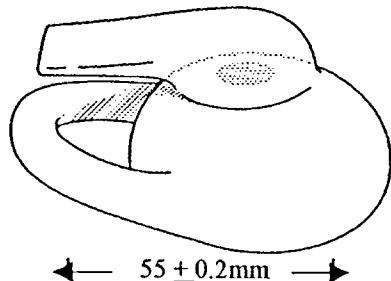


Lea's Shield® **PHYSICIAN LABELING**



Lea's Shield® is a one-size, single-patient use, reusable vaginal barrier contraceptive device. Approximately the size of a diaphragm, it is composed entirely of medical grade silicone rubber. The device is washable, and reusable. *Lea's Shield®* should be used with nonoxynol-9, a spermicidal lubricant.

Lea's Shield® has a cup-shaped design that is intended to cover the cervix without being held by the cervix. The *Lea's Shield®* weighs 38.0 (± 1) gram. The posterior thick lip of the device is designed to fill the posterior vaginal fornix. The primary mechanism of action is to block sperm access to the cervix by covering the cervix.

The *Lea's Shield®* is held in place by the vaginal wall and not by the cervix. The device has a valve and a loop. The valve facilitates insertion by venting the air trapped between the cervix and the device, creating a tight fit; the loop is intended to aid in insertion and removal of the *Lea's Shield®*.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR FAMILY PLANNING HEALTH CARE PROVIDER.

INDICATION FOR USE

The *Lea's Shield®* is indicated for use by women of childbearing age who desire to prevent or postpone pregnancy.

CONTRAINDICATIONS

- ❖ This device should not be used in the presence of vaginal, cervical, or pelvic infections.
- ❖ This device should not be used in the presence of vaginal or cervical lacerations.

WARNINGS

- The *Lea's Shield®* is a single-patient use device. It may be reused only by the person for whom it is prescribed following cleaning and reapplication of spermicide.
- Patients should be counseled to contact a health care professional immediately if she notices a foul odor while the device is in place, or if the *Lea's Shield®* has a bad odor upon removal.
- The use of *Lea's Shield®* may increase a woman's chance of contracting an infection of the urinary tract caused by *E. coli* or vaginal infection.

- Patients with a history of sensitivity to spermicide or silicone should consider another form of contraception.

PRECAUTIONS

- ◆ The *Lea's Shield®* will not help to reduce the risk of transmission of sexually transmitted infections (STIs). Patients at increased risk for STIs should consider an alternative form of contraception.
- ◆ *Lea's Shield®* is to be used with a spermicide containing Nonoxynol 9. Studies have shown that nonoxynol 9 (N-9) is an epithelial irritant that may increase risk of disruption of vaginal epithelium, especially in women who use it frequently.
- ◆ The safety and effectiveness on the use of *Lea's Shield®* during the post-partum or post-abortal period have not been established.
- ◆ *Lea's Shield®* should be left in the vagina for 8 hours following sexual intercourse. Removing it within eight hours may lower its contraceptive efficacy.
- ◆ *Lea's Shield®* should not be left in the vagina for more than 48 hours without removing and washing it.
- ◆ *Lea's Shield®* should be replaced if it shows signs of being worn or damaged such as holes, tears or other deterioration, e.g. discoloration of the *Lea's Shield®*. Such changes in the material could cause injury to the woman or her partner, or increase the risk of pregnancy.
- ◆ Patients should be counseled to consult a health care professional before using the *Lea's Shield®* in the following situations:
 - If she is not able to properly insert the *Lea's Shield®*, because improper insertion and placement of the device may decrease its effectiveness as a contraceptive.
 - If she or her partner feels, or is made uncomfortable by the presence of the *Lea's Shield®*.
 - If she or her partner experiences any pain during or following use of the *Lea's Shield®*. Pain may come from incorrect *Lea's Shield®* insertion, an abnormal pelvic condition, constipation or incompatible fit. Pain should be reported immediately to a health care professional.
 - If her partner notices abrasions on his penis, following intercourse using the *Lea's Shield®*. If this occurs, she should consider another form of contraception.
 - If her partner reports a burning sensation within the urethra, develops urinary frequency, perineal pain, penile discharge and/or painful ejaculation. (These could be symptoms or signs of ascending infection, e.g. prostatitis.) He should report these symptoms to his physician. She should consider another form of contraception.

- If the *Lea's Shield*[®] slips out of place when she walks, coughs, sneezes, or strains.
 - If there is blood on the shield when she removes it. Bloody discharge may indicate a medical condition or injury that may lead to a serious illness if it is not treated.
 - If she is unable to remove the *Lea's Shield*[®].
- ♦ **Toxic Shock Syndrome (TSS)** has been linked to menstrual tampon and contraceptive diaphragm use. An association has not been established between the use of *Lea's Shield*[®] and TSS, however this remains a possibility. Symptoms of TSS include sudden high fever (usually 102° or more), vomiting, diarrhea, dizziness, fainting or near fainting when standing up, or a rash that looks like sunburn. Other signs of TSS may include sore throat, weakness, aching of muscles and joints, and redness of the eyes.

If your patient experiences a high fever and one or more of the other TSS symptoms, she should remove the *Lea's Shield*[®] and contact her health care provider immediately.

- Use caution when prescribing the *Lea's Shield*[®] for patients with a prior history of TSS.
- Use of this device may increase the risk of TSS. Counsel patients to immediately report possible signs and symptoms of TSS.
- *Lea's Shield*[®] should not be used during menstruation because it might prevent normal drainage of blood from the uterus or increase the risk of infection such as TSS.

Adverse Events

Sixty percent of subjects in the "Treatment Population (110 of 182 patients) reported at least one adverse event involving the urogenital system. Of these, 34.6% (63 of 182 patients) reported serious and/or unexpected adverse events involving the urogenital system that were possibly or probably related to the *Lea's Shield*[®].

The most commonly reported unexpected complaints related to *Lea's Shield*[®] were:

Adverse Event	Rate
Abnormal bleeding or spotting	6.0%
Male partner pain or discomfort due to the device	8.2%
Female partner genital pain or discomfort due to the device	6.6%
Urinary tract infection	3.8%
Vaginitis	4.4%
Abnormal Pap test	3.9%

Other serious and/or unexpected but less common adverse events included: cervicitis, cervical erosion, superficial injury of vulva and contusion of penis (one case).

SUMMARY OF PIVOTAL CLINICAL TRIAL FOR CONTRACEPTIVE EFFICACY

Purpose: The purpose of this study was to evaluate the contraceptive efficacy of *Lea's Shield*[®] used with and without spermicidal lubricant, and to evaluate the safety and user acceptability of the device.

Study Endpoints: The primary (efficacy) outcome measure was pregnancy. This was measured by urine pregnancy tests and confirmed by physical examination and/or ultrasound. All adverse experiences, grouped by body system, were the primary safety outcome measures. User acceptability was also evaluated by questionnaire and by interview regarding reasons for discontinuation from the study.

Method: The contraceptive efficacy study was a prospective, randomized, double-blinded clinical trial conducted at six investigational sites. One hundred and eighty-two subjects comprised the Treated Population. These subjects were randomized to the *Lea's Shield*[®] with lubricant containing 3% nonoxynol-9 or to *Lea's Shield*[®] with a non-spermicidal lubricant. The sponsor, investigator and subjects were blinded to the lubricant with or without spermicide. One hundred and forty-six patients comprised the Efficacy Population, (patients that contributed effectiveness data) of whom 79 used the *Lea's Shield*[®] with spermicide and 67 used *Lea's Shield*[®] used with non-spermicidal lubricant. Of these, forty were discontinued from the study. Reasons for discontinuation included pregnancy, loss to follow up, device-related reasons, personal reasons unrelated to the device, medical reasons and protocol violations. One hundred and six participants, 59 in the *Lea's Shield*[®] with spermicide group and 47 who used the *Lea's Shield*[®] non-spermicidal lubricant, completed the study by relying on the *Lea's Shield*[®] for contraception for six months without becoming pregnant.

Patient Accountability

Number of Patients	<i>Lea's Shield</i> [®] with Spermicide	<i>Lea's Shield</i> [®] without Spermicide
"Treated Population"	90	92
Nulliparous	17	13
Parous	73	79
"Efficacy Population"	79	67
Discontinued	31	42
Protocol Violation	9	10
Undesired	6	10
Pregnancy		
Device-related	7	6
Personal reason		
Non-device related	2	1
Personal reason		
Medical reasons	1	2
Desired pregnancy	1	0
Unable to contact subject	5	13
Pregnant at Enrollment	0	3
Completed Study (6-months of use without discontinuation)	59	47

One hundred forty six (146) patients contributed to the Efficacy Population. Seventy-nine (79) of these used spermicide and 67 used non-spermicidal lubricant. Of the Efficacy Population, 106 (73%) completed six months of relying on the device for contraception without becoming pregnant: 59 spermicide users and 47 non-spermicide users.

Results

Primary Endpoint: Pregnancy Rates

The unadjusted gross cumulative pregnancy rates per 100 women in the Efficacy Population was 8.7% for spermicide users. The failure rate was higher for the study population that did not use spermicide. The upper limit of the 95% confidence interval for the six-month cumulative pregnancy rate was 16.6%. The 12-months pregnancy rate of 15% with *Lea's Shield®* is a projected rate. The upper limit of the 95% confidence interval for 12 months is 28%.

None of the nulliparous subjects in this study became pregnant. However, the study was too small to conclude that nulliparous women have a lower risk of pregnancy using the *Lea's Shield®* than parous women.

The following table shows pregnancy rates from different studies and various types of contraceptives compared to the *Lea's Shield®*:

Contraceptive Method	Pregnancy Rate After 6-months	Pregnancy Rate After 12-months ¹
‣ Surgical Sterilization ‣ Injectable Hormones ‣ IUDs	Less than 1%	Less than 1%
Hormone pills, vaginal ring	1-2%	1-2%
Male condom	7%	11% ¹
Contraceptive Diaphragm	8%	16.7%
Cervical Cap	11%	17%
Female condom	13%	21% ¹
<i>Lea's Shield®</i>	8.79%	15%

¹ Most barrier studies today are conducted as 6-month studies.

1-year rates are projected.

Study Endpoint: Device Acceptability

Of the Treated Population in the Pivotal Study, 13.4% reported difficulty with insertion of the *Lea's Shield®* and 11.1% reported difficulty with removal. Eleven percent reported that the device rotated during use. In this survey, 12.8% reported that their partner could feel the device during intercourse.

OTHER CLINICAL INVESTIGATIONS OF LEA'S SHIELD®

Microbiology and Colposcopy Study

The purpose of this study was to evaluate additional safety data for the *Lea's Shield®*. In particular, the study objectives were to study evidence of vaginal and cervical irritation following 8

weeks of *Lea's Shield®* use (for at least 12 coital acts), and to study changes in vaginal and cervical flora.

There was an increase in colony-forming units (CFU) of vaginal bacteria at the final visit compared to the enrollment visit. Increases in the CFUs in the vagina were observed for anaerobic Gram (-) rods (5.1×10^4 to 1.9×10^7), *Enterococcus* species (4.0×10^4 to 2.3×10^7), and *E. coli* (none to 1.8×10^8) between enrollment and the final visit. Vaginal *Gardnerella vaginalis* CFUs also increased from enrollment to 8 weeks.

The effect of the *Lea's Shield®* on the tissue of the vulva, vaginal fornices, vaginal walls and cervix were evaluated by analysis of new colposcopic findings seen at follow up. These product-related abnormal findings were primarily erythema and peeling of the superficial epithelium. There was one case of scaling of the labia majora and grossly apparent vulvar edema, and a case of petechiae (disrupted blood vessels) in two subjects who were discontinued from the study. There were no reports of deep epithelial disruption.

Seventy percent of the cases involved the cervical epithelium, 20% involved the vaginal fornices and 15% involved the external genitalia.

PATIENT SELECTION

Best results can be expected from highly motivated, compliant patients.

FITTING INSTRUCTIONS

The Instructions for Use should be followed (see below) during the initial fitting procedure. This is best done by the patient with clinician observation and, if needed, assistance, until the patient can demonstrate competence in device insertion and removal prior to its actual use during intercourse.

The device may be considered correctly in place when the insertion instructions have been correctly followed, the device is comfortable for the patient, the cervix is covered, and the removal loop does not protrude from the introitus.

If a *Lea's Shield®* device is to be used for fitting patient, be sure to clean the device (following the Instructions for Use, Care of the Device) and sterilize (autoclave, 121°C for 15 minutes) the "fitting device" between patients.

PATIENT COUNSELING

Patients should be advised that *Lea's Shield®* does not afford protection from sexually transmitted diseases.

It is recommended that patients have a back-up form of contraception available while they and their partner are learning how to use the *Lea's Shield®* in the event that they are not able to use the *Lea's Shield®* for contraception.

Patients should be advised that the *Lea's Shield®* is a single-patient use device and may not be shared with other users.

Reference

Mauck C, Glover LH, Miller E, Allen S, Archer DF, Blumenthal P, Rosenzweig BA, Dominik R, Sturgen K, Cooper J, Fingerhut F, Peacock L, Gabelnick HL. Lea's Shield: a study of the safety and efficacy of a new barrier contraceptive used with and without spermicide. Contraception 1996; 53:329-335.

INSTRUCTIONS FOR USE

INSERTION

Step 1: Wash hands before handling and inserting the device. Insert *Lea's Shield®* in advance prior to each act of intercourse.

Preparation:

Step 2: A total of about two teaspoons of commercially-available spermicide will be needed to coat the device. First, coat the inside of the bowl. **Do not fill the bowl.** Form a circle around the hole in the bowl.

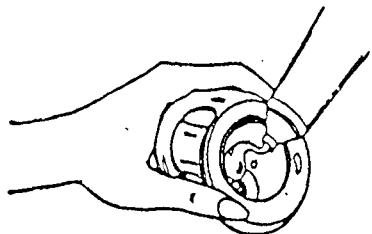


Figure 1. Coating inside of bowl with spermicide.

Step 3: Apply a small amount of gel along the leading edge of the bowl (the part away from the loop) to make insertion easier.

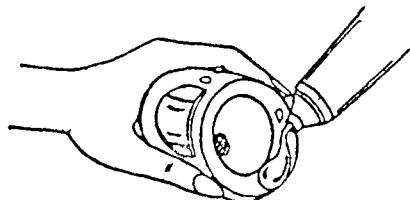


Figure 2. Coating leading edge of bowl with spermicide.

Step 4: Apply small amount of spermicide gel along the outer part of the valve, as seen in Figure 3.

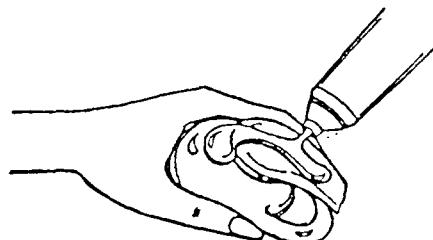


Figure 3. Coating valve with spermicide.

Insertion Positions for *Lea's Shield®*

Position 1: Leg-up Method

For right-handed user, raise left foot, placing it on a stool, and then bend forward slightly. If user is left-handed, raise right foot.

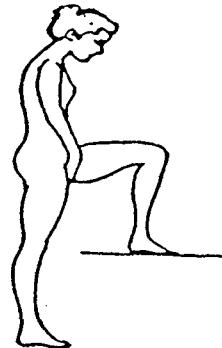


Figure 4. Leg-up position.

Position 2: Reclining

The patient may prefer to insert the shield while in a semi-reclining position.

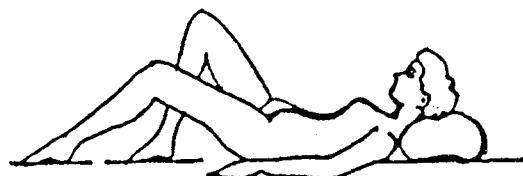


Figure 5. Semi-reclining position.

Step 5: Press the rims on each side of the bowl together between thumb and index finger. The fully compressed *Lea's Shield®* will shape itself into a slim half egg (as in Figure 6).

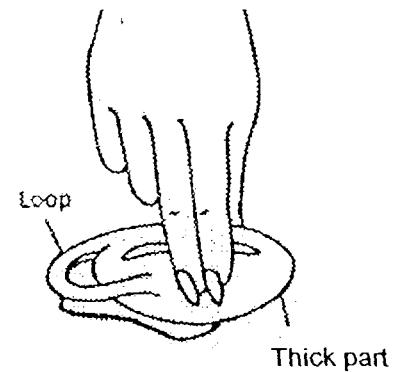


Figure 6. Compressing *Lea's Shield®* prior to insertion.

Lea's Shield® is now ready for insertion. **Note:** Insert the part opposite the loop (i.e. the thickest part) first.

Step 6: While holding the *Lea's Shield®* with the "Valve" facing DOWNWARD and the loop outward (as in Figure 7), use the fingers to insert the folded *Lea's Shield®*.

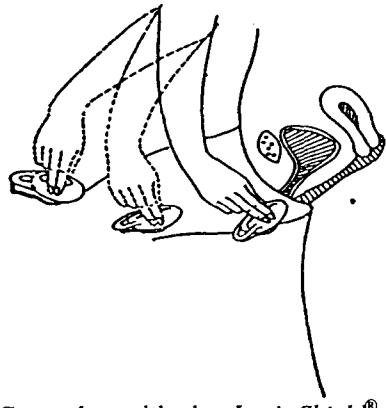


Figure 7. Correctly positioning *Lea's Shield®* for insertion.

Step 7: Insert *Lea's Shield®* into the vagina, pushing it upward as far as it will comfortably go past the opening of the vagina. This can be done by placing the index finger on the body of the device and pushing in. The concave aspect of the bowl should be facing anteriorly when the device is inserted. It now sits over the cervix.

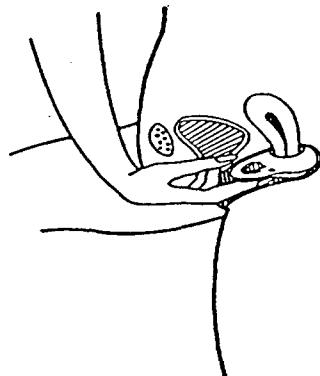


Figure 8. Pushing *Lea's Shield®* into upper part of vagina.

While pushing the device in, the patient might feel air venting out. This is normal. (For proper positioning, all of the air between the cervix and the device must be vented through the valve to create the proper seal. Other things the patient can do to remove air are: (1) pressing on the valve several times; and (2) walking a few steps.)

Step 8: Make sure that the loop is not sticking out of the vaginal opening; if it is, simply push it in further.

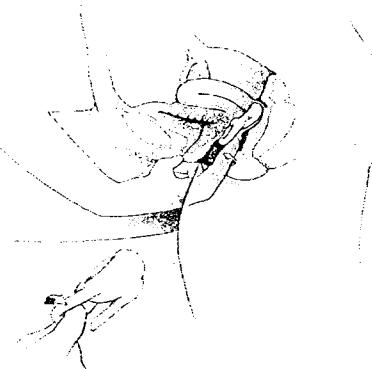


Figure 9. Ensuring that *Lea's Shield®* is as far up into the vagina as it can go.

REMOVAL

The device must **NOT** be removed sooner than eight hours after the most recent sexual intercourse. This time interval is crucial because to remove it earlier may allow any remaining live sperm to enter the womb, thereby increasing the chances of pregnancy.

CAUTION: While removing the device, the patient should be careful to avoid scratching the vagina with a fingernail.



Step 9: When preparing to remove the *Lea's Shield®* the patient should try to relax the muscles of the pelvic floor. With muscles relaxed, she should insert the index finger and grasp the loop (see Figure 10). Once the finger is holding the loop (from above or below), **TWIST UNTIL THE SUCTION IS BROKEN (popping sound)**. Once the suction has been broken, pull down and out with a gentle twisting motion, if needed.

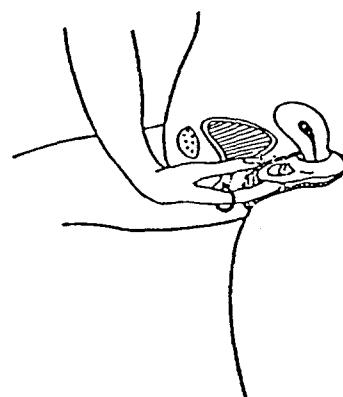


Figure 10. Breaking the suction by twisting, prior to pulling out *Lea's Shield®*.

During removal, if the vaginal muscles seem to hold the *Lea's Shield®* tightly, have the patient bear down as during Valsalva to ease removal. Squatting is probably the best position to remove the device (see Figure 11).

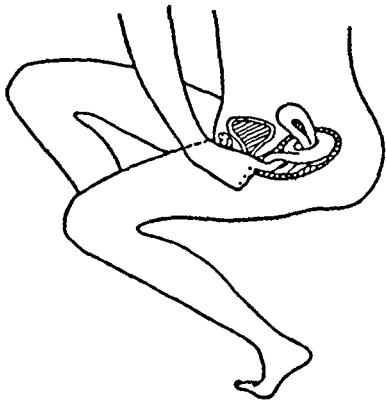


Figure 11. Squatting position.

If for any reason the patient can't find the loop, the suction can be broken by using the thumb and the index finger as shown in Figure 12. The squatting position helps to bring the device downward allowing the thumb to go into the bowl of the device. This method can also assure easy breakage of the suction (seal).



Figure 12. Breaking the suction without using the loop.

Patient Follow-Up:

- The frequency of return visits should be determined on a case-by-case basis, depending on patient motivation and compliance.
- A two-week follow-up visit after prescribing is recommended. Have the patient wear the *Lea's Shield®* to the office and confirm that the device is in the correct position.
- During each follow-up visit, the vagina should be carefully inspected for evidence of pressure or allergic reaction. Patient should be questioned concerning any discomfort during coitus.
- Have the patient report any pain experienced by her or by her partner.
- Have the patient use the *Lea's Shield®* every time she has intercourse.
- After 8 hours have past since the last act of intercourse, have the patient remove and wash the *Lea's Shield®* with mild soap and water.

- Do not recommend wearing the *Lea's Shield®* more than 48 hours.

Care of the Device:

Lea's Shield® is a medical grade silicone material, that is compatible with water-based cleaning agents, lubricants, and with commercially available spermicidal gels.

- ◆ To clean the *Lea's Shield®*, use two pumps of mild liquid soap and wash for approximately two minutes. A COTTON TIP APPLICATOR CAN BE USED TO CLEAN THE AREA OF THE VALVE THAT MIGHT BE DIFFICULT TO REACH WITH A FINGER.
- ◆ Rinse under tap water for one minute. Visually inspect the *Lea's Shield®* for debris, and repeat the cleaning procedure if necessary. Then dry it with a towel. Store it in the pouch provided.
- ◆ *Lea's Shield®* should be replaced if it shows signs of wear and tear or deterioration.

IMPORTANT INFORMATION

- Latex condoms for men are highly effective at preventing sexually transmitted infections (STIs) including AIDS (HIV infection), if used properly. However, use of *Lea's Shield®* will not reduce the risk of STIs.
- For contraceptive purposes, *Lea's Shield®* only works when you use it. Use it every time you have sex.
- Before trying *Lea's Shield®* patients should read the directions and be instructed in its proper use.
- Each patient should be counseled that if intercourse occurs within 8 hours of the 48-hour maximum, she should remove the *Lea's Shield* during a "safe" interval (i.e. when more than 8 hours have elapsed since the last intercourse) and clean it. She should then reapply spermicide and reinser the *Lea's Shield®* prior to intercourse. Reinsertion resets the clock on the maximum wear time.
- While a couple is becoming accustomed to use of the *Lea's Shield®*, they may wish to have a back-up form of contraception available, such as a condom, while they and their partner are learning how to use the *Lea's Shield®* in the event that they are not able to not to use the *Lea's Shield®* for contraception. If necessary, they may wish to discuss Emergency Contraception with her doctor.

For further information, contact:



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Lea's Shield®

USER MANUAL

For your information after your doctor or health care provider prescribes Lea's Shield® for you.

Before using your Lea's Shield® read the entire booklet, even if you are sure you know how to use it. If there is anything you do not understand, or if you have further questions, talk to your doctor or health care provider before using Lea's Shield® for contraception.

Lea's Shield® is a "single-patient use" device that may be re-used, after cleaning, by its owner. It is unsafe for more than one woman to use the same Lea's Shield®.

Introduction

This booklet is to allow you to become familiar with the Lea's Shield® and its usage. The instructions in this booklet are suitable for most women, however, you should also pay attention to any specific instructions and techniques that are recommended by your doctor or health care provider based on his/her expertise with this method of contraception.

Indication for Use

The Lea's Shield® is indicated for use by women of child-bearing age who desire to prevent or postpone pregnancy.

Contraindications

If you believe you have an injury (such as a cut) or infection of the uterus, vagina, or external genitalia, do not use Lea's Shield®.

Using a device such as the Lea's Shield® under these circumstances could make such problems serious and more difficult to treat. Call your doctor for medical advice and/or alternative contraceptive.

Warnings

- Lea's Shield® is a "single-patient use" device that may be re-used, after cleaning, by its owner. It is unsafe for more than one woman to use the same Lea's Shield®.

- Contact your doctor if you notice a foul odor while the device is in place, or if the Lea's Shield® has a bad odor upon removal. This odor might be a sign of a serious infection.
- Use of Lea's Shield® may increase your chance of contracting an infection of the urinary tract caused by E. coli or vaginal infection.
- Patients with a history of sensitivity to spermicide or silicone should consider another form of contraception.
- Use of the Lea's Shield® will not help to reduce the risk of transmission of sexually transmitted infections (STIs). If you are at increased risk for STIs you should consider an alternative form of contraception.
- Lea's Shield® should be used with a spermicide containing Nonoxytol-9. Studies have shown that Nonoxytol-9 is an epithelial irritant that may increase risk of injury to vagina, especially in women who use it frequently.
- Do not use Lea's Shield® for contraception if you have recently been pregnant (within 4-6 weeks) because the opening of the uterus is larger during this time, making it easier for you to become pregnant while using this device. The safety and effectiveness of the use of Lea's Shield® during these periods have not been established.
- Do not remove the Lea's Shield® for at least 8 hours after your most recent sexual intercourse. Removing it within eight hours after your last intercourse may allow live sperm to enter your womb and increase your chances of becoming pregnant.
- Do not leave Lea's Shield® in the vagina for more than 48 hours without removing and washing the device because it might cause infection or damage the lining of the vagina.
- Dispose of your Lea's Shield® if it shows signs of wear and tear or is damaged. If you use a damaged or worn Lea's Shield®, you may increase your chances of injury to you or your partner and you may increase your chances of becoming pregnant.
- In the following situations, you should consult your doctor or health care provider before using the Lea's Shield®:
 - Do not use the Lea's Shield® if you are not able to insert it because if it is not in place the effectiveness as a contraceptive may decrease.
 - Do not use the Lea's Shield® if you or your partner is made uncomfortable by the presence of the device.
 - If you experience any discomfort or pain while the Lea's Shield® is in place Pain may come from incorrect Lea's Shield® insertion, an abnormal pelvic condition, constipation or incompatible fit. Depending on the cause for this discomfort, your chances of becoming pregnant could increase.
 - If your partner notices a sore on the penis following intercourse using the Lea's Shield®. This could possibly lead to a penile injury (although this is not known to have occurred). If this occurs, you should consider another form of contraception.
 - If your partner reports frequent urination, a burning sensation in his penis, painful ejaculation, pain in the area between the penis and the anus, and/or penile discharge. He should report these symptoms to his doctor. You should consider another form of contraception.
 - If the Lea's Shield® slips out of place when you walk, cough, sneeze, or strain. Improper fit will increase your risk of pregnancy.

- If there is blood on the Lea's Shield® when you remove it. Bloody discharge may indicate a medical condition or injury that may lead to a serious illness if it is not treated.
- If you are unable to remove your Lea's Shield® or if it fits so tightly that you cannot remove and care for it properly, it is unlikely that Lea's Shield® will be a workable contraceptive device for you.
- Toxic Shock Syndrome (TSS) has been linked to menstrual tampon and contraceptive diaphragm use. An association has not been established between the use of Lea's Shield® and TSS, however this remains a possibility. Symptoms of TSS include sudden high fever (usually 102° or more), vomiting, diarrhea, dizziness, fainting or near fainting when standing up, or a rash that looks like sunburn. Other signs of TSS may include sore throat, weakness, aching of muscles and joints, and redness of the eyes. If your patient experiences a high fever and one or more of the other TSS symptoms, you should remove the Lea's Shield® and contact your health care provider immediately.

- You may want to consider another form of contraception if you have a prior history of TSS.
- You should not use Lea's Shield® during menstruation because it might prevent normal drainage of blood from the uterus or increase the risk of infection such as TSS.

HOW THE Lea's Shield® WAS TESTED

One hundred and seventy-nine volunteer couples used Lea's Shield® for up to six months as their only method of contraception. Half of these couples used Lea's Shield® with a lubricant containing a spermicide. The other half of the participants used a non-spermicidal lubricant.

Some couples voluntarily withdrew from the study and some were dismissed from the study by the investigators for reasons related to the rules for participation.

One hundred and forty six couples contributed data that can be "counted" in the study. Of these, there were seven pregnancies out of 79 couples who used Lea's Shield® with spermicide, for a pregnancy rate of 8.7%. There were ten pregnancies out of 67 couples who did not use spermicide, for a cumulative six-month pregnancy rate of 12.9%. Therefore, better contraceptive efficacy was achieved by the couples who used spermicide.

EXPECTED PERFORMANCE AS A CONTRACEPTIVE DEVICE

During a clinical study of couples who used the Lea's Shield® for contraception for six months, there was a 8.7% pregnancy rate. However, because of the small study size, the six-month pregnancy probability may truly be as high as 16.6%. The pregnancy rate at one year has been estimated to be 15%, although this one-year rate could be as high as 28%.

To help you decide what type of contraceptive is best for you, the following table lists one-year pregnancy rates for some of the products currently available.

Contraceptive Method	Pregnancy Rate After 12-months ¹
• Surgical Sterilization	Less than 1 %
• Injectable Hormones	
• IUDs	
• Implantable	
Hormone pills, vaginal ring	1.2 %
Male condom	11 %
Contraceptive Diaphragm	16.7 %
Cervical Cap	17 %
Female condom	21 %
Lea's Shield®	15 %

¹ Most barrier studies today are conducted as 6-month studies. 1-year rates are projected.

There are large differences in these one-year pregnancy rates. That does not mean that methods with higher pregnancy rates are not beneficial. The availability of different methods is important so that the needs of all women desiring contraception can be met. For example, some women can't take hormones because of medical reasons or because they smoke. Also, some women prefer to use condoms because they provide some protection from sexually transmissible infections.

You should discuss the risks and benefits of these methods with your doctor and choose which one best suits your needs. Remember that consistent and correct use will help you achieve maximum efficacy with all of these methods.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR FAMILY PLANNING HEALTH CARE PROVIDER.

Instructions for Use for Lea's Shield®

A. WHEN TO INSERT AND REMOVE Lea's Shield®

There are several rules that must be followed regarding how long you should leave the Lea's Shield® in place.

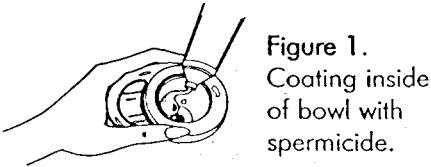
1. You must leave Lea's Shield® in place for at least 8 hours after your most recent sexual intercourse. Removing it within eight hours after your last intercourse may allow live sperm to enter your womb and increase your chances of becoming pregnant.
2. If eight hours or more have passed since you had your most recent intercourse, you may remove the Lea's Shield® and wash it. Be sure to reinsert Lea's Shield® with spermicide prior to your next act of intercourse.
3. If you wish, you may leave the Lea's Shield® in the vagina for a maximum continuous wear time of 48 hours. Wearing Lea's Shield® for longer than 48 hours could cause serious injury and/or infection to the tissues of the vagina, cervix and uterus.
4. If you think you might have intercourse during the last 8 hours of this 48-hour period, remove the Lea's Shield® during a safe time (i.e. more than 8 hours since the last intercourse) and wash it. Prior to intercourse, reapply spermicide and reinsert it into the vagina. Doing this will reset the 48-hour clock for the maximum wear time.

B. INSERTION

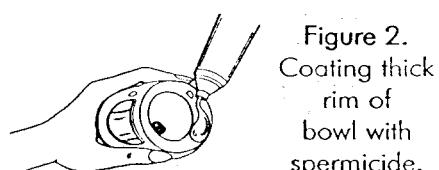
Step 1: Wash your hands before handling and inserting the device. Insert Lea's Shield® in advance every time you have sex.

Preparation:

Step 2: You will need approximately two teaspoons full of commercially available spermicide to coat the Lea's Shield®. First, coat the inside of the bowl with commercially available spermicidal gel. Do not fill the bowl. Form a circle around the hole in the bowl. If you use too much gel the insertion will be slippery and messy



Step 3: Apply a small amount of gel along the thickest part of the bowl (the part away from the loop) to make insertion easier. Do not apply gel where your fingers hold the device.



Step 4: Apply small amount of spermicide gel along the outer part of the valve, as seen in Figure 3.



Insertion Positions for Lea's Shield®

Position 1: Leg-up Method

If you are right-handed, raise your left foot, placing it on a stool, and then bend forward slightly. If you are left-handed, raise your right foot.

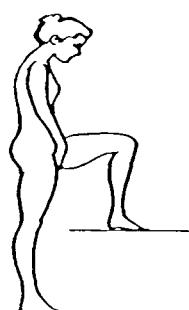


Figure 4. Leg-up position.

Position 2: Reclining

You may prefer to insert the shield while in a semi-reclining position.

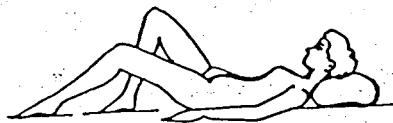
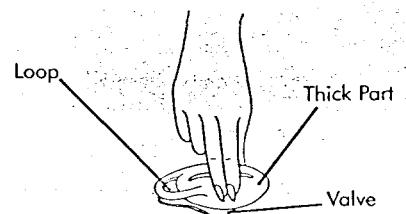


Figure 5. Semi-reclining position.

Step 5: Press the rims on each side of the bowl together between your thumb and the index finger. The fully compressed Lea's Shield® will shape itself into a slim half egg (as in the figure).



Lea's Shield® is now ready for insertion. Note: Insert the part opposite the loop (i.e. the thickest part) first.

Step 6: While holding the Lea's Shield® with the "Valve" facing DOWNWARD and the loop outward (as in Figure Below), use the fingers to insert the folded Lea's Shield®.

WARNING: Do not insert Lea's Shield® sideways or upside down. If Lea's Shield® is sideways or upside down, you have a much greater chance of getting pregnant.

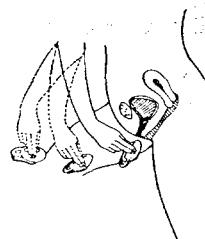


Figure 7. Correctly positioning Lea's Shield® for insertion.

Step 7: Insert Lea's Shield® into the vagina, pushing it upward as far as it will comfortably go past the opening of the vagina. This can be done by placing the index finger on the body of the device and pushing in. It now sits over the cervix.

While pushing the device in, you might feel air venting out. This is normal. (For proper positioning all the air between the cervix must be vented through the valve to create the proper

seal. Other things you can do to remove air are pressing on the valve several times or walking a few steps.)

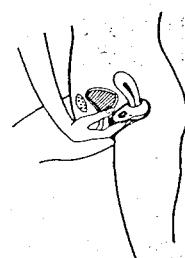


Figure 8. Pushing Lea's Shield® into upper part of vagina.

Step 8: Make sure that the loop is not sticking out of the vaginal opening; if it is, simply push it in further

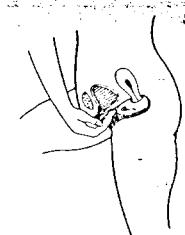


Figure 9. Ensuring that Lea's Shield® is as far up into vagina as it can go.

C. REMOVAL

The device must NOT be removed sooner than eight hours after you last had sex. This time interval is crucial because to remove it earlier may allow any remaining live sperm to enter your womb, and increase your chances of getting pregnant.

CAUTION: While removing the device be careful to avoid scratching your vagina with your fingernail.

Step 9: To remove the Lea's Shield®, insert your index finger and grasp the loop (see Figure 10). Once the finger is holding the loop (from above or below), **TWIST UNTIL THE SUCTION IS BROKEN** (popping sound). Once the suction has been broken, pull down and out with a gentle twisting motion, if needed.



Figure 10. Breaking the suction by twisting, prior to pulling out Lea's Shield®.

During removal, if the vaginal muscles seem to hold the Lea's Shield® tightly, bear down as you would during a bowel movement to ease the removal

of the device. Squatting is probably the best position to remove the device (see Figure 11).

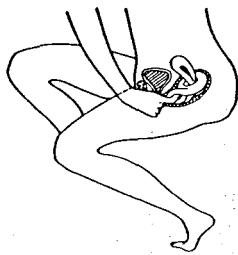


Figure 11.
Squatting
position.

If for any reason you can't find the loop, the suction can be broken by using the thumb and the index finger as shown in Figure 12. The squatting position helps to bring the device downward allowing the thumb to go in the bowl of the device. This method can also assure easy breakage of the suction (seal).



Figure 12.
Breaking
the suction
without using
the loop.

ANSWERS TO COMMONLY-ASKED QUESTIONS REGARDING Lea's Shield®

Question 1. When should I insert my Lea's Shield®?

Answer. Lea's Shield® can be inserted anytime prior to intercourse, but must be left in place at least eight hours after sex.

Question 2. Can I douche with the Lea's Shield® in place in the vagina?

Answer. Douching may be performed after removal, but it is not recommended because the effect of douching on the contraceptive efficacy of Lea's Shield® is not known. Also, douching has been associated with pelvic infection.

Question 3. What should I do if the Lea's Shield® becomes dislodged in my vagina?

Answer. Simply push the device back into place. If you believe the device has been displaced during sex, you should not remove the device for at least eight hours following intercourse. If it has been more than eight hours since you had intercourse, you should remove it. After cleaning, it may be re-inserted prior to next intercourse.

Question 4. How often should I use the Lea's Shield®?

Answer. Use the device for every sex act. You should not use the Lea's Shield® during menstruation because of the possible risk of TSS.

Question 5. Do I have to use spermicide with Lea's Shield®?

Answer. It is recommended that you use spermicide as directed with the Lea's Shield®. The reason for this is that the clinical study conducted to see how well the Lea's Shield® works to prevent pregnancy showed that it works better when it is used in combination with spermicide containing Nonoxynol-9. This can be purchased from your pharmacy without a prescription.

D. CARE OF Lea's Shield®

Lea's Shield®, is a medical grade silicone material that is compatible with water-based ~ cleaning ~ agents, lubricants, and with commercially available spermicidal gels.

- ◆ To clean the Lea's Shield®, use two pumps of mild liquid soap and wash for approximately two minutes. YOU CAN USE A COTTON TIP APPLICATOR TO CLEAN THE AREA OF THE VALVE THAT MIGHT BE DIFFICULT TO REACH WITH A FINGER.
- ◆ Rinse under tap water for one minute. Visually inspect the Lea's Shield® for debris, and repeat the cleaning procedure if necessary. Then dry it with a towel. Store it in the pouch provided.
- ◆ Lea's Shield® should be replaced if you notice signs of wear or deterioration.

IMPORTANT INFORMATION

- ◆ Latex condoms for men are highly effective at preventing sexually transmitted infections (STIs), including AIDS (HIV infection), if used properly. However, use of Lea's Shield® will not reduce the risk of STIs.
- ◆ For contraceptive purposes, Lea's Shield® only works when you use it. Use it every time you have sex.
- ◆ Before you try Lea's Shield® be sure to read the directions and learn how to use it properly.

◆ In the event that you and your partner decide not to use the Lea's Shield®, you may wish to have a back-up form of contraception available, such as a condom, if the device is not used for contraception. If necessary, you may wish to discuss Emergency Contraception with your doctor.

◆ Lea's Shield® must be left in place for a full 8 hours after intercourse for maximum contraceptive efficacy. The Lea's Shield® may be left in place safely for a maximum of 48 hours. If intercourse occurs within 8 hours of the 48-hour maximum, remove the Lea's Shield® during a "safe" interval (i.e. when more than 8 hours have elapsed since the last intercourse) and clean it. You should then reapply spermicide and reinsert the Lea's Shield® prior to intercourse. Reinsertion resets the clock on the maximum wear time.

For further information, contact:

Yama, Inc.

Union, NJ 07083

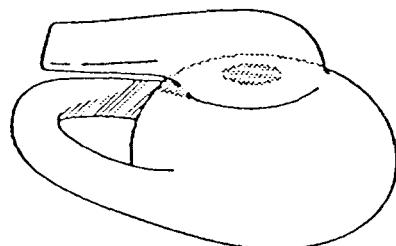
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