STERILE SILICONE PESSARY

EN

INSTRUCTIONS FOR USE – STERILE PESSARY DEVICE
USE PERMITTED FOR MEDICAL PERSONNEL ONLY

1. INTRODUCTION

First of all, we would like to thank you for choosing a For.me.sa. product. The medical device purchased has been manufactured in compliance with the applicable Regulations concerning the safety of products intended for medical use. This document has been prepared in order to provide general information about the device and to provide instructions for use, maintenance and storage requirements necessary for its correct handling.
Carefully read these instructions for use at the time of purchase and BEFORE USING the device. Keep these instructions for future reference.

2. OBLIGATIONS OF MEDICAL PERSONNEL

The device must be used SOLELY AND EXCLUSIVELY BY QUALIFIED AND AUTHORIZED MEDICAL PERSONNEL.
Medical personnel MUST MANDATORILY provide the patient with the instructions for use, if they are not already clearly in the patient's possession.
Before, during and after insertion of the device, all actions and behaviours consistent with medical and healthcare procedures must be observed. Operate in a suitable environment. Clearly explain to the patient every activity that must subsequently be carried out in order to correctly maintain the device in position, including any periodic follow-up examinations deemed appropriate.
Use the device in compliance with applicable laws and according to its intended purpose (see also section 4).

3. DEVICE IDENTIFICATION

For.me.sa. identifies the device by means of labelling affixed directly to the device or to the packaging containing it. Keep such references readily available.
For greater safety, before proceeding with use of the device, the medical personnel (or the patient) must write down, in the space below, the batch number indicated on the specific label.
Batch No. _____
Explanation of certain symbols appearing on the labelling:

LOT **AB123**	Indicates the LOT number to which the specific device refers.
	Indicates that the user/patient must READ and UNDERSTAND the INSTRUCTIONS FOR USE before use.
 **AAAA-MM**	Indicates the expiration date of the device to the user. After this date, the device must be replaced with a newly manufactured one or one whose expiration date has not passed.
STERILE EO	Indicates that the device has been sterilized with Ethylene Oxide.

4. INTENDED PURPOSE

The Pessary is intended to be used to support the containment of uterine prolapse in adult female patients of any age affected by grade II prolapse or higher.

Continuous use of the device is permitted for a maximum period of 6 months, subject to periodic evaluation by the attending gynecologist.
The device is intended for SINGLE-PATIENT USE.
Observe the contraindications described in section 5; any other uses not expressly indicated herein shall be considered improper and therefore PROHIBITED.

5. CONTRAINDICATIONS

Use of the Pessary is contraindicated in the following conditions:

- Known allergy to silicone and/or natural rubber
- Impairment of the immune system
- Presence of thromboembolic disorders
- Presence of recurrent urinary tract infections
- Presence of frequent vaginal infections and recurrent episodes of vaginal bleeding
- Presence of abrasions or lesions of the vaginal mucosa

Do not use the device in pregnant or breastfeeding women.
Use of the pessary is not permitted in patients under 18 years of age.
Do not reuse the device on another patient. This device is intended for single-patient use.
It is prohibited to use the device for a period longer than 6 months.
Do not use the device in combination with or as part of other medical devices.
It is prohibited to modify or alter the components and/or characteristics of the device.
Use of the pessary is not compatible with certain vaginal medications. In particular, the concomitant use of estrogen-based vaginal creams or ovules, spermicides, oil-based antifungals, oil-based lubricants and topical antibiotics may alter the device material or increase the risk of irritation and infections.
Reuse of the device on the same patient without first cleaning the device is prohibited. Do not use the device if the packaging is damaged.

6. PRECAUTIONS AND WARNINGS FOR MEDICAL PERSONNEL AND THE PATIENT

Any counterfeiting and/or improper use shall be prosecuted according to applicable law.

- Strictly comply with the intended purpose of the device.
- Use of the device may, at the discretion of the attending physician, require periodic check-ups.
- Carefully follow the instructions provided by qualified medical personnel.
- Continuous use of the Pessary device is permitted for a maximum period of 6 months, subject to periodic evaluation by the attending gynecologist. During this period, the device is considered safe and effective if used according to the instructions for use provided by the manufacturer. After 6 months of use, the device must be disposed of.
- If treatment requires a period longer than 6 months, a new Pessary must be used.
- Before use, the device must be cleaned as indicated in section 12.
- In the event of any abnormal sensation of discomfort not previously indicated or explained by medical personnel, immediately consult the attending healthcare professional.
- Before reusing the device, wash it using lukewarm water and mild soap, then rinse with saline solution, as indicated in section 12.

Use of the Pessary may cause the following side effects:

- Allergic reaction to latex and/or natural rubber
- Sensation of discomfort
- Displacement of the Pessary
- Vaginitis
- Bacterial vaginosis
- Increased vaginal discharge

    - Vaginal pain
    - Abrasions of the vaginal mucosa and bleeding
- Select the correct size based on professional experience in the field: incorrect and/or unsuitable sizes may not provide the expected benefits.
- Do not leave the device unattended before use and do not place it on hot surfaces or surfaces with edges or sharp parts, but only on inert surfaces having the required level of hygiene.
- Do not attempt to repair a damaged device; in such cases, the device must be disposed of as indicated in section 13.
- Any serious incident occurring in relation to the medical device supplied by us must be reported to the manufacturer and to the competent authority of the Member State in which the user is established.

7. STORAGE AND PRESERVATION

The device is supplied in a medical-grade paper pouch that guarantees maintenance of sterility prior to use.

To ensure correct long-term preservation, it is recommended to always use the original packaging and to store the device in a dry environment at temperatures between +1°C and +40°C, away from direct heat sources, protected from dust and harmful materials and out of the reach of children. Avoid placing excessive weight on the device and do not subject it to mechanical stress.

8. PACKAGE CONTENTS

The package contains the pessary medical device sterilized with Ethylene Oxide and these instructions for use.

9. PRELIMINARY CHECKS BEFORE USE

Before unpacking, verify that the device is intact and sealed inside the specially designed polyethylene pouch. If damaged parts are present, DO NOT USE the device and contact the device retailer directly. For any clarification, always consult your trusted pharmacist/physician.

Before use, verify that the device:

- is intact and undamaged (e.g. presence of cracks, dents, tears).
- has not changed colour and shows no uneven discolouration, surface mould or similar signs; if any of these are present, DO NOT USE THE DEVICE AND REPLACE IT IMMEDIATELY.

IMPORTANT!!! A whitish surface coloration caused by the protective talc film, or equivalent product, used during the manufacturing process is not indicative of poor storage conditions or a damaged product.

10. CHARACTERISTICS

Device validity if used normally: see labeling			
SINGLE-PATIENT device	**YES**	Medical device class	**II b**
Device supplied STERILE	**YES**	CUSTOM-MADE device	**NO**

Ø Diameter in mm											
SIZE	50	55	60	65	70	75	80	85	90	95	100

11. PRELIMINARY OPERATIONS BEFORE USE

The medical device is supplied sterile; therefore, the responsible medical personnel must apply the device to the patient while observing the fundamental hygiene practices listed below:

- wash hands with disinfectant solution
- wear clean gloves
- proceed with the insertion operations described below

The Pessary must be inserted as follows:

1. Pass beyond the vaginal introitus.
2. Fold the ring into an elliptical shape to facilitate insertion.
3. Position around the cervix.

Do not insert the device if it falls out of the packaging or if the packaging is not intact.

12. CLEANING (WASHING) AFTER FIRST USE

The sterile pessary is supplied in sterile packaging and must not be washed before first use, i.e. upon opening of the package.
Washing is permitted exclusively if the device is removed for inspection and subsequently reinserted. In such cases, clean the device with lukewarm water and mild soap, then rinse with saline solution.
For cleaning operations, use only soft sponges; do not use brushes or other abrasive tools that could alter or damage the surface of the device.
Do not use alcohol, solvents, acids or other liquids potentially capable of compromising the integrity of the material.
After cleaning, the device must not be left unattended and must be repositioned immediately in the vaginal cavity.
If necessary, the device may be sterilized in a steam autoclave for a maximum of two consecutive cycles set at 121°C for 15 minutes.

13. DISPOSAL

Dispose of the device at the end of use in compliance with local waste disposal regulations. No toxic substances are present. The components of the device, as previously stated, are made of silicone.