DESCR.:

PESSARY

USE ALLOWED TO TRAINED MEDICAL STAFF ONLY

MANUFACTURER

for.me.sa. forniture mediche sanitarie

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INSTRUCTIONS FOR USE

ENGLISH

CE 0476
ECC/93/42

1 INTRODUCTION

Thank you for choosing a FOR.ME.SA product. The Medical device you have bought has been manufactured in compliance with all current regulations on safety of products for 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. is entitled to make any changes and/or improvements to the production of their Devices and is not forced these instructions for use carefully UPON PURCHASE of the Device and get used to the symbols on the label (see also Chapter 3). Keep these instructions in a safe place for further consultation.

2 DUTIES OF THE MEDICAL STAFF

The Device must be used SOLELY by 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 insertion, 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 device correctly into position, including check-ups you think will be necessary. Use the device in compliance with current regulations and according to its intended use.

3 DEVICE IDENTIFICATION

FOR.ME.SA 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 below the batch number indicated on the label.

Lot no.	

Here is the description of symbols you may find on the 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 is past its expiration date, it must be replaced by a new one or a device with a date which has not expired.*
STERILE EO	*It indicated the Device it has been sterilized with ethylene oxide.*

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 SINGLE PATIENT.

4.1 SIDE EFFECTS

The trained medical staff who performs the insertion of the 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:

- Use in contact with injured parts (wounds).
- Reuse the Device for another patient.
- Use for a longer time than indicated by medical staff.
- Use in combination with or as a part of other medical devices.
- Modify or change its components and/or characteristics.
- Use of drugs or substances considered as or comparable to drugs, in combination / together with the Device.
- Abuse.
- Reuse in the same patient without performing cleaning device if the packaging is damaged.

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 ups. Stick meticulously to the indications you will receive from the medical staff.
- Before operation make sure that the package is well closed and not damaged.
- Use the device with care.

7 STORAGE

The Device is supplied in medical paper, which guarantees its correct maintenance of sterility prior to use.
For a correct storage if the device, keep the original packaging. Store in a cool and dry place, 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 it contain Medical Device sterilized with ethylene oxide and these instructions for use.

9 PRECAUTIONARY VERIFICATIONS PRIOR TO USE

Before unpacking, make sure that the Device is intact and sealed inside its medical paper which has been specially arranged.
If you think there are damaged parts. NO 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),
- did not change color or take on uneven colorings, does not show surface molds, etc.

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

10 CHARACTERISTICS

Shelf life of the device if used correctly: see label.												
One patient Device:				**YES**	Class of Medical Device							**IIb**
Supplied STERILE:				**YES**	Custom-made Device							**NO**
MEASURES	50	55	60	65	70	75	80	85	90	95	100	

11 PREPARATORY PROCEDURES PRIOR TO USE

The medical device is provided sterile, so the medical professionals should seek to apply the device to the patient respecting basic hygiene practices such as:

- wash your hands with disinfectant solution;
- wear clean gloves;
- proceed with the placing below.

The pessary is inserted operating as follows:

1. exceed the entrance osteo-vaginal;
2. bend the ring ellipse to facilitate their entry;
3. circle the neck of the uterus.

Do not insert the device in the event falling out of its package, or in case the packaging is not integrate.

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, the device must be scrapped 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) TIED TO REUSE THE DEVICE

Prior to re-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 silicon 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. For the reuse, the Device 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.
The constituent parts of the device, as already said, are made of silicone.

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