women who are seeking natural and safe contraception.



CONTRACEPTION... HER WAY!

There is a new trend among young, modern women—they prefer everything to be all natural; from their food to cosmetics, and now when it comes to their contraception! These women prefer the non-hormonal Caya® diaphragm over a hormonal alternative.

As a provider, you can offer your patient the Caya® diaphragm to give her another option of contraception to decide what method she may prefer.

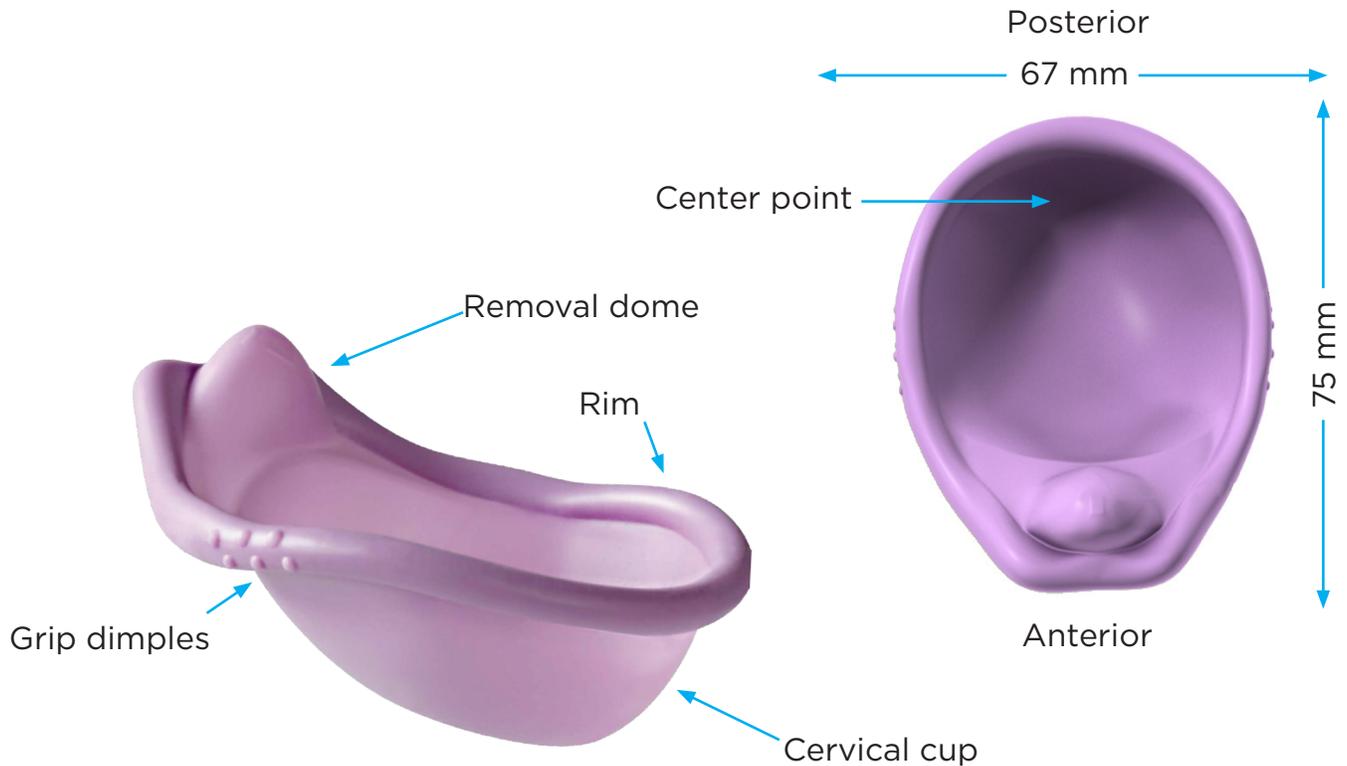
Many women do not tolerate the “pill” and have experienced major difficulties with the IUD. Spotting, unnecessary pain or decreased libido can be reasons to review your patient’s previously used method of contraception.

The Caya® contoured diaphragm is the birth control method of choice for women who want to use safe and hormone-free contraception. It does not interfere with their hormonal balance and their natural cycle is maintained. The Caya® diaphragm is a contraceptive barrier device; it is placed in front of their cervix, thus preventing the sperm cells from entering the uterus. The Caya® diaphragm is always used in combination with a contraceptive gel.

Another advantage: Your patient only needs to use contraception when having sex! They do not have to take or use something continuously over a period of *several months or years!*



PRODUCT DESCRIPTION



Cervical cup: Made of a thin silicone material that covers the cervix and accommodates a range of cervical sizes.

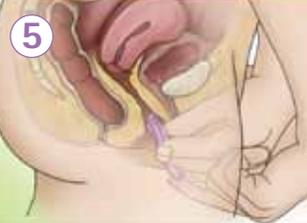
Rim: Flexible, provides stability and helps guide Caya® deep into the vagina as the woman pushes on the anterior edge. Holds the diaphragm in place and ensures that it is positioned correctly.

Grip dimples: Orient the woman's finger and provide a tactile cue for where to hold and squeeze the rim.

Removal dome: Allows for easy removal; a woman's finger can fit under or over the dome to remove the device.

Center point: Palpable center point for a better positioning of the diaphragm.

CAYA® INSERTION GUIDE

 <p>1</p>	<p>Before insertion, the Caya® is folded using grip nubs on each side. About 4ml (one teaspoon) of contraceptive gel is poured into each fold of the Caya®.</p>	 <p>8</p>	<p>In case of repeated sexual intercourse, the diaphragm remains in the vagina. To ensure continued safety, before the second coitus, additional gel must be introduced into the vagina using a gel applicator.</p>
 <p>2</p>	<p>A small amount of contraceptive gel is spread on the rim. This will help facilitate insertion into the vagina.</p>	 <p>9</p>	<p>The diaphragm must remain in the vagina at least 6 hours before it is removed. (Otherwise, motile sperm might ascend into the then unprotected cervical canal.)</p>
 <p>3</p>	<p>The Caya® diaphragm and contraceptive gel can be applied up to 2 hours before coitus.</p>	 <p>10</p>	<p>The Caya® is pulled out of the vagina using the recessed grip.</p>
 <p>4</p>	<p>The diaphragm is held in one hand. During insertion, the arrow on it points toward the body.</p>	 <p>11</p>	<p>After removal from the vagina, the Caya® diaphragm is rinsed with water and soap and dried in the open case.</p>
 <p>5</p>	<p>Caya® is pushed past the vaginal portion of the cervix into the posterior fornix. The recessed grip fills the retropubic space completely.</p>	 <p>12</p>	<p>For protection against external influences, the Caya® should always be stored in the supplied case.</p>
 <p>6</p>	<p>Caya® is correctly placed when the cervix is completely covered by the diaphragm and placed between the retropubic arch and the niche on the pubic bone.</p>	 <p>13</p>	<p>Important: The Caya® diaphragm should never remain in the vagina for more than 24 hours.</p>
 <p>7</p>	<p>The placement should be controlled with the finger after insertion. It is correct when the cervix can be felt through the membrane of the diaphragm (feels like the tip of a nose). Otherwise, the diaphragm must be removed and inserted again.</p>	<p>14</p> <p>The Caya® diaphragm can be used for 2 years from the first application.</p>	

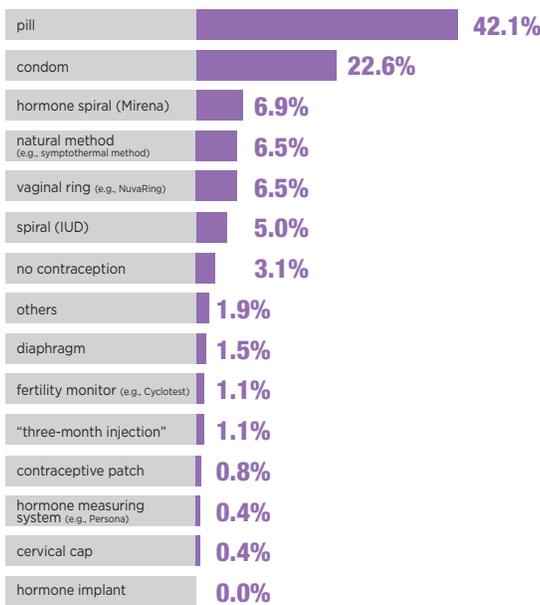
CAYA® SURVEY RESULTS

Results of the fourth Caya® Post-Marketing Survey of 262 women from May-June 2017

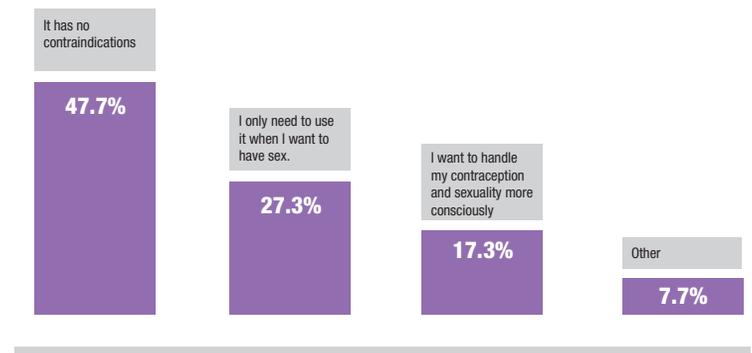
More than 100,000 women worldwide successfully use the Caya® diaphragm for contraception. It is available in more than 30 countries in Europe, Australia, Canada, and also in the USA. The results from this survey confirm and build additional evidence that the Caya® contoured diaphragm is appropriate for use by women of all ages and different situations in their lives and relationships. The most important factor that motivates women to use Caya® is looking for a non-hormonal method.

42% of users previously used the pill!

Most women in this survey reported their previously used method was a hormonal pill. About 57% of the participants had previous experience with hormonal methods before they decided to use a Caya® diaphragm.



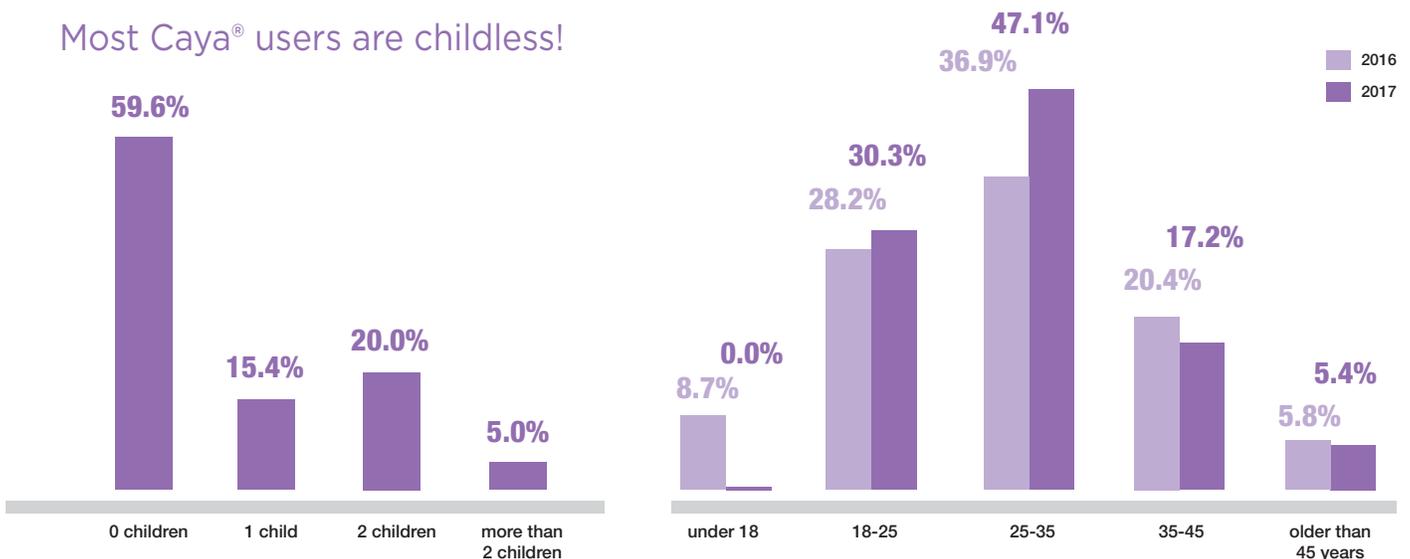
The survey showed the awareness of the importance of contraception and sexuality has significantly increased. 17% of the women using Caya® reported their wish to be more aware of their own contraception and sexuality. An important aspect for the decision to use Caya®: it's hormone-free.



Almost half of the respondents are between 25 and 35 years old

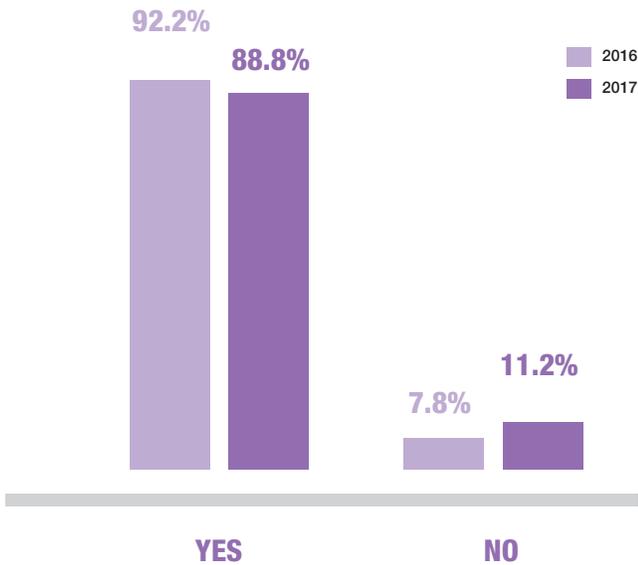
Caya® diaphragm is used by women of all ages and in different situations of their lives. Compared to the survey in year 2016, the group of women in the age between 35 and 45 years decreased. The percentage of women under 18 years has decreased as well compared to the previous surveys in 2016.

Most Caya® users are childless!



CAYA® SURVEY RESULTS

About 90% of users are in stable relationships.



How are users finding out about Caya®?

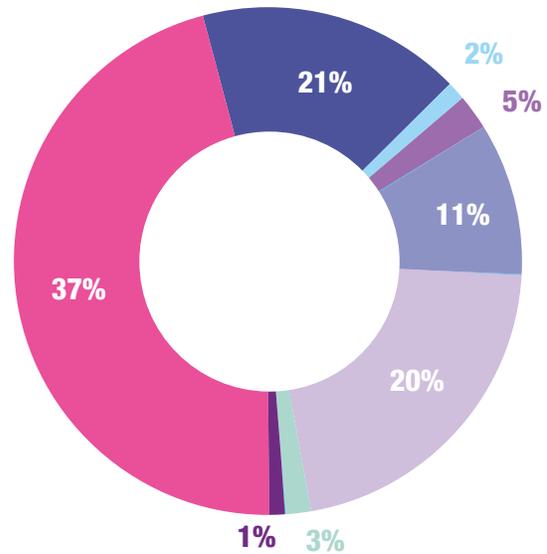
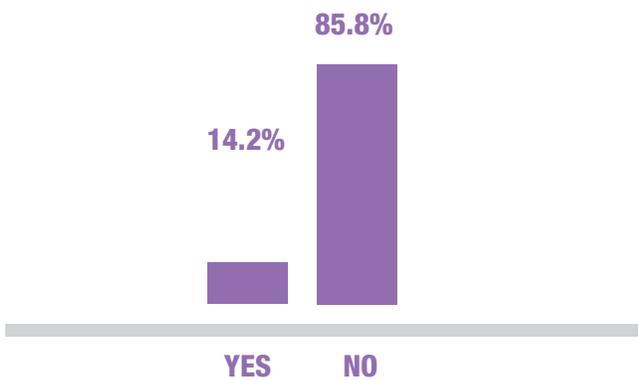
58% of the participants reported they learned about Caya® diaphragm via the internet - 21% of this group specifically reported they learned about Caya® by Facebook. For two years now, women who are interested in Caya® or those who use it regularly get information via Facebook. Facebook is a good way to reach women for this female contraceptive barrier device.

Healthcare providers, such as gynecologists, are the next most cited source of information about Caya®. About 20% of the participants reported they first got notice about the Caya® diaphragm at their regular check-up visit at the gynecological practice. This trend underlines the need to continue the systematic outreach to healthcare providers with basic information about the Caya® Diaphragm.

Caya® is as easy to use as a tampon!

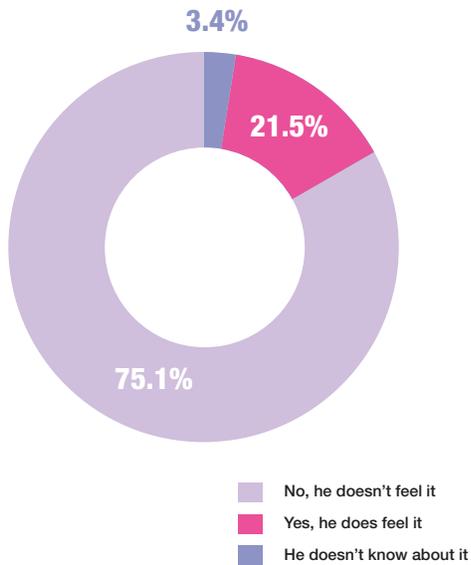
Most of the women in this survey were using this product and this method for the first time in their life. About 86% reported having no problems using Caya®.

This also was documented during clinical studies implemented in the United States with respect to the use of the Caya® diaphragm. It was reported that out of the 500 participants, nearly 80% correctly inserted and confirmed correct position of the diaphragm in the vagina after just reading the instructions (i.e., without any coaching or counseling from a healthcare provider)



- Internet
- Facebook
- Caya Homepage
- Others
- Friend
- Gynecologist
- Information Center
- Magazine

CAYA® SURVEY RESULTS

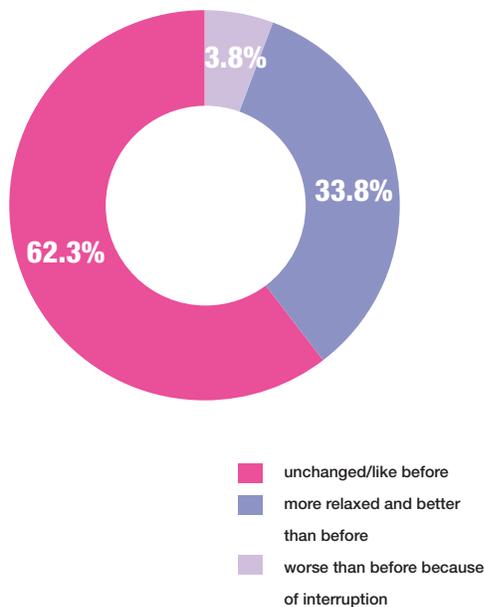
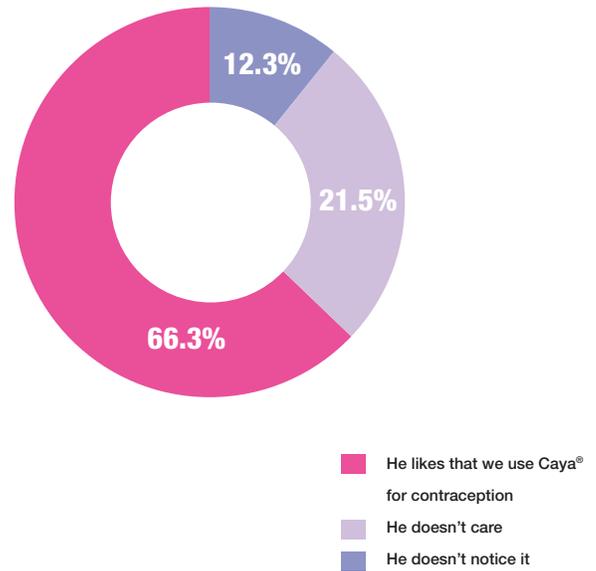


Does the partner feel the Caya® during sex?

As before, we asked again in this survey whether the male partner could feel the Caya® diaphragm while having sex: 75% of the participants reported that their partner did not feel the Caya® diaphragm at all or did not feel it as disturbing. This is an increase of 15% compared to last year's survey.

What does the partner think about Caya®?

The majority (66.3%) of the participants indicated that their partner also liked Caya® as the chosen method of contraception. This indicates that contraception by all means is a matter of partnership and that both partners should agree with the method of contraception. Nevertheless, 21.5% said that their partner doesn't care.



Caya® has a positive influence on sex and libido!

Similar to results from the surveys in 2015 and 2016, the answers about the impact of the Caya® diaphragm on the sexual activity indicate that Caya® does not interfere with sex for the females. About 34% of women confirmed that having sex with the Caya® diaphragm is even better than before and more relaxed.

How safe is the Caya® diaphragm?

No contraceptive method can guarantee 100% safety from unwanted pregnancy. The Caya® diaphragm is as safe as the classic diaphragm. The more often the Caya® diaphragm is used, the more confident the patient will become in using this contraceptive method and the more safety this method will offer them.

How will your patient know that Caya® is inserted correctly and fits?

The patient should use their longest finger (usually the middle finger) to verify the correct position of the diaphragm, check whether or not the cup covers the cervix and the removal dome is located securely behind the pubic bone. If this is the case, they are well protected.

For how long can the patient use the Caya® diaphragm?

The Caya® diaphragm can be used up to 2 years after the first use.

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

Sperm cells are no longer active after this period. These 6 hours are for the patient's own safety and to prevent an unwanted pregnancy.

The Caya® is a “one size fits most” diaphragm; what size range does the Caya® fit?

The Caya® diaphragm fits most women who fall into the 65-80mm size range. The Caya® does not require to be fitted like the traditional diaphragm. If a patient would like to be fitted, HPSRx Enterprises offers free test fit units that we can send you.

Can the patient have repeated intercourse with the Caya® diaphragm?

Yes, the Caya® will remain in position; however, the patient will need to reapply additional contraceptive gel with the aid of an applicator.

Can the Caya® break or tear?

This is nearly ruled out. However, if the patient notices that the Caya® is damaged in some way after intercourse, we suggest seeing the patient immediately (within 5 days) to discuss the possibility of emergency contraception (“morning-after pill”).

Which lubricants are safe to use with the Caya®?

It is suggested to use a water-based lubricant only, such as Gynol II.

In case of a vaginal infection, what should the patient do?

During treatment of a vaginal infection (fungus), we suggest having the patient use an alternative method of birth control, such as condoms, and not the Caya® diaphragm. Upon completing treatment for infection, the patient should purchase and use a new Caya® diaphragm for their safety.

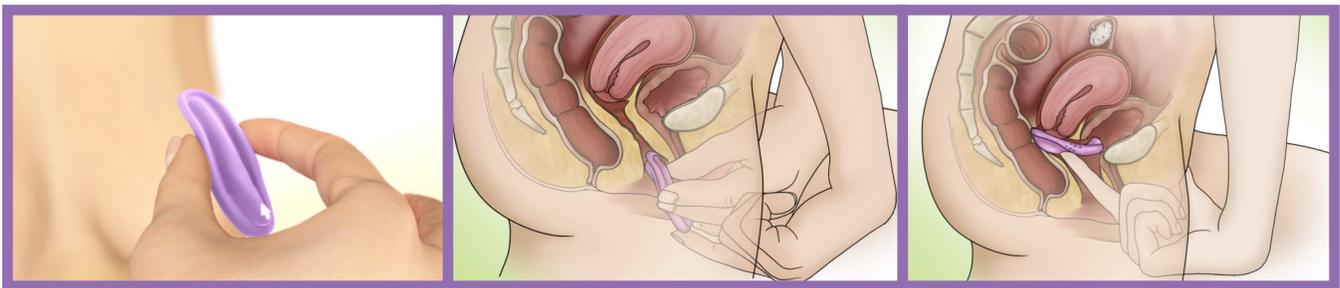
How is the Caya® diaphragm cleaned and stored?

After removal from the vagina, the Caya® diaphragm is rinsed with water and soap and dried in the open case. The Caya® diaphragm should be stored in the provided case to protect it from external influences.

CAYA® GYNECOLOGICAL EXAMINATION

1. Palpate the inside of the symphysis and the cervix of the patient. They should not show any anatomic changes such as descensus uteri or absence of a retropubic space.
2. Insert the patient's Caya® diaphragm. It should completely cover the cervix and be "anchored" between the posterior fornix and the niche on the pubic bone. Let the patient feel the correct seating with her finger.
3. The Caya® diaphragm must not exert pressure or be perceived as an unpleasant foreign object.
4. Vaginal self-examination is recommended. It helps the user get acquainted with the anatomical structures in her vagina (cervix, retropubic niche). The user should first learn to feel her cervix and symphysis with one or two fingers (index and middle finger). This is necessary to control the proper intravaginal seating of the Caya® diaphragm after insertion.

The need for size determination as in the classic diaphragm is obviated. Caya® diaphragm is available in one size and fits most women (corresponding to traditional diaphragm sizes 65, 70, 75, and 80 mm).



CAYA® CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute contraindications

- Application in the first 6 weeks after childbirth
- If previously diaphragms of size 60 mm or 85 mm and larger have been used
- Acute or chronic-recurrent urinary tract infections
- Infections of the genital organs and the true pelvis
- Pronounced descensus uteri and vaginae
- Cystocele with obliteration of the retropubic niche in the vagina
- Weakly formed or absent retropubic niche

Relative contraindications

- Marked and/or fixed retroversion/retroflexion
- Psychological or somatic difficulties with the application
- If required, contraindications can be excluded by a gynecological examination.



INTERESTED IN CAYA®?

Getting Caya® Into Your Office:

1. Free, Single-Use “Test Fit” Samples

While the Caya® diaphragm does not require a traditional fitting, we understand that in some cases a patient may have a particular concern if it will work for them or not, especially in cases such as a retroverted uterus. Therefore, we have, available for free, “Test Fit” samples of Caya® diaphragms just for that situation! These samples are single-use, disposable units for you to assist your patient and ascertain if the Caya® will work for them!

2. Dispense Caya® in Your Office

You can order the Caya® diaphragm directly from HPSRx Enterprises and dispense Caya® in your office. Convenience for your patient, income for your practice.

WAYS TO PRESCRIBE CAYA® FOR YOUR PATIENT:

You can write, fax, or e-scribe a prescription for Caya® diaphragm to your patient's pharmacy or the Caya® Mail Order Pharmacy. Be sure to give the McKesson and Cardinal order numbers to your patient. This will help facilitate the pharmacy's order of the Caya® for your patient.

McKesson order number 3486917

Cardinal order number 5290770

NDC number 63704-0020-01

Caya® Mail Order Pharmacies:

1. American Mail Order Pharmacy
Phone: 888-772-3811
Fax: 586-772-6873
23290 Schoenherr Road
Warren, Michigan 48089
E-Script: American Mail Order Pharmacy
2. Health Warehouse
Phone: 800-748-7001
Fax: 888-870-2808



Available at most retail pharmacies, including but not limited to:

TARGET	WALMART
CVS	RITE-AID
FOOD CITY	COSTCO
GIANT EAGLE	WEGMAN'S
MEIJER	WINN-DIXIE

Be sure to check the local independent pharmacies to see if they can order Caya®!



Caya®

Mail Order Pharmacy ORDER FORM

Pharmacy Information

Phone: 888-772-3811

Fax: 586-772-6873

Mailing Address:

American Mail Order Pharmacy
23290 Schoenherr Road
Warren, MI 48089

Instructions:

The Caya® contoured diaphragm requires a prescription from your doctor. It is available in one size and fits most women (conventional diaphragm sizes of 65 mm to 80 mm); while a pelvic exam or traditional diaphragm fitting is not required for Caya® use, if your size is unknown you should consider having your provider determine your size or test-fit Caya® to confirm that Caya® will work for you.

1. Complete this form
2. Obtain a prescription from your physician or healthcare provider
 - They may call, fax, e-script, or e-prescribe the Rx directly to the pharmacy
 - Or they may provide you with a written prescription
3. Send this form to the pharmacy by fax or mail
 - If you were given a written prescription, you MUST mail in both this order form and the written prescription from your physician or healthcare provider

Full Name: _____		
Street Address: _____		
City: _____	State: _____	Zip: _____
Phone: _____	Cell Phone: _____	
Email: _____	Date of Birth: _____	

Credit Card Information:	
Type (Visa, MC, Amex, Discover)	
Cardholder: _____	
Billing Address: _____	
City: _____	State: _____
Zip: _____	
Credit Card Number: _____	
Exp Date (mm/yy): _____	CVV Code: _____

Prescription Card Insurance Information:	
Cardholder's Name: _____	
Card ID#: _____	
Grp#: _____	
Bin#: _____	PCN#: _____
Insurance Name: _____	
Insurance Phone: _____	
Relationship: self ___ spouse ___ child ___ other ___	
Employer Name: _____	

Item Description	QTY	Unit Price (For Cash Customers)	Unit Price (For Insurance Customers)	Extended Price
Caya® Diaphragm		\$80.00	NA <small>(copay may be required)</small>	
Options Gynol II Vaginal Contraceptive Gel (multi-dose tube with applicator)		\$17.50	\$17.50	
Options Conceptrol Vaginal Contraceptive Gel (Box of 10 prefilled applicators)		\$18.50	\$18.50	
Shipping Options: 1st Class USPS = \$5 Expedited USPS = \$25			Shipping	
			Grand Total	

Successful history of development: Caya® Contoured Diaphragm

In 1885, the physician C. Haase, alias Wilhelm Mensinga from Northern Germany, could not foresee that his invention of the “occlusive pessary,” as the first diaphragm was called, would rise to new eminence in the early 21st century.

Between 1920 and 1960, diaphragms had been one of the most important contraceptives in the USA. During the last ten years, in research of new, non-hormonal contraceptives, a foundation in the United States, in cooperation with the famous CONRAD research institute (www.conrad.org), has designed a completely new diaphragm.

Under the research name “SILCS” (single-size contraceptive barrier device), this method was improved in evolutionary design with new materials, shapes and properties.

The round shape of the classic diaphragm was changed in favor of a more anatomical oval shape. Instead of a spring of metal, nylon was selected for shaping. The silicone membrane is light (only 4 grams), easy to fold and insert.

The scientific support of this research was provided by CONRAD’s research group in Arlington (near Washington, D.C.). For the first time, MRI images with the new diaphragm in the body were taken. Furthermore, fundamental issues of the adaptation of diaphragm size were addressed. It could be shown that the “SILCS” obviates the need for adaptation, as it fits most women.

Acceptance of the diaphragm method and the new Caya® diaphragm was determined in various countries, including Thailand and South Africa—even where the method had previously been completely unknown. The project preliminary completed with the safety study with 450 couples at a total of 10 sites in the US. This multicentric study was published in April 2015 (Schwartz, Jill, et. al).

In 2010, the US foundation, which also controls the patents and the further research on SILCS, found a partner for manufacture and approval in Europe and the US: the company KESSEL medintim GmbH is based in Walldorf near Frankfurt/M, Germany.

This company specialized in the marketing of barrier contraceptives since 1987. It has assumed the task of evolving the completely researched and developed product into an approved, marketable barrier contraceptive. KESSEL is an ISO-13485-certified manufacturer of medical devices, qualified to develop the product “SILCS” into a marketable diaphragm: the “CAYA® contoured diaphragm.”

The Caya® diaphragm is manufactured in Germany and has received CE certification in March 2013. Canada followed in Feb. 2014. Australian TGA recognized Caya® diaphragm in Oct. 2014.

FDA clearance for the US market was in August 2014.

Four years after sales start, Caya® contoured diaphragms are available worldwide in 30 countries. More than 100,000 women use Caya® as their personal and effective contraceptive method.

THE NEXT GENERATION

CAYA® CONTRACEPTIVE DIAPHRAGM



Distributed by HPSRX Enterprises Inc.

Phone (800) 850-1657 Fax (800) 361-6984

www.hpsrx.com

www.caya.us.com

<https://www.facebook.com/CayaUSA>

