DESCR.:	**PESSARY** **USE ALLOWED TO TRAINED MEDICAL STAFF ONLY**

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INSTRUCTIONS FOR USE

EN

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1 INTRODUCTION

Thank you for choosing a For.me.sa Srl product.
The Medical Device you have purchased has been manufactured in compliance with all current EEC Directives/regulations on safety of Medical Device for only medical use.
This document has been prepared to supply you with a general description of the Device and its Instructions for use, maintenance, storage and all those information we deemed necessary.
For.me.sa Srl is entitled to make any changes and/or improvements to the production of their Medical Devices.

For.me.sa Srl is not obliged to ensure that these instructions for use and the corresponding symbols on the packaging will be closely followed by the buyer (see also Chapter 3).

Please keep these instructions for use in a safe place for further consultation.

2 DUTIES OF THE MEDICAL STAFF

This Medical Device must be only handled by a qualified medical staff properly trained to use it.
The medical staff MUST ALWAYS give these instructions for use to their Patient in case the Patient does not have them already.
Before, during and after the insertion of pessary, all criteria and behaviors regarding professional procedures and appropriate environment must be respected. Explain clearly to the Patient all the procedures to be followed to keep the medical Device correctly into position, including check-ups you think will be necessary.
Use the medical device according with current regulations and according to its intended use.

3 DEVICE IDENTIFICATION

For.me.sa Srl identifies the Device through a label applied on the item itself or on the package containing it.
Keep these references where they can be easily found.
As a further safety precaution, prior to use, the medical staff (or the Patient) must copy in the space reported below the batch number indicated on the product label.

Lot no.	

Below the symbols description you may find on the product label (instructions to be followed if the SYMBOL is present:

LOT AB123	*It indicates the BATCH number to which the specific Device refers to.*

	*It indicates that the user/Patient must READ and BE AWARE of the INSTRUCTION FOR USE prior to use.*

 YYYY - MM	*It indicates the Device expiry date. If the Device has past its expiration date, it must be replaced by a new one or a Device with a date which has not expired.*

4 INTENDED USE

This Device is meant to be used for uterine prolapse.
Continuous use on the Patient must be fixed by trained medical staff.
Respect all the PROHIBITIONS as indicated in USE NOT ALLOWED (Chapter 5). The Device is not intended for use other than expressly indicated.
Any other different use must be considered as improper and therefore unauthorized. This Device is for SINGLE PATIENT.

4.1 SIDE EFFECTS

The trained medical staff who performs the insertion of the Medical Device must explain possible side effects deriving from its use.

5 USES NOT ALLOWED

Here are a few uses of the Device which are not allowed and therefore should be considered as UNAUTHORIZED:

- Do not use in contact with injured parts (wounds).
- Do not reuse the Device for another Patient.
- Do not use for a longer time than indicated by medical staff.
- Do not use in combination with or as a part of other medical Devices.
- Do not modify or change its components and/or characteristics.
- Do not use of drugs or substances considered as or comparable to drugs, in combination / together with the Device.
- Don't abuse.

6 WARNINGS AND PRECAUTIONS FOR MEDICAL STAFF AND PATIENT

- Any infringements and/or improper use will be prosecuted as prescribed by law.
- Strictly stick to the intended use of the Device (see Chapter 4).
- The use of the Device can be, at the discretion of the medical staff in charge, subject to periodic check up. Stick meticolously to the indications you will receive from the medical staff.
- The Device must be cleansed prior to use (see Chapter 14).
- Use the Device with care.

7 STORAGE

The Device is supplied inside FOR.ME.SA. standard packaging. FOR.ME.SA. guarantees its correct storage prior to use.
For a correct storage of the Device, keep the original packaging in a dry place with a temperature ranging from +1°C to +40°C, not in direct contact with heat sources, sheltered from powders and harmful materials. Keep out of reach of children. Do not pile up heavy object on the Device. Do not expose the Device to mechanical stress.

8 PACKAGE CONTENTS

The medical paper contains the Medical Device in a non-sterile packaging and these instructions for use.

9 PRECAUTIONARY VERIFICATIONS PRIOR TO USE

Before unpacking, make sure that the Device is intact and sealed inside its PE bag which has been specially sealed.
If you think there are damaged parts, DO NOT USE it but refer to the person who sold you the Device.
For any explanations, please address to your Chemist/Medical professional.
Prior to use, make sure that the Device:

- is intact and undamaged (e.g. verify presence of cracks, dents, tearing),
- has not changed colour or take on uneven colourings, does not show surface moulds, etc.

In any of these events, DISCARD the Device and REPLACE IT IMMEDIATELY.
IMPORTANT !!! *A surface whitish colouring does not correspond to a wrong preservation (or a damaged product); it is due to talc, or another equivalent product, on the protective film which has been used during its production.*

10 CHARACTERISTICS

Shelf life of the Device if used correctly: see label.			
ONE PATIENT Device:	**YES**	CLASS of Medical Device	**IIb**
Supplied STERILE:	**NO**	CUSTOM-MADE Device	**NO**

Material	**Diameter (centimeters)**													
RUBBER	50	55	60	63	65	70	75	80	83	85	89	90	95	100
SILICONE	50	55	60	65	70	75	80	85	90	95	100			

11 PREPARATORY PROCEDURES PRIOR TO USE

Perform a cleaning before use as defined in Chapter 14 and insert it in the following way:

1. Exceed the entrance osteo-vaginal;
2. Bend the ring ellipse to facilitate their entry;
3. Circle the neck of the uterus.

12 MEDICAL STAFF PROCEDURES

- Operate in a safe environment and conditions avoiding any potential dangerous situations for operators, the Patient or others.
- Identify the right size to be used relying on the expertise developed on the filed. wrong and/or inappropriate sizes do not lead to expected results.
- Prior to use, do not leave the Device unattended and do not put it on hot surfaces or surfaces with edges or sharp parts. Leave it only on a flat surface which has been duly sanitized.
- Do not try to repair a damaged Device. In this event, discaed the Device as per Chapter 15.

13 INSTRUCTIONS FOR USE FOR THE PATIENT

- Use the Device observing every precaution (obligations, prohibitions, recommendations, etc.) carried out by the medical staff in charge during its insertion.
- The Patient must never intervene on the Device on her own initiative.
- In case of abnormal discomfort not prognosticated or explained by the medical staff, refer immediately to your medical professional.

14 CLEANING (CLEANSING) PRIOR TO USE

- Prior to use, cleanse the Device with tepid water and mild soap, then rinse with a physiologic solution. Do not use brushes during cleansing but only soft sponges so not to scratch the surface of the Device.
- Do not use alcohol, solvents, acids or any other liquids that could damage the surfaces of the Device.
- After cleansing, do not leave the Device unattended but place it immediately into the vagina. This Device, for the first use, is autoclavable up to two consecutive cycles set at 121 ° C for 15 minutes.

15 DISPOSAL

In case of replacement or breaks, dispose of the Device according to local regulations on wastes disposal. Toxic substances are not present.