PESSARY

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INSTRUCTIONS FOR USE – PESSARY DEVICE - NON-STERILE
USE PERMITTED ONLY BY MEDICAL PERSONNEL

1. INTRODUCTION

First of all, we would like to thank you for choosing a For.me.sa. product. The purchased medical device has been manufactured in compliance with all applicable regulations regarding product safety for medical use. This document has been prepared in order to provide general knowledge of the device and to offer instructions for use, maintenance rules, and storage guidelines necessary for its proper 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 ONLY AND EXCLUSIVELY BY QUALIFIED AND AUTHORIZED MEDICAL PERSONNEL.
Before, during, and after insertion of the device, comply with all actions and behaviours consistent with medical and healthcare methodologies. Operate in a suitable environment. Clearly explain to the patient every activity they will subsequently need to carry out in order to correctly maintain the device in position, including any periodic follow-up visits deemed appropriate.
Use the device in compliance with current laws and according to its intended use (see also section 4).

3. DEVICE IDENTIFICATION

For.me.sa. identifies the device through labeling placed on the device itself or on the packaging containing it. Keep such references in an easily accessible place.
For greater safety, before using the device, medical personnel (or the patient) must transcribe in the space below the batch number found 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.

4. INTENDED USE

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 or higher prolapse.
Continuous use of the device is permitted for a maximum period of 6 months, subject to periodic evaluation by a gynecologist.
The device is considered SINGLE-PATIENT.
Observe the contraindications described in section 5; any other uses not expressly indicated herein are 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 THE STAFF DOCTOR AND THE PATIENT

Any counterfeiting and/or improper use shall be punishable by law.

- Strictly comply with the intended use of the device.
- Use of the device may, at the discretion of the attending physician, be subject to periodic checks.
- Carefully follow the instructions of qualified medical personnel.
- Continuous use of the Pessary device is permitted for a maximum of 6 months, subject to periodic evaluation by the gynaecologist. During this period, the device is considered safe and effective if used according to the instructions 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 feeling of discomfort not foreseen or explained by medical personnel, contact them immediately.
- Before reusing the device, wash it using lukewarm water and neutral soap and 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
  - Feeling of discomfort
  - Displacement of the Pessary
  - Vaginitis
  - Bacterial vaginosis
  - Increased vaginal discharge
  - Vaginal pain
  - Abrasions of the vaginal mucosa and bleeding

- Identify the correct size to use based on professional experience: incorrect and/or unsuitable sizes will 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 with 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 marketed in standard For.me.sa. packaging, which guarantees proper storage before use. To maintain proper preservation over time, it is recommended to always use the original packaging together with a dry environment with temperatures between +1 °C and +40 °C, away from direct heat sources, protected from dust and harmful materials, and out of reach of children. Avoid placing excessively heavy loads on the device and do not subject it to mechanical stress.

8. PACKAGE CONTENTS

The package contains the non-sterile pessary medical device and these instructions for use.

9. PRELIMINARY CHECKS BEFORE USE

Before unpacking, check that the package is intact and sealed inside the specially prepared polyethylene bag. If

damaged parts are present, DO NOT USE the device, but contact the device retailer directly.
For any clarification, always contact your trusted pharmacist/doctor.
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 another equivalent product used during the manufacturing process, is not synonymous with 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	**NO**	CUSTOM-MADE device	**NO**

Material	Diameter in mm										
RUBBER	50	55	60	65	70	75	80	85	90	95	100
SILICONE	50	55	60	65	70	75	80	85	90	95	100

11. PRELIMINARY OPERATIONS BEFORE USE

Perform cleaning before use as defined in section 12 and proceed with insertion as follows:

- Pass beyond the osteo-vaginal opening;
- Fold the ring into an ellipse shape to facilitate insertion;
- Surround the cervix.

12. CLEANING (WASHING) BEFORE USE

Before using the device, wash it using lukewarm water and neutral soap and then rinse with saline solution.
Do not use brushes for washing, but only soft sponges so as not to scratch the surface of the device. Do not use alcohol, solvents, or acids to clean the surfaces of the device, nor liquids that could damage the device.
After cleaning, do not leave the device unattended, but place it immediately in the vaginal site.
The device can be sterilized for first use in a steam autoclave for up to two consecutive cycles set at a temperature of 121°C for 15 minutes.

13. DISPOSAL

Dispose of the device at the end of its use in compliance with local waste disposal regulations. No toxic substances are present.