for.me.sa.
forniture medico sanitarie

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C.F. / P.IVA: IT01714420344
R.E.A. Parma: 173353
Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

REG. N. 3685-A

UNI CEI EN ISO 13485:2016

TECHNICAL DATA SHEET OF THE DEVICE

NATURAL RUBBER PESSARY

REF.		RDM	CND	GMDN
FOR.70.52045	*Ø45*	2192440	U089005	34867
FOR.70.52050	*Ø50*	1945056		
FOR.70.52053	*Ø53*	2192442		
FOR.70.52055	*Ø55*	1945060		
FOR.70.52060	*Ø60*	1945061		
FOR.70.52063	*Ø63*	1945062		
FOR.70.52065	*Ø65*	1945063		
FOR.70.52070	*Ø70*	1945064		
FOR.70.52075	*Ø75*	1945065		
FOR.70.52080	*Ø80*	1945066		
FOR.70.52083	*Ø83*	1945067		
FOR.70.52085	*Ø85*	1945068		
FOR.70.52090	*Ø90*	1945070		
FOR.70.52095	*Ø95*	1945071		
FOR.70.520100	*Ø100*	1945072		

PHOTOGRAPH

GENERAL DESCRIPTION

Device used for the containment of uterine prolapse.
It is an invasive device that penetrates into the body through a natural orifice (and therefore differs from surgical invasive devices); it is not intended to be connected to an active medical device.
The duration of its continuous use must be established by qualified medical personnel.
DEVICE CLASS: IIb

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the polyethylene bag provided.
Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.
N.B.!!! A whitish surface colour caused by the protective film of talcum powder, or an equivalent product, used in the production process should not be considered an indication of poor preservation (or a damaged product).

CLEANING BEFORE USE

Before using the device, wash with warm water and neutral soap and then rinse with saline solution.
To avoid scratching the surface of the device, use soft sponges, not brushes, for washing.
Do not use alcohol, solvents, acids or fluids that could damage the device to clean its surfaces.
After cleaning, do not leave the device unattended, insert it into the vagina immediately. The device can be sterilised for first use in a steam autoclave with up to two consecutive cycles set to a temperature of 121 °C for 15 minutes.

INSTRUCTIONS FOR USE

Compress the ring into an ellipse to facilitate its insertion. Pass the vaginal opening. Place it around the cervix.
Use the device as instructed by the responsible healthcare professionals at the time of insertion.
Never intervene on the device of your own initiative.
Seek medical advice in the event of any unusual discomfort.

MATERIALS

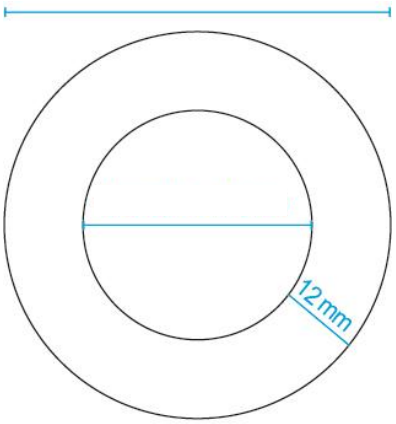
Latex- and phthalate-free natural rubber.

TECHNICAL SPECIFICATIONS

Components	Percentage %	Weight g Natural
rubber	49.45	20.73
Calcium carbonate	48,17	20,19
Zinc oxide	2,17	0,91

Thickness: 12 mm

external diameter
internal diameter



external diameter – thickness =
internal diameter

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical device; in the case of damage the medical device must be disposed of.

PACKAGING

Individually bagged in a box.

STORAGE

The device is placed on the market with the standard For.me.sa. Srl packaging, which ensures its correct storage before use.
For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Fabbricante/ *Manufacturer*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **0476**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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Cod. Destinatario: KRRH6B9

REG. N. 3685-A
UNI CEI EN ISO 13485:2016

TECHNICAL DATA SHEET OF THE DEVICE

SILICONE PESSARY

REF.		RDM	GMDN	CND
FOR.70.51750	*Ø 50*	19867	35237	U089005
FOR.70.51755	*Ø 55*	1160127		
FOR.70.51760	*Ø 60*	1160128		
FOR.70.51765	*Ø 65*	1160129		
FOR.70.51770	*Ø 70*	1160130		
FOR.70.51775	*Ø 75*	1160131		
FOR.70.51780	*Ø 80*	1160132		
FOR.70.51785	*Ø 85*	1160133		
FOR.70.51790	*Ø 90*	1160134		
FOR.70.51795	*Ø 95*	1160135		
FOR.70.517100	*Ø 100*	1160136		

PHOTOGRAPH

GENERAL DESCRIPTION

Device used for the containment of uterine prolapse.
It is an invasive device that penetrates into the body through a natural orifice (and therefore differs from surgical invasive devices); it is not intended to be connected to an active medical device.
The duration of its continuous use must be established by qualified medical personnel. DEVICE CLASS: IIb

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the polyethylene bag provided.
Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.
N.B.!!! A whitish surface colour caused by the protective film of talcum powder, or an equivalent product, used in the production process should not be considered an indication of poor preservation (or a damaged product).

CLEANING BEFORE USE

Before using the device, wash with warm water and neutral soap and then rinse with saline solution.
To avoid scratching the surface of the device, use soft sponges, not brushes, for washing.
Do not use alcohol, solvents, acids or fluids that could damage the device to clean its surfaces.
After cleaning, do not leave the device unattended, insert it into the vagina immediately. The device can be sterilised for first use in a steam autoclave with up to two consecutive cycles set to a temperature of 121 °C for 15 minutes.

INSTRUCTIONS FOR USE

Compress the ring into an ellipse to facilitate its insertion. Pass the vaginal opening. Place it around the cervix.
Use the device as instructed by the responsible healthcare professionals at the time of insertion.
Never intervene on the device of your own initiative.
Seek medical advice in the event of any unusual discomfort.

MATERIALS

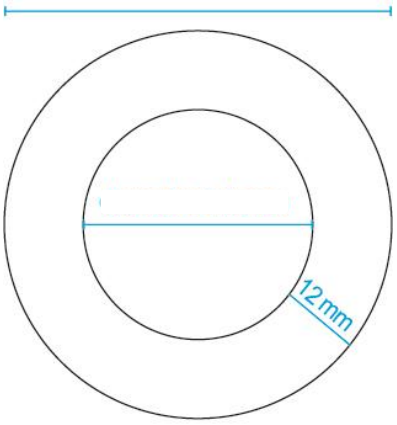
100% food grade silicone, latex- and phthalate-free.

TECHNICAL SPECIFICATIONS

Components	
Food grade silicone	100%
Silicon grade	GP500
Colour	transparent

Thickness: 12 mm

external diameter
internal diameter



external diameter – thickness =
internal diameter

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical device; in the case of damage the medical device must be disposed of.

PACKAGING

Individually bagged in a box.

STORAGE

The device is placed on the market with the standard For.me.sa. Srl packaging, which ensures its correct storage before use. For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children. Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations. The original material does not contain any toxic substances.

Fabbricante/ *Manufacturer*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **0476**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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Cod. Destinatario: KRRH6B9

REG. N. 3685-A
UNI CEI EN ISO 13485:2016

TECHNICAL DATA SHEET OF THE DEVICE

STERILE SILICONE PESSARY

REF.		RDM	GMDN	CND
FOR.70.51950	*Ø 50*	1295458	35237	U089005
FOR.70.51955	*Ø 55*	1295786		
FOR.70.51960	*Ø 60*	1295789		
FOR.70.51965	*Ø 65*	1295791		
FOR.70.51970	*Ø 70*	1295793		
FOR.70.51975	*Ø 75*	1295794		
FOR.70.51980	*Ø 80*	1295796		
FOR.70.51985	*Ø 85*	1295797		
FOR.70.51990	*Ø 90*	1295799		
FOR.70.51995	*Ø 95*	1295801		
FOR.70.519100	*Ø 100*	1295802		

PHOTOGRAPH

GENERAL DESCRIPTION

Device used for the containment of uterine prolapse.
It is an invasive device that penetrates into the body through a natural orifice (and therefore differs from surgical invasive devices); it is not intended to be connected to an active medical device. The duration of its continuous use must be established by qualified medical personnel.
STERILE: ethylene oxide-sterilised device.
DEVICE CLASS: IIb

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the polyethylene bag provided.
Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.
N.B.!!! A whitish surface colour caused by the protective film of talcum powder, or an equivalent product, used in the production process should not be considered an indication of poor preservation (or a damaged product).

CLEANING BEFORE USE

Before using the device, wash with warm water and neutral soap and then rinse with saline solution.
To avoid scratching the surface of the device, use soft sponges, not brushes, for washing.
Do not use alcohol, solvents, acids or fluids that could damage the device to clean its surfaces.
After cleaning, do not leave the device unattended, insert it into the vagina immediately. The device can be sterilised for first use in a steam autoclave with up to two consecutive cycles set to a temperature of 121 °C for 15 minutes.

INSTRUCTIONS FOR USE

Compress the ring into an ellipse to facilitate its insertion. Pass the vaginal opening. Place it around the cervix.
Use the device as instructed by the responsible healthcare professionals at the time of insertion.
Never intervene on the device of your own initiative.
Seek medical advice in the event of any unusual discomfort.

MATERIALS

100% food grade silicone, latex- and phthalate-free.

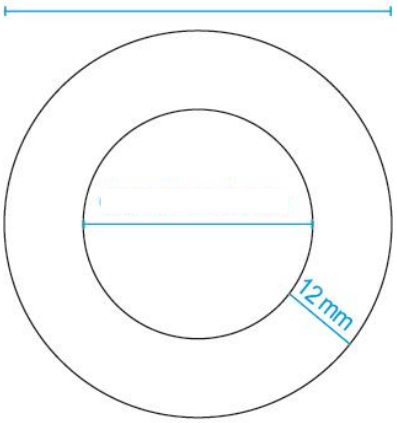
TECHNICAL SPECIFICATIONS

Components	
Food grade silicone	100%
Colour	Blue dye

Thickness: 12 mm.

Sterilisation by ethylene oxide.

external diameter
internal diameter



external diameter – thickness = internal diameter

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical device; in the case of damage the medical device must be disposed of.

PACKAGING

Individually wrapped with medical paper, in its box.

STORAGE

The device is placed on the market with the standard For.me.sa. Srl packaging, which ensures its correct storage before use.
For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Fabbricante/ *Manufacturer*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **0476**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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Cod. Destinatario: KRRH6B9

IMQ CERTIFIED
QUALITY MANAGEMENT SYSTEM ISO 13485:2016

TECHNICAL DATA SHEET OF THE DEVICE

CUBE PERFORATED PESSARY

CODE		REF	RDM	CND
FOR.71.52525	*Ø25*	157	2137673	U089005
FOR.71.52529	*Ø29*	158	2137674	
FOR.71.52532	*Ø32*	159	2137675	
FOR.71.52537	*Ø37*	160	2137676	
FOR.71.52541	*Ø41*	161	2137677	
FOR.71.52545	*Ø45*	162	2137678	

PHOTOGRAPH

GENERAL DESCRIPTION

The pessary is inserted into the vagina to provide the pelvic organs with additional support. This restores the anatomical relationship between the pelvic organs and prevents/reduces the likelihood of prolapse.
The duration of its continuous use must be established by qualified medical personnel.
The perforated silicone cube pessary is cube-shaped with concave sides that have holes to allow the drainage of vagina discharge. It also has a string to facilitate its removal.
Cube models should be used when other types of pessary prove ineffective. The size is stated on the product and on the label.
DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:

- is intact and undamaged (i.e. has no cracks, dents or tears)
- is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc.
- If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary.
Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature.
Continuous use of the pessary should not exceed 12 hours.
If the patient is unable to self-manage the insertion and removal of the silicone cube pessary, a different model of pessary should be considered. Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).
The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.
The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours). After treatment the product must be allowed to cool to room temperature.
To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush. The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water.The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder. Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse. For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger). The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body. The pessary should not drop under stress or cause
micturition problems or pain. When possible, patients should be instructed so that they can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position.
Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below. To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2). Then turn the pessary so that the flat parts adapt to the walls of the vagina (fig. 3). The removal string must
be easily accessible. When self-managing the insertion of the pessary, the woman should choose the position she finds most convenient (lying down, standing up, etc.).

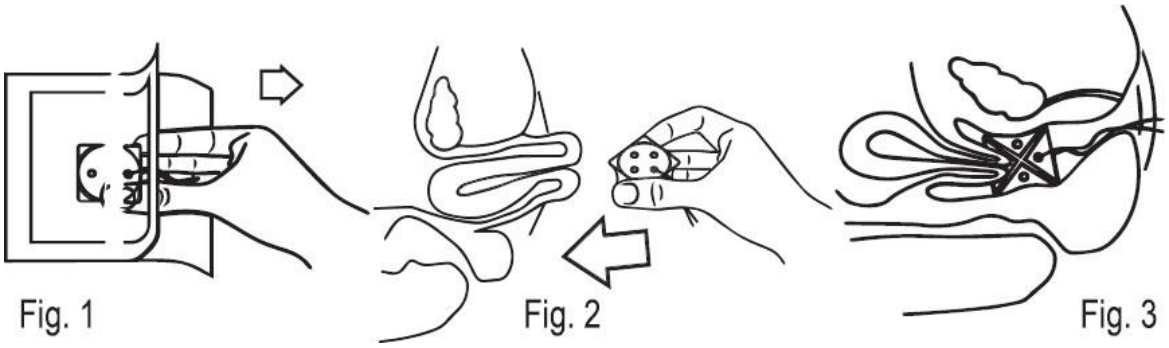


Fig. 1 Fig. 2 Fig. 3

To remove the pessary, the patient should grasp the string and, with gentle, oscillating movements, remove the pessary from her vagina. Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary is minimal.
When self-managing the insertion of the pessary, the patient can rest a leg on a chair or the side of a bed, before inserting the cube pessary into her vagina. In the case of problems inserting the pessary with straight legs, it is advisable to lean against a wall or to adopt a prone position.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months). Continuous use of the pessary should not exceed 12 hours. **The pessary can be used when exercising provided it is removed at night**. No specific side effects have been reported when the pessary is used properly.
An inflammatory process (non-specific reaction to a foreign body) may develop, in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

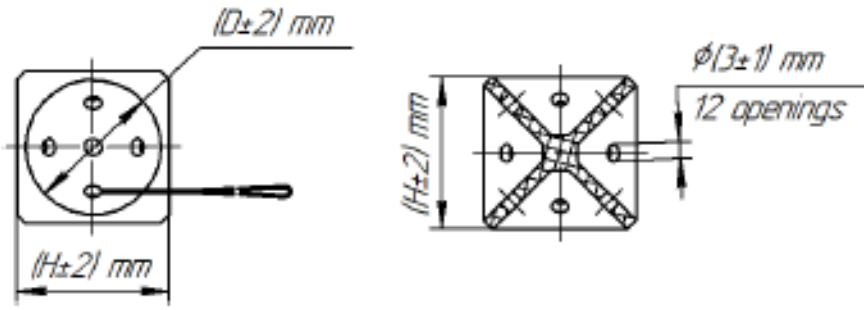
GUIDANCE FOR PATIENTS

Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.
Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.
The frequency of consultations should be established depending on the patient's individual needs. This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.
The pessary must be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for about 1 minute and rinsed again under running water. **Vaginal inflammations may develop during use of the pessary.** To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. If complications/side effects occur, seek immediate medical advice.

MATERIALS

Evrosil A40 biologically-inert, hypoallergenic medical silicone; lavsan thread (polyethylene terephthalate). Available in the following sizes: 25, 29, 32, 37, 41, 45 mm.

TECHNICAL SPECIFICATIONS



Modifications	25	29	32	37	41	45
D, mm	23	27	30	35	39	43
H, mm	25	29	32	37	41	45

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical devices; in the case of damage the medical device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Distributore / *Distributor*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **1434**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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C.F. / P.IVA: IT01714420344
R.E.A. Parma: 173353
Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

TECHNICAL DATA SHEET OF THE DEVICE

"GELLHORN" SILICONE MUSHROOM PESSARY

CODE		REF.	RDM	CND
FOR.71.52250	*Ø50*	163	2137679	U089005
FOR.71.52255	*Ø55*	164	2137680	
FOR.71.52260	*Ø60*	165	2137681	
FOR.71.52265	*Ø65*	166	2137682	
FOR.71.52270	*Ø70*	167	2137683	
FOR.71.52275	*Ø75*	168	2137684	
FOR.71.52280	*Ø80*	169	2137685	
FOR.71.52285	*Ø85*	170	2137686	
FOR.71.52290	*Ø90*	171	2137687	

PHOTOGRAPH

GENERAL DESCRIPTION

The silicone mushroom pessary features a dish-shaped part connected to a handle with a knob that facilitates its use. This knob is designed to keep it as deep as possible within the vagina. This device can be used when other types of pessary prove ineffective. The pessary is inserted into the vagina to provide the pelvic organs with additional support. This restores the correct anatomical relationship between the pelvic organs and prevents/reduces the likelihood of a prolapse. The size is stated on the product and on the label.
DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:

- is intact and undamaged (i.e. has no cracks, dents or tears)
- is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary. Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature. Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).

The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.

The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours). After treatment the product must be allowed to cool to room temperature.

To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush. The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water. The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder. Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse. For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger). The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body. The pessary should not drop under stress or cause micturition problems or pain. When possible, patients should be instructed so that they
can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position. Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below. To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2). Then turn the pessary so that the dish-shaped part is facing
outwards (fig. 3). The handle of the pessary must be easily accessible. When self-managing the insertion of the pessary, the woman should choose the position she finds most convenient (lying down, standing up, etc.).

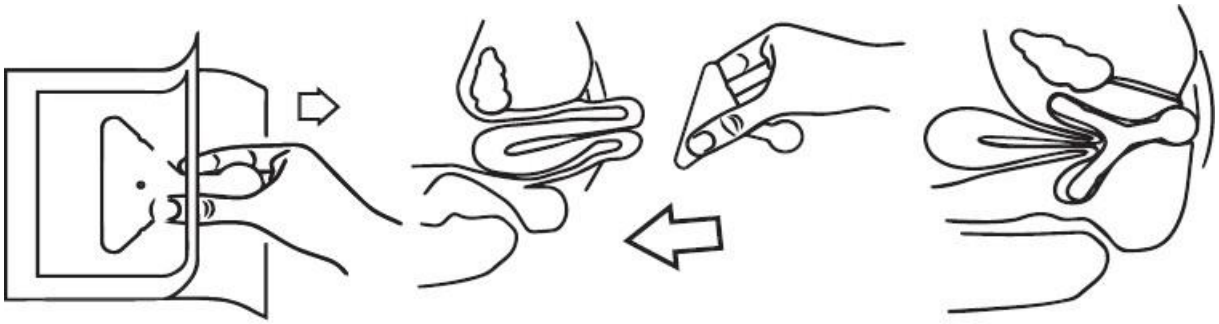


Fig. 1 Fig. 2 Fig. 3

To remove the pessary: grasp the product with your fingers, compress it slightly, and remove it from the vagina. Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary
is minimal.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months). Continuous use of the pessary should not exceed 12 hours. The pessary can be used when exercising provided it is removed at night. No specific side effects have been reported when the product is used properly. An inflammatory process (non-specific reaction to a foreign body) may develop, in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

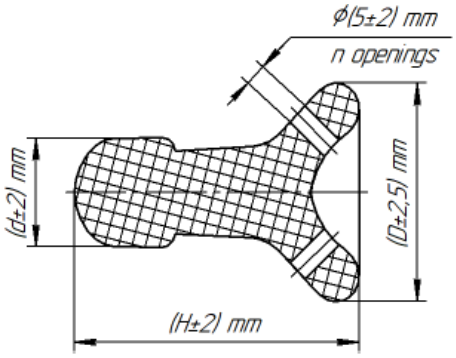
GUIDANCE FOR PATIENTS

Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.
Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.
The frequency of consultations should be established depending on the patient's individual needs. This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.
After cleaning, the pessary must be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for about 1 minute and rinsed again under running water. **Vaginal inflammations may develop during use of the pessary.** To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. If complications/side effects occur, seek immediate medical advice.

MATERIALS

Evrosil A40 biologically-inert, hypoallergenic medical silicone. Available in the following sizes: 50, 55, 60, 65, 70, 75, 80, 85, 90 mm.

TECHNICAL SPECIFICATIONS



Misure	50	55	60	65	70	75	80	85	90
D, mm	50	55	60	65	70	75	80	85	90
d, mm	25	25	25	25	25	25	26	26	26
H, mm	64	65	66	68	69	70	72	73	74
n	3	3	4	4	4	4	4	4	4

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical devices; in the case of damage the medical device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Distributore / *Distributor*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **1434**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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fornitore medico sanitario

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C.F. / P.IVA: IT01714420344
R.E.A. Parma: 173353
Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

TECHNICAL DATA SHEET OF THE DEVICE

SILICONE BOWL-SHAPED URETHRAL PESSARY

CODE		REF.	RDM	CND
FOR.71.52955	*Ø55*	121	2139312	U089005
FOR.71.52960	*Ø60*	122	2139318	
FOR.71.52965	*Ø65*	123	2137754	
FOR.71.52970	*Ø70*	124	2137756	
FOR.71.52975	*Ø75*	125	2137757	
FOR.71.52980	*Ø80*	126	2137761	
FOR.71.52985	*Ø85*	127	2137764	
FOR.71.52990	*Ø90*	128	2137767	

PHOTOGRAPH

GENERAL DESCRIPTION

The pessary is inserted into the vagina to provide the pelvic organs with additional support. This restores the anatomical relationship between the pelvic organs and prevents/reduces the likelihood of prolapse. The duration of its continuous use must be established by qualified medical personnel.
The silicone urethral bowl pessary is bowl-shaped with an oval knob and a large central opening. The knob on the outer edge of the ring is designed to ensure greater in situ fixation of the urethrovesical segment. The size is stated on the product and on the label.
DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary. Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature. Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).

The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.

The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours). After treatment the product must be allowed to cool to room temperature.

To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush. The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water. The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder. Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse. For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger). The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body. The pessary should not drop under stress or cause micturition problems or pain. When possible, patients should be instructed so that they
can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position. Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below. To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2). Then turn the pessary so that the cervix (vaginal vault) is positioned in the opening of the pessary (fig. 3).

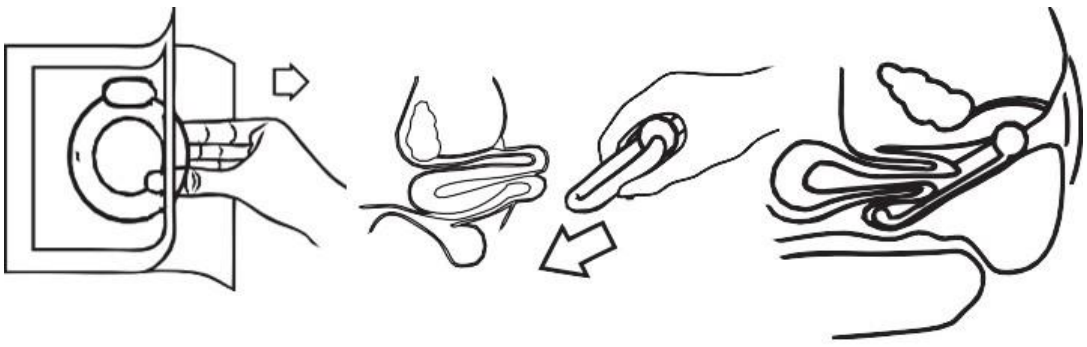


Fig. 1 Fig. 2 Fig. 3

To remove the pessary: grasp the product with your fingers, squeeze it slightly and, once it is compressed, and remove it from the vagina. Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary is minimal.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months). Continuous use of the pessary should be established in accordance with the patient's individual requirements and for an average of 20-25 days. The pessary can be used when exercising provided it is removed at night. No specific side effects have been reported when the product is used properly. An inflammatory process (non-specific reaction to a foreign body) may develop,
in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

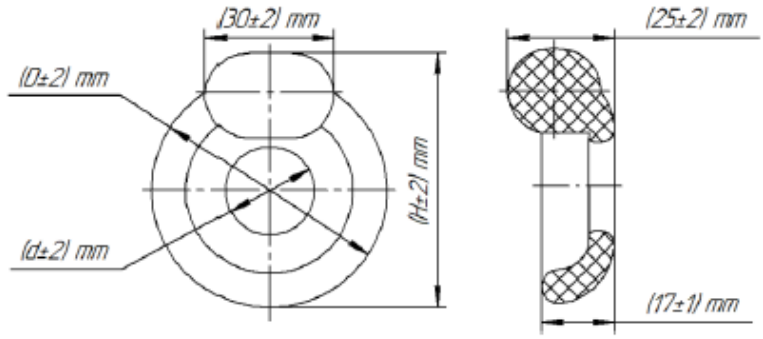
GUIDANCE FOR PATIENTS

Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.
Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.
The frequency of consultations should be established depending on the patient's individual needs. This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.
After cleaning, the pessary must be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for about 1 minute and rinsed again under running water. **Vaginal inflammations may develop during use of the pessary.** To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. If complications/side effects occur, seek immediate medical advice.

MATERIALS

Evrosil A40 biologically-inert, hypoallergenic medical silicone. Available in the following sizes: 55, 60, 65, 70, 75, 80, 85, 90 mm.

TECHNICAL SPECIFICATIONS



Misure	55	60	65	70	75	80	85	90
D, mm	55	60	65	70	75	80	85	90
d, mm	21	26	31	36	41	46	51	56
H, mm	60	65	70	75	80	85	90	95

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical devices; in the case of damage the medical device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Distributore / *Distributor*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **1434**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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forniture medico sanitarie

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Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

IMQ CERTIFIED
QUALITY MANAGEMENT SYSTEM ISO 13485:2016

TECHNICAL DATA SHEET OF THE DEVICE

SILICONE URETHRAL INCONTINENCE PESSARY

CODE		REF	RDM	CND
FOR.71.53645	*Ø45*	109	2139319	U089005
FOR.71.53650	*Ø50*	110	2139322	
FOR.71.53655	*Ø55*	111	2139323	
FOR.71.53660	*Ø60*	112	2139326	
FOR.71.53665	*Ø65*	113	2134971	
FOR.71.53670	*Ø70*	114	2137667	
FOR.71.53675	*Ø75*	115	2137669	
FOR.71.53680	*Ø80*	116	2137669	
FOR.71.53685	*Ø85*	117	2137670	
FOR.71.53690	*Ø90*	118	2137671	
FOR.71.53695	*Ø95*	119	2138130	
FOR.71.536100	*Ø100*	120	2138131	

PHOTOGRAPH

GENERAL DESCRIPTION

The pessary is inserted into the vagina to provide the pelvic organs with additional support. This restores the anatomical relationship between the pelvic organs and prevents/reduces the likelihood of prolapse. The duration of its continuous use must be established by qualified medical personnel.
The silicone urethral pessary takes the form of a ring reinforced by an elastic material, with an oval knob. The knob on the outer edge of the ring is designed to ensure greater in situ fixation of the urethrovesical segment. The size is stated on the product and on the label.
DEVICE CLASS: IIa

RECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary.
Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature.
Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).
The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.
The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours). After treatment the product must be allowed to cool to room temperature.
To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush. The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water. The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder. Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse. For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger). The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body. The pessary should not drop under stress or cause micturition problems or pain. When possible, patients should be instructed so that they
can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position. Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below. To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2).
Then turn the pessary so that the cervix (vaginal vault) is positioned in the opening of the pessary (fig. 3).

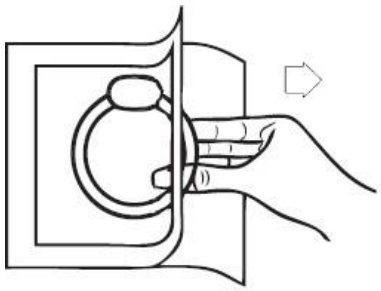


Fig. 1

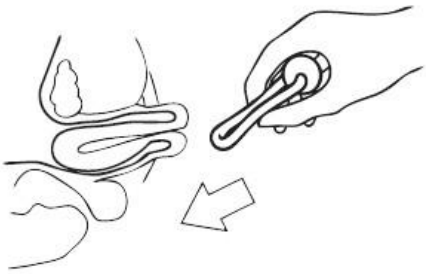


Fig. 2

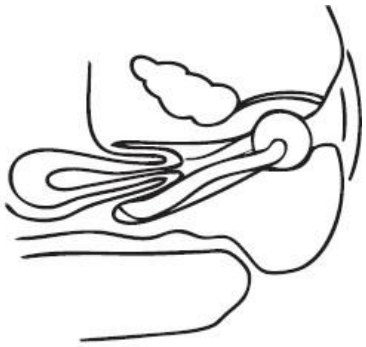


Fig. 3

To remove the pessary: grasp the product with your fingers, squeeze it slightly and, once it is compressed, remove it from the vagina. Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary is minimal.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months). Continuous use of the pessary should be established in accordance with the patient's individual requirements and for an average of 20-25 days. The pessary can be used when exercising provided it is removed at night. No specific side effects have been reported when the product is used properly. An inflammatory process (non-specific reaction to a foreign body) may develop, in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

GUIDANCE FOR PATIENTS

Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.

Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.

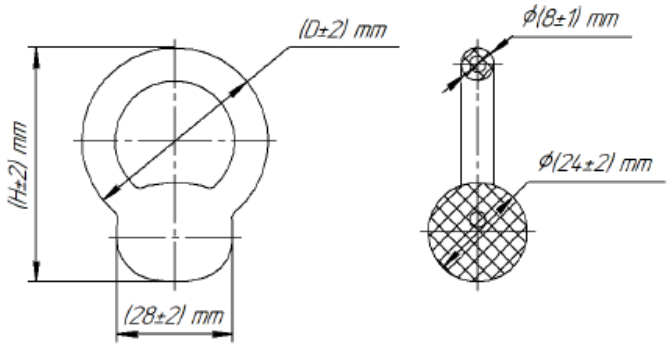
The frequency of consultations should be established depending on the patient's individual needs. This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.

The pessary must be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for about 1 minute and rinsed again under running water. **Vaginal inflammations may develop during use of the pessary.** To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. If complications/side effects occur, seek immediate medical advice.

MATERIALS

Evrosil A40 biologically-inert, hypoallergenic medical silicone. Available in the following sizes: 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 mm.

TECHNICAL SPECIFICATIONS



Misure	45	50	55	60	65	70	75	80	85	90	95	100
D, mm	45	50	55	60	65	70	75	80	85	90	95	100
H, mm	56,5	61,5	66,5	71,5	76,5	81,5	86,5	91,5	96,5	101,5	106,5	111,5

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical devices; in the case of damage the medical device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

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Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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C.F. / P.IVA: IT01714420344
R.E.A. Parma: 173353
Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

TECHNICAL DATA SHEET OF THE DEVICE

PERFORATED SILICONE BOWL-SHAPED PESSARY

CODE		REF .	RDM	CND
FOR.71.52455	*Ø55*	100	2139282	U089005
FOR.71.52460	*Ø60*	101	2137770	
FOR.71.52465	*Ø65*	102	2137774	
FOR.71.52470	*Ø70*	103	2137776	
FOR.71.52475	*Ø75*	104	2137779	
FOR.71.52480	*Ø80*	105	2137781	
FOR.71.52485	*Ø85*	106	2137783	
FOR.71.52490	*Ø90*	107	2137786	
FOR.71.52495	*Ø95*	108	2139297	

PHOTOGRAPH

GENERAL DESCRIPTION

The pessary is inserted into the vagina to provide the pelvic organs with additional support. This restores the anatomical relationship between the pelvic organs and prevents/reduces the likelihood of prolapse.
The duration of its continuous use must be established by qualified medical personnel.
The perforated silicone bowl-shaped pessary is bowl-shaped-shaped with a large central opening and further openings with a smaller diameter around the outside. The size is stated on the product and on the label. DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:

- is intact and undamaged (i.e. has no cracks, dents or tears)
- is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary.
Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature.
Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).
The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.
The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours). After treatment the product must be allowed to cool to room temperature.
To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush. The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water. The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder. Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse. For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger). The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body. The pessary should not drop under stress or cause micturition problems or pain. When possible, patients should be instructed so that they can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position.
Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below. To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2). Then turn the pessary so that the cervix (vaginal vault) is positioned in the opening of the pessary (fig.3).

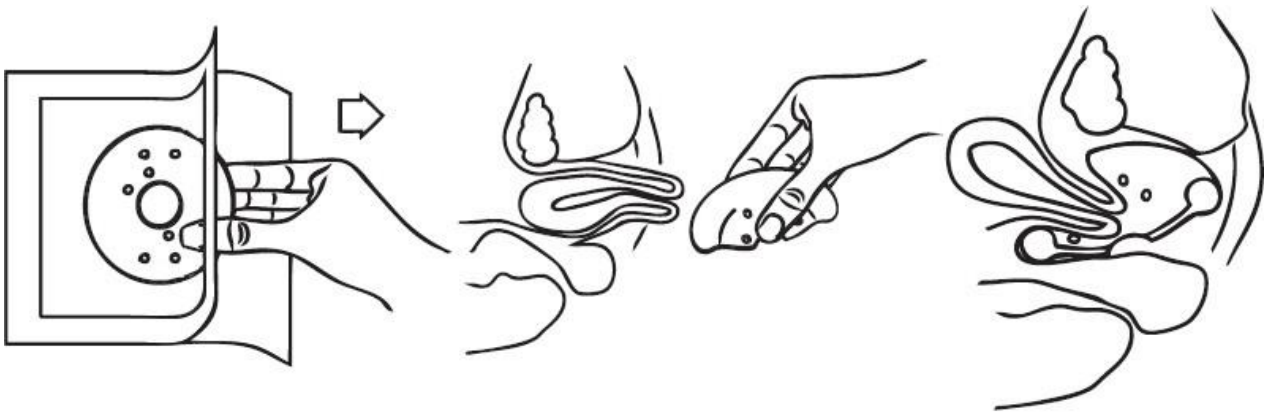


Fig.1 Fig.2 Fig.3

To remove the pessary: grasp the product with your fingers, squeeze it slightly and, once it is compressed, remove it from the vagina. Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary is minimal.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months). Continuous use of the pessary should be established in accordance with the patient's individual requirements and for an average of 20-25 days.
The pessary can be used when exercising provided it is removed at night.
No specific side effects have been reported when the product is used properly.
An inflammatory process (non-specific reaction to a foreign body) may develop, in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

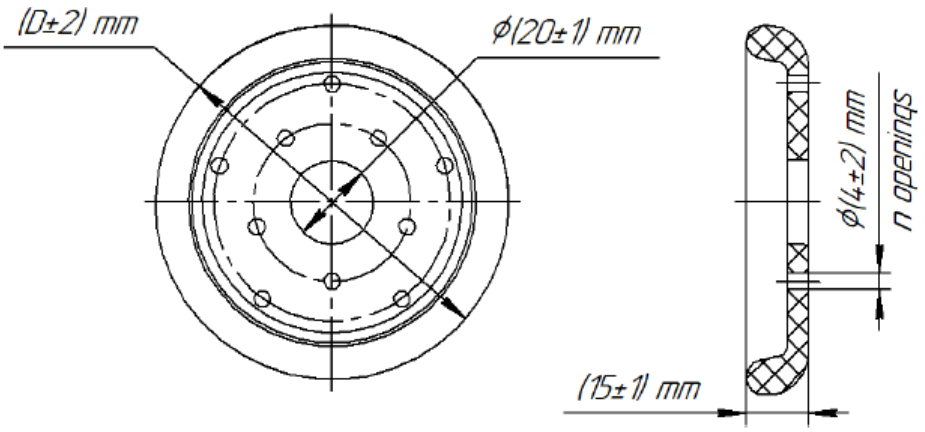
GUIDANCE FOR PATIENTS

Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.
Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.
The frequency of consultations should be established depending on the patient's individual needs. This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.
After cleaning, the pessary must be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for about 1 minute and rinsed again under running water. **Vaginal inflammations may develop during use of the pessary.**
To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. If complications/side effects occur, seek immediate medical advice.

MATERIALS

Evrosil A40 biologically-inert, hypoallergenic medical silicone. Available in the following sizes: 55, 60, 65, 70, 75, 80, 85, 90 and 95 mm.

TECHNICAL SPECIFICATIONS



Misure	55	60	65	70	75	80	85	90	95
D, mm	55	60	65	70	75	80	85	90	95
n	4	6	6	8	8	8	10	10	10

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.

- Do not attempt to repair damaged medical devices; in the case of damage the medical device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

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R.E.A. Parma: 173353
Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

TECHNICAL DATA SHEET OF THE DEVICE

PERFORATED SILICONE CERVICAL PESSARY - GYNAECOLOGY

CODE		REF.	RDM	CND
FOR.71.523651732	*External Ø 65 - h 17 - Internal Ø 32*	138	2214953	
FOR.71.523651735	*External Ø 65 - h 17 - Internal Ø 35*	139	2215701	
FOR.71.523652132	*External Ø 65 - h 21 - Internal Ø 32*	140	2215733	
FOR.71.523652135	*External Ø 65 - h 21 - Internal Ø 35*	141	2215736	
FOR.71.523652532	*External Ø 65 - h 25 - Internal Ø 32*	142	2215741	
FOR.71.523652535	*External Ø 65 - h 25 - Internal Ø 35*	143	2215742	
FOR.71.523653035	*External Ø 65 - h 30 - Internal Ø 35*	144	2215745	U089005
FOR.71.523701732	*External Ø 70 - h 17 - Internal Ø 32*	145	2215746	
FOR.71.523701735	*External Ø 70 - h 17 - Internal Ø 35*	146	2215748	
FOR.71.523702132	*External Ø 70 - h 21 - Internal Ø 32*	147	2215749	
FOR.71.523702135	*External Ø 70 - h 21 - Internal Ø 35*	148	2215750	
FOR.71.523702532	*External Ø 70 - h 25 - Internal Ø 32*	149	2215753	
FOR.71.523702535	*External Ø 70 - h 25 - Internal Ø 35*	150	2215754	

PHOTOGRAPH

GENERAL DESCRIPTION

The perforated silicone cervical pessary is shaped like a deep bowl with a large central hole and lateral drainage holes. The pessary is inserted inside the vagina allowing additional support to the pelvic organs, this restores the anatomical interrelationship between the pelvic organs and eliminates/decreases the manifestations of prolapse. The continuous use of the pessary on the patient should be defined by the appropriate medical personnel. The perforated cervical silicone pessary is used in gynecological and obstetrical settings.
The size is indicated on the product and on the label.
DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided. Before use, make sure the device:

- is intact and undamaged (i.e. has no cracks, dents or tears)
- is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

Allergic reactions to the material of the pessary.
Inflammatory diseases of the female pelvic organs and genital tract bleeding.

UNDESIRED EFFECTS

Inflammatory diseases of the pelvic organs may develop during use of the silicone pessary.

WARNINGS

The product must not be used by other patients (single-patient device) and it must be stored at room temperature.
Do not use after the expiry date stated on the product pack or if the surface of the product is damaged (cuts, cracks, etc.).
The pessary is supplied non-sterile. Before first use, the pessary must be prepared for the treatment to be carried out before insertion into the vagina.
The pessary can be sterilised using steam (cycle temperature 121 °C, for a time of not less than 15 minutes) or hot air (cycle temperature 160 °C, exposure time 2 hours).
After treatment the product must be allowed to cool to room temperature.
To reuse the pessary, wash under running water with neutral liquid soap and using a soft brush.
The pessary must also be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) for one minute and rinsed again under running water.
The properties of the material make it possible to repeat the treatment several times.

CHOOSING THE SIZE OF PESSARY

The choice of the pessary to be used is made by the obstetrician/gynaecologist according to the anatomical characteristics of the patient. During the initial pessary adaptation phase, the patient should assume a lithotomy position (on the bed in the gynaecologist's office) with a full bladder.
Therapy should be carried out using the pessary with the smallest diameter able to eliminate or reduce the symptoms of prolapse.
For the size of the pessary to be considered correct, there should be a small gap between the pessary and the vaginal wall (10-15 mm, the width of a phalanx of a finger).
The correctness of pessary positioning should be assessed by contracting the abdominal muscles (for example by coughing or creating tension) and moving the body.
The pessary should not drop under stress or cause micturition problems or pain. When possible, patients should be instructed so that they can self-manage the removal and insertion of their pessary.

INSERTION AND REMOVAL OF THE PESSARY

Before the pessary is inserted, the prolapsed organs must be returned to their correct anatomical position.
Remove the pessary from the pack (fig. 1) and insert it as shown in the figure below.
To facilitate the insertion procedure, lubricate the pessary with a small amount of lubricant, squeeze it and, once it is compressed, insert it into the vagina (fig. 2).

The pessary must then be turned so that its convex surface is facing towards the cervix (fig. 3).

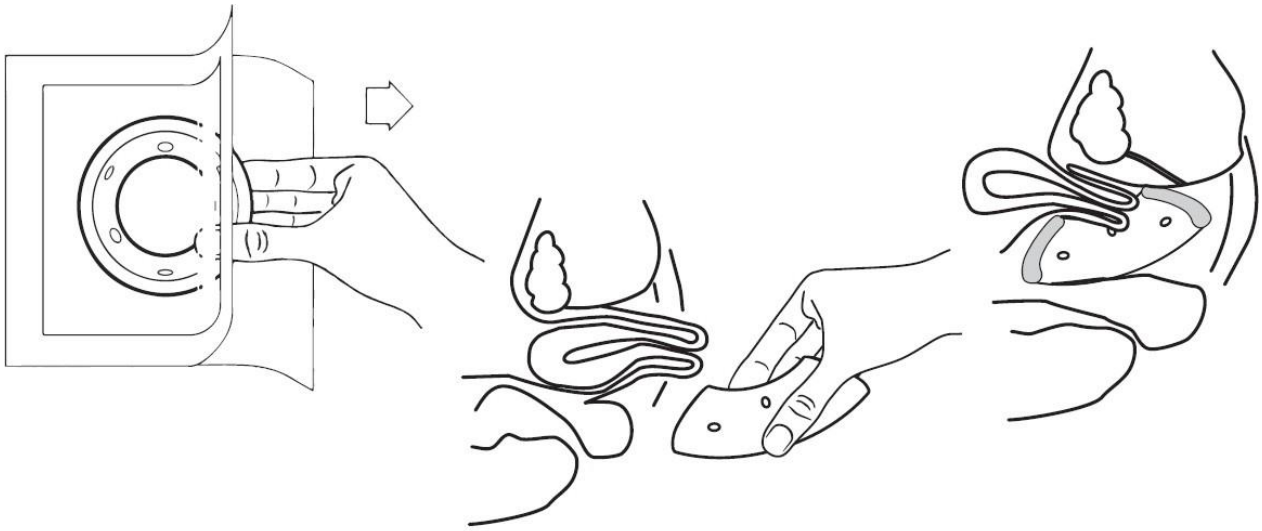


Fig. 1 Fig. 2 Fig. 3

To remove the pessary: grasp the product with your fingers, squeeze it slightly and, once it is compressed, remove it from the vagina.
Thanks to the elastic properties of the silicone, patient discomfort during the insertion and removal of the pessary is minimal.

PATIENT MONITORING

Patients must have regular gynaecological examinations during use (at least once every six months).
Continuous use of the pessary should be established in accordance with the patient's individual requirements and for an average of 20-25 days.
The pessary can be used when exercising provided it is removed at night. No specific side effects have been reported when the product is used properly.
An inflammatory process (non-specific reaction to a foreign body) may develop, in which case the pessary must be removed and sanitised. Once the pessary has been sanitised, it can be inserted again.

GUIDANCE FOR PATIENTS

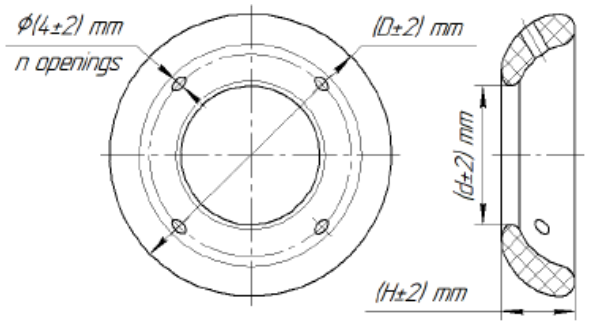
Keep these instructions for use, they contain important information for safe use of the pessary. Once the pessary has been inserted, make sure you do not have any discomfort or problems urinating and that the pessary does not displace under stress. In the case of vagina pain, or if the pessary drops out, a different pessary must be used.
Under a gynaecologist's supervision, patients can be educated to self-manage the insertion and removal of their pessary.
During use of the pessary, patients should have gynaecological consultations the frequency of which should be established based on their individual requirements (not less than once every 6 months).
This is essential in order to assess the effectiveness of the therapy and to choose the right time for continuous use of the pessary. At home, clean the product by washing thoroughly under running water and using a cleaning product.
The pessary must then be treated with an antiseptic solution that is compatible with the skin and mucous membranes and authorised for medical use (in compliance with the instructions for use of the disinfectant).
When treating the pessary, avoid damaging the surface of the product (do not use

abrasive materials).
Vaginal inflammations may develop during use of the pessary.
To prevent inflammatory complications, follow your physician's instructions, perform hygiene practices carefully and comply with the conditions for continuous use of the pessary. At its expiry date, the pessary must be disinfected and disposed of
in compliance with current legislation.

MATERIALS

Evrosil A60 biologically-inert, hypoallergenic medical silicone.

TECHNICAL SPECIFICATIONS



Modifications (Ref)	138	139	140	141	142	143	144	145	146	147	148	149	150
D, mm	65	65	65	65	65	65	65	70	70	70	70	70	70
H, mm	17	17	21	21	25	25	30	17	17	21	21	25	25
d, mm	32	35	32	35	32	35	35	32	35	32	35	32	35
n	4	4	6	6	6	6	6	4	4	6	6	6	6

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

• Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
• Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
• Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
• Do not attempt to repair damaged medical devices; in the case of damage the device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

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Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*

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Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

TECHNICAL DATA SHEET OF THE DEVICE

PERFORATED SILICONE CERVICAL PESSARY - OBSTETRICS

CODE		REF.	RDM	CND
FOR.71.523651732	*External Ø 65 - h 17 - Internal Ø 32*	138	2214953	U089005
FOR.71.523651735	*External Ø 65 - h 17 - Internal Ø 35*	139	2215701	
FOR.71.523652132	*External Ø 65 - h 21 - Internal Ø 32*	140	2215733	
FOR.71.523652135	*External Ø 65 - h 21 - Internal Ø 35*	141	2215736	
FOR.71.523652532	*External Ø 65 - h 25 - Internal Ø 32*	142	2215741	
FOR.71.523652535	*External Ø 65 - h 25 - Internal Ø 35*	143	2215742	
FOR.71.523653035	*External Ø 65 - h 30 - Internal Ø 35*	144	2215745	
FOR.71.523701732	*External Ø 70 - h 17 - Internal Ø 32*	145	2215746	
FOR.71.523701735	*External Ø 70 - h 17 - Internal Ø 35*	146	2215748	
FOR.71.523702132	*External Ø 70 - h 21 - Internal Ø 32*	147	2215749	
FOR.71.523702135	*External Ø 70 - h 21 - Internal Ø 35*	148	2215750	
FOR.71.523702532	*External Ø 70 - h 25 - Internal Ø 32*	149	2215753	
FOR.71.523702535	*External Ø 70 - h 25 - Internal Ø 35*	150	2215754	

PHOTOGRAPH

USE OF THE PERFORATED CERVICAL PESSARY IN OBSTETRICS

The cervical pessary is dish-shaped with lateral drainage holes and is indicated for pregnant women with cervicoisthmic incompetence. This pessary redistributes pressure from the cervicouterine junction to the front wall of the uterus. This decreases the pressure on the cervix. The duration of its continuous use must be established by qualified medical personnel. The size is stated on the product and on the label.
DEVICE CLASS: IIa

PRECAUTIONARY CHECKS BEFORE USE

Before unpacking, make sure the pack is intact and sealed inside the medical sachet provided.
Before use, make sure the device:
• is intact and undamaged (i.e. has no cracks, dents or tears)
• is not discoloured, does not have an uneven colour, and does not have any mould on the surface, etc. If any of the defects indicated above are present DO NOT USE THE DEVICE and REPLACE IT IMMEDIATELY.

CONTRAINDICATIONS

This method must not be used in clinical situations in which prolonging pregnancy is unthinkable and when the anatomical characteristics of a patient prevent the correct positioning of the pessary.
It is also contraindicated in the case of inflammatory diseases of the vagina, uterus and external genitalia (preliminary sanitisation with the following bacteriological control agent is required).

UNDESIRED EFFECTS

Inflammatory diseases of the female pelvic organs may develop during use of the silicone pessary.
Using an unsuitable size may result in the onset of pain in the area involved. Incorrect pessary size choices can result in the development of cervical oedema.

WARNINGS

Pessaries can be inserted in the presence of first- and second-degree vaginal pH (normal vaginal pH conditions). The device must not be used by other patients (single-patient device). The pessary is supplied non-sterile; before first use, the device must be prepared for the treatment to be carried out before insertion into the vagina. This treatment consists in rinsing the pessary under running water with a neutral liquid soap suitable for the treatment of the skin and mucous membranes. The device should also be treated with an antiseptic solution for medical use. Disinfection in healthcare facilities must be carried out in compliance with provisions set out in applicable regulations for silicone rubber products and in compliance with the instructions for use of the disinfectant. The properties of the material permit the repeated treatment of the product.

CHOOSING THE SIZE

The type of pessary is chosen (based on table 1) by the obstetrician/gynaecologist on a case-by-case basis and depending on the parameters of the cervix and the volume of the vagina.
The guidelines for choosing a pessary of the correct size are provided in table 2.

Table 2

Pessary version	Pessary parameters (external diameter/ height/ diameter of the central opening)	Volume of the vagina (in the vaginal delivery history)		Cervical parameters (transvaginal ultrasound)			
				Length of the closed part of the cervical canal		Diameter of the cervix at the external orifice	
		YES	NO	less than 25 mm	greater than 25 mm	up to 25 mm	26 – 33 mm
1	65/17/32		✓		✓	✓	
2	65/17/35		✓		✓		✓
3	65/21/32		✓	✓	✓	✓	
4	65/21/35		✓	✓	✓		✓
5	65/25/32		✓	✓		✓	
6	65/25/35		✓	✓			✓
7	65/30/35		✓	✓			✓
8	70/17/32	✓			✓	✓	
9	70/17/35	✓			✓		✓
10	70/21/32	✓		✓	✓	✓	
11	70/21/35	✓		✓	✓		✓
12	70/25/32	✓		✓		✓	
13	70/25/35	✓		✓			✓

The pessary must not slip under stress, or cause urination problems or vaginal pain.

INSERTION AND REMOVAL OF THE PESSARY

Pessary insertion and removal are medical manoeuvres. The procedure
can be carried out in outpatient clinics and hospitals.
Anaesthesia is not required for pessary insertion and removal.
The pessary is supplied non-sterile and requires disinfection before use (see above).

Conditions for pessary insertion:

- absence of contraindications for use;
- normal uterine tone;
- first- and second-degree vaginal pH (normal vaginal pH conditions)
- patient consent.

Insertion

Pessary insertion must be carried out in compliance with the general rules for aseptic environments.
Remove the pessary from the pack (fig. 4). After disinfection, treat the product with a small amount of ointment used in obstetrics.
Squeeze the pessary (fig. 5) and insert it into the vagina. Then turn the pessary so that the middle of the pessary is aligned with the cervix (fig. 6) and its lateral surfaces
fit snugly against the vaginal vaults.

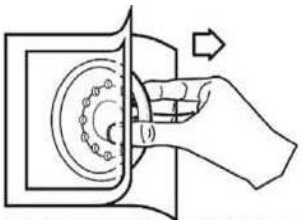


Figure 4

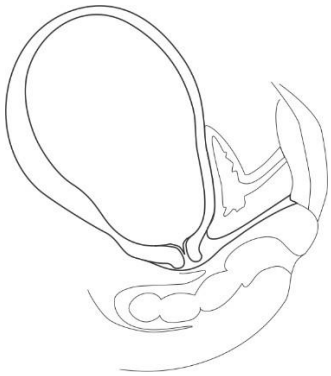
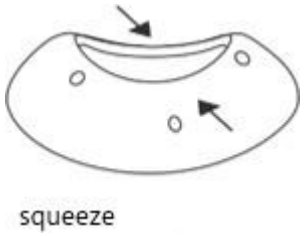


Figure 5



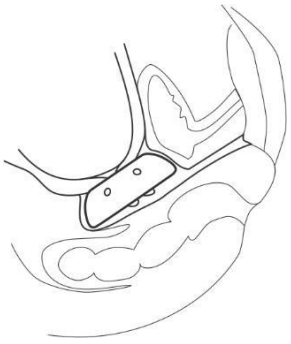


Figure 6

Removal

Pessaries are usually removed between the 37th and 38th week of pregnancy in an outpatient clinic or hospital.
If difficulties are encountered when removing the pessary (cervical oedema), cut the pessary using scissors before removing the product.
Once the pessary has been removed, it is advisable to sanitise the genital tract depending on the vaginal microflora.

There are certain clinical situations that require premature pessary removal

- emergency childbirth;
- amniotic fluid leakage;
- onset of labour;
- chorioamnionitis;
- leakage of discharge containing traces of blood from the genital tract (another pessary can be inserted if necessary);
- pain caused by the pessary (a smaller pessary can be inserted).

EXAMINATIONS AND MONITORING

A bacterioscopic cervicovaginal smear test every 2-3 weeks is mandatory.
The condition of the cervix should be monitored taking the dynamic ultrasound findings into account (every 3-4 weeks).
The treatment of ICI using a pessary can be combined with any pharmacological therapy.
When using a pessary, patients should be advised against having sexual intercourse. In the event of colpitis, sanitisation may be carried out even in the presence of a pessary.
If sanitisation carried out with the pessary in place is not effective, the device should be removed before repeating sanitisation and then replacing the pessary.

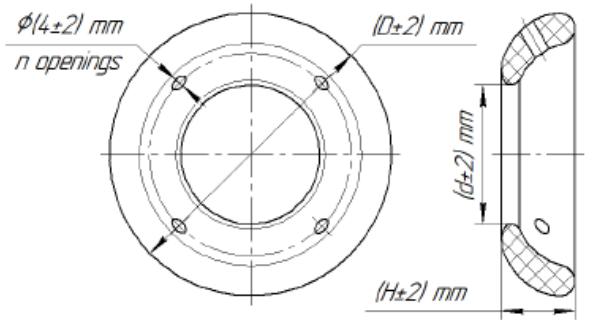
GUIDANCE FOR PATIENTS

The pessary is designed to prevent premature birth in the case of cervical prolapse (cervicoisthmic incompetence).
When this condition is diagnosed, the device is inserted into the vagina so as to reduce the pressure on the "incompetent" cervix. The period for which the pessary is kept in the vagina should be established on a case-by-case basis.
Pessaries are usually removed in the 37th or 38th week of pregnancy. There are certain clinical situations that require premature (temporary or permanent) pessary removal.
When using a pessary, patients must attend regular obstetrician/gynaecologist appointments and should abstain from sexual intercourse; they may also notice an increase in vaginal discharge (in this case, inflammation must be ruled out).

MATERIALS

Evrosil A60 biologically-inert, hypoallergenic medical silicone.

TECHNICAL SPECIFICATIONS



Modifications (Ref)	138	139	140	141	142	143	144	145	146	147	148	149	150
D, mm	65	65	65	65	65	65	65	70	70	70	70	70	70
H, mm	17	17	21	21	25	25	30	17	17	21	21	25	25
d, mm	32	35	32	35	32	35	35	32	35	32	35	32	35
n	4	4	6	6	6	6	6	4	4	6	6	6	6

Do not expose to ultraviolet radiation.

SHELF LIFE

5 years

PROHIBITED USE

- Use in contact with wounds.
- Reuse of the device in another patient.
- Use for a longer period than that defined by the healthcare professional.
- Use in combination with or as a part of other medical devices.
- Modifying or altering the constituent parts and/or characteristics of the product.
- Use of medicinal products or substances considered to be such or equivalent to them, in combination with/together with the device.
- Misuse.

PRECAUTIONS AND WARNINGS FOR HEALTHCARE PROFESSIONALS AND PATIENTS

- Any counterfeiting and/or misuse shall be prosecuted to the full extent permitted by law.
- Observe the intended use of the device scrupulously.
- The device may be used at the physician's discretion, subject to regular monitoring. Follow the instructions you receive from the responsible healthcare professionals scrupulously.
- The device must be washed before use.
- Use the device conscientiously.

OPERATING PROCEDURES FOR HEALTHCARE PROFESSIONALS

- Work in safe conditions and settings, avoiding any situation of potential hazard for yourself, the patient or others.
- Identify the right size to be used based on your experience in the field: incorrect and/or unsuitable sizes will not give the desired benefits.
- Do not leave the device unattended before use and do not place it on surfaces that are hot or have sharp edges or parts, but only on inert surfaces with the required degree of sanitisation.
- Do not attempt to repair damaged medical devices; in the case of damage the device must be disposed of.

PACKAGING

Individually packed with medical paper + PET/PP laminated film.

STORAGE

For proper long-term storage, always store the device in the original packaging, in a dry moisture-free environment, not in direct contact with radiating sources of heat, away from dust and harmful materials and out of the reach of children.
Do not place excessive loads on top of the device and do not subject it to mechanical stress.

DISPOSAL

In case of replacement or failure, dispose of the device in compliance with local waste disposal regulations.
The original material does not contain any toxic substances.

Distributore / *Distributor*	For.me.sa. Srl
Campo di applicazione/ *Application advice*	Adulti (Adults) CE **1434**
Conformità / *Compliance*	Dispositivo Medico classe IIa, conforme alla Direttiva CEE 93/42 *Medical device class IIa, in compliance with Regulation EEC 93/42*