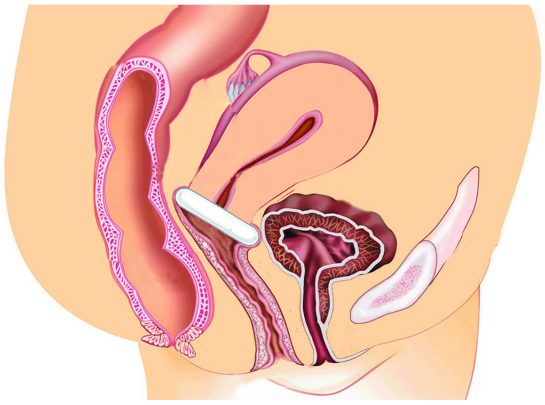
BOWL-SHAPED PERFORATED PESSARY

The indications are similar to those of classic ring pessaries. However, thanks to the support of the inner membrane, this model guarantees support up to the third degree of uterine prolapse and is ideal following hysterectomy procedures.

A ring pessary with membrane is shown on the left. In addition to the central hole, it also has vaginal discharge drainage holes.

This medical device is bowl-shaped perforated and it is indicated for forms of pelvic sagging and mild prolapse, although this model provides greater support than the classic ring pessary.
As a matter of fact, in patients with cystocele, this type of pessary provides both medial and lateral support.
It is also used in the rehabilitation of patients with vaginal vault prolapse, following hysterectomy and in combination with pelvic floor therapy.
For best results, it should only be used in cases where the pelvic floor is sufficiently intact.

In order for ring pessaries with membranes to yield good results, the pelvic floor must be sufficiently intact to be able to hold the pessary in place.
Once the right size has been identified, the pessary must be positioned so that it supports the vaginal vault or uterus.
The disk is made of soft, flexible silicone, which makes insertion and removal more simple and easier.
Once it has reached body temperature, the silicone of the pessary becomes soft and malleable, allowing the patient to use it without running any risks.
The holes on the membrane allow the drainage of vaginal discharge.



Uterus pessary rectum vagina urethra pubis bladder

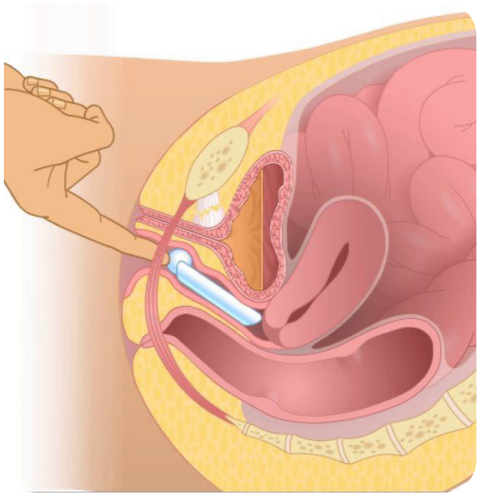
The figure on the right shows the correct position for a ring pessary with membrane. Observing the section, it is possible to note the similarities with the use of ring pessaries without membranes.

General precautions
If the patient is unable to urinate, or if incontinence is made worse by the pessary, the device must be removed and a model with a different diameter should be chosen.
Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.
Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.
Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).
Contraindications: silicone allergies.

BOWL-SHAPED URETHRAL PESSARY

The shape of this pessary makes it ideal for cases of incontinence and when the pelvic floor and genital organs require greater support. As a matter of fact, the knob has been specifically designed to act on the urethra.

A bowl-shaped urethral pessary is shown in the figure above, on the left is the knob to be positioned on the urethra, in order to correct stress incontinence.



The figure above shows how a bowl-shaped urethral pessary should be positioned.

The knob that characterises this type of medical device is designed to engage with the urethra.
More specifically, this model of pessary, with its "dish" shape, is designed to solve problems of: conservative correction of uterine prolapse, cystocele and other complications of stress urinary incontinence. Doctors may also decide to use it as an alternative to or in preparation for a surgical procedure. Manufactured using silicone, it assures adequate support while maintaining the comfort characteristics typical of the material.
In order to use the medical device, the pelvic floor must still be stable. The "knob", i.e. the protuberance present on the pessary, should shift the urethrovesical junction upwards and forwards.
The position of the knob of the pessary prevents urine from unintentionally entering the urethra, as occurs in situations of urge incontinence or stress incontinence, for example, coughing or pelvic strain.
In addition, the bowl-shaped urethral pessary guarantees better positional stability than the urethral ring pessary (the thinner device used for cases of mild prolapse).

When it is inserted for the first time, the pessary is guided through the posterior vaginal vault so that the knob lifts the urethrovesical junction, tilting it upwards. It will be necessary to simulate stress situations - such as coughing - to check the correct positioning and size of the medical device.
The patient should be able to urinate normally and without discomfort.
Bowl-shaped urethral pessaries are usually worn during the day: the patient must be able to self-manage its removal and its repositioning the following morning. If this is not possible, it is necessary to consider that the medical device can remain in situ for a maximum of 30 consecutive days; after this time, the physician may recommend additional measures, such as hormone therapy or creams that facilitate the insertion and replacement of the pessary and, if necessary, favour epithelium and tissue formation.
When self-managing insertion and removal, the patient can rest one leg on a chair, or she may prefer a supine position.
If, in the long-term, the size of the pessary proves to be inappropriate, the device must be removed and a different diameter considered.

General precautions
If the patient is unable to urinate, or if incontinence is made worse by the pessary, the device must be removed and a model with a different diameter should be chosen.
Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.
Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.
Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).
Contraindications: silicone allergies.

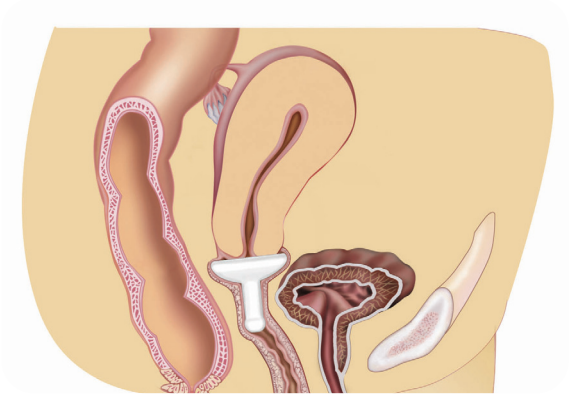
FUNGIFORM PESSARY

The special shape of this model of pessary makes it particularly indicated in cases of third- and fourth-degree uterine prolapse. It represents a valid alternative to the cube pessary, when the patient has complications associated with the urethra and incontinence.

A fungiform pessary - with its curved base and short stem - is shown above. It also has vaginal discharge drainage holes and a knob on the stem to allow a better grip during the removal phase.

The fungiform pessary is the best alternative to the cube pessary, especially in cases in which the patient has complications associated with incontinence. Although the silicone material makes it soft and adaptable, it should be pointed out that this model has a certain degree of stiffness. This characteristic makes it suitable above all when greater vaginal wall support and the repositioning of any cystocele or rectocele are required. There are holes on the cap of the pessary, suggesting that it is particularly ideal for use by patients with heavy vaginal discharge. It is also indicated for the conservative treatment of the female genital organs, including vaginal vault prolapse after hysterectomy.

Before a fungiform pessary is inserted for the first time, the specialist must reposition the prolapsed organs. The pessary can then be positioned in the manner and at the angle deemed to be best suited to the patient's needs, so that it supports the uterus and/or bladder and/or rectum.
To make sure the pessary is not likely to be displaced, patients are usually asked to simulate a few coughs in a supine position and with their legs apart on foot rests. It is also advisable to walk around the room for a few minutes. To ensure that the pessary is in the right position and that the right size has been chosen, patients should be asked to urinate before leaving the practice or clinic: if micturition is excessively difficult, try a smaller size or a different model and repeat the entire procedure.
At the practice or clinic, women should be helped to familiarise with their device and they should be able to remove the pessary and understand how to reposition it themselves. For patients who are not fully self-sufficient, it may be necessary to educate a carer.



Fungiform pessaries require greater care on the physician's part when choosing the size and during the first application than other models.

Although fungiform pessaries are also suitable in cases in which the pelvic floor tissues are not intact and elastic, it is essential for the physician to ensure that the device does not cause the patient discomfort or pain and that it is positioned properly.

General precautions
If the patient is unable to urinate, or if incontinence is made worse by the pessary, the device must be removed and a model with a different diameter should be chosen.
Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.
Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.
Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).
Contraindications: silicone allergies.

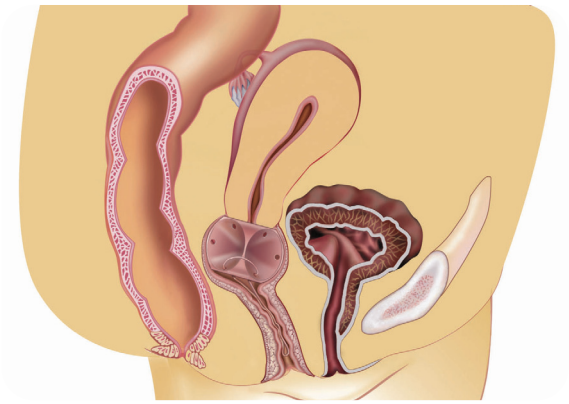
PERFORATED CUBE PESSARY

The special shape of the pessary makes it suitable for the containment of pelvic organ prolapse of all degrees. This model is one of the most appropriate options for women with an active lifestyle.

An example of a cube pessary, showing the vaginal discharge drainage holes and the string for easy removal of the medical device.

The cube pessary contains prolapse by fitting snugly against the walls of the vagina and creating a kind of vacuum effect. Its use does not therefore necessarily require the pelvic floor to be intact.
This device is indicated, above all, in cases of third- and fourth-degree uterine prolapse, in the presence of cystocele or rectocele, in the treatment of micturition disorders or in disorders during sexual intercourse and before surgery.
It is the ideal solution for effective support during the patient's daily activities (work, sport) and when she is able to self-manage the insertion and removal of the device (for example before sexual intercourse or going to bed).

The doctor must choose the right size for the patient with great care: in this phase it is recommended to use a lubricant (at the practitioner's discretion and in certain situations, an antibiotic gel could be chosen). Once positioned correctly, the device should neither cause the patient discomfort nor move from its position.
When self-managing insertion of the pessary at home, the patient should proceed in the same way as when inserting a tampon, placing one foot on a chair or the edge of a bed, or lying down, if necessary, then pushing the cube towards the vagina, using the full length of her fingers. It is also advisable to use a lubricant to make this delicate manoeuvre easier during self-management at home.
To remove the pessary, it is sufficient to pull the cub downwards using the string, trying to pull it in different directions in order to remove the "vacuum" effect and make removal easier.



An example of a cube pessary inserted in the vaginal canal is shown here.

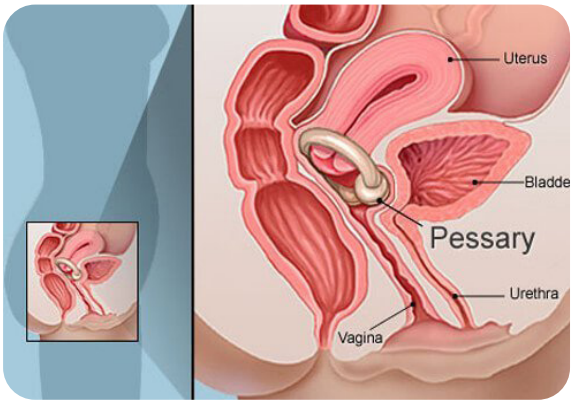
In the figure, the device is positioned with the function of containing uterine prolapse; in the presence of cystocele or rectocele, a pessary size making it possible to reposition also the bladder and/or rectum is usually used.

General precautions
If the patient is unable to urinate, or if incontinence is made worse by the pessary, the device must be removed and a model with a different diameter should be chosen.
Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.
Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.
Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).
Contraindications: silicone allergies.

URETHRAL PESSARY FOR INCONTINENCE

The shape of this pessary makes it indicated for cases of incontinence and prolapse through to the second degree of complexity. As a matter of fact, the knob has been specifically designed to act on the upper part of the urethra.

A urethral ring pessary is shown in the figure above, on the left is the knob to be positioned on the urethra, in order to correct stress incontinence.



The figure above shows how a urethral ring pessary should be positioned.

The knob that characterises this type of medical device is designed to engage with the upper part of the urethra. It can be effectively combined with therapy for uterine prolapse and cystocele.
Doctors may also decide to use it as an alternative to or in preparation for a surgical procedure.
Manufactured using silicone, it guarantees excellent comfort and easy of use that will rapidly allow the patient to self-manage the insertion and removal of the device.
In order to use this type of pessary, the pelvic floor must still be stable.

The "knob", i.e. the protuberance present on the pessary, is designed to shift the urethrovesical junction upwards and forwards.
The position of the knob of the pessary prevents urine from unintentionally entering the urethra, as occurs in situations of urge incontinence or stress incontinence, for example, coughing or pelvic strain.

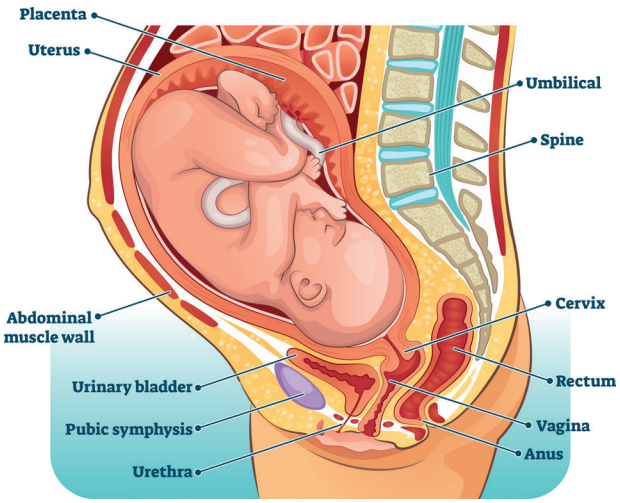
When it is inserted for the first time, the pessary is guided through the posterior vaginal vault so that the knob lifts the urethrovesical junction, tilting it upwards.
It will be necessary to simulate stress situations - such as coughing - to check the correct positioning and size of the medical device.
The patient should be able to urinate normally and without discomfort.
Urethral pessaries are usually worn during the day: the patient must be able to self-manage its removal and its repositioning the following morning.
If this is not possible, it is necessary to consider that the medical device can remain in situ for a maximum of 30 consecutive days.
The physician may recommend additional measures, such as hormone therapy or creams that facilitate the insertion and replacement of the pessary and, if necessary, favour epithelium and tissue formation.
When self-managing insertion and removal, the patient can rest one leg on a chair, or she may prefer a supine position.
If, in the long-term, the size of the pessary proves to be inappropriate, the device must be removed and a different diameter considered.

General precautions
f the patient is unable to urinate, or if incontinence is made worse by the pessary, the device must be removed and a model with a different diameter should be chosen.
Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.
Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.
Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).
Contraindications: silicone allergies.

PERFORATED CERVICAL PESSARY

Indicated for pregnant women with cervical dilation and therefore at risk of a premature birth, cervical pessaries support the cervix.

A cervical pessary is shown on the left. In addition to the central hole, it also has vaginal discharge drainage holes. The figure below shows the correct position for a cervical pessary during pregnancy.



The medical device is dish-shaped with drainage holes and is indicated for preventing premature births in women at risk of prolapse, who are subject to physical stress such as prolonged standing, increased intrauterine pressure (polyhydramnios/multiple pregnancies) or short cervix.
The purpose of the pessary is not to occlude the cervix, rather to reduce tension on the cervical tissues and alter the uterocervical angle.

After disinfection, the product must be lubricated and then squeezed and inserted into the vagina.
The pessary must then be turned so that its convex surface is facing towards the cervix and the lateral surfaces fit perfectly against the vaginal vaults.

Conservative (non-surgical) correction of genital prolapse, including vaginal vault prolapse following a full hysterectomy, prevention of postoperative vaginal adhesions.

N.B.:
Particular attention should be paid to cases in which the risk of a premature multiple birth is associated with a previous pre-28th week miscarriage.
Remove during the 37th or 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)

Warnings
Conditions for pessary insertion:

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

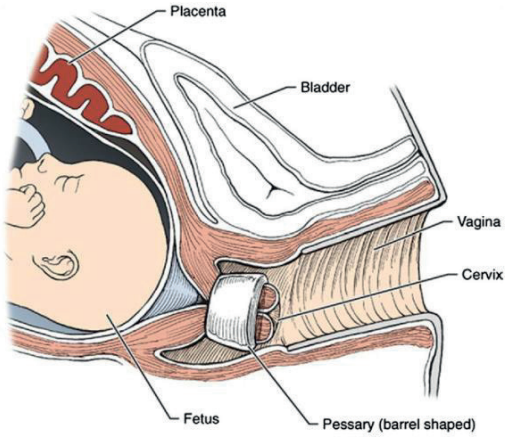


Figura 5

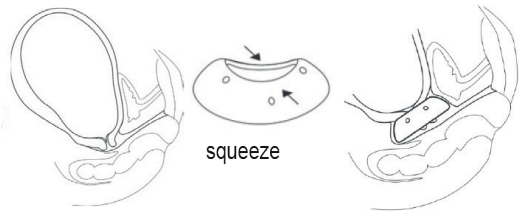


Figura 6

Examining and monitoring pregnant women using a pessary

A bacterioscopic cervicovaginal smear test every 2-3 weeks is mandatory.

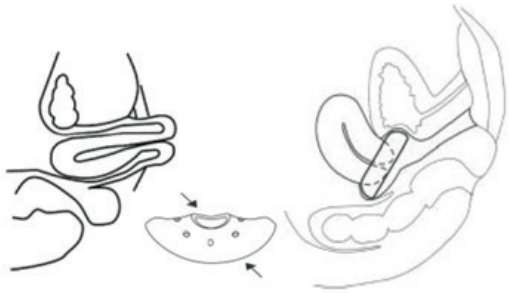
The condition of the cervix should be monitored taking the dynamic ultrasound findings into account (every 3-4 weeks).

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, they may also notice an increase in vaginal discharge (in this case, inflammation must be ruled out).

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 pessary should be removed before repeating sanitisation and then replacing the pessary.



Conservative (non-surgical) correction of genital prolapse, including vaginal vault prolapse following a full hysterectomy, prevention of postoperative vaginal adhesions.

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	√		√			√

General precautions

Patients should be told to report any problems, discomfort or pain associated with use of the medical device as soon as possible.

Cleaning: the device can be washed under running water with or without neutral soap. Use of additional disinfectants is not recommended. In exceptional cases a soft toothbrush may be used.

Material: European silicone. The pessary is manufactured using biologically inert material. The product does not contain any derivatives of human blood, tissues of animal origin, harmful chemicals or medicinal substances. The safety of all the materials forming the pessary has been confirmed using the following testing protocols: 011/958/08-01.0115/959/08-01 (cytotoxicity, irritation, sensitisation).

Contraindications: silicone allergies.