

BALANCE GELLHORN PESSARY

INSTRUCTIONS FOR USE AVAILABLE MODELS



Short Stem



Standard Stem

Sizes Available

Size	0	1	2	3	4	5	6	7	8	9
Outer Diameter (in mm)	38	45	51	57	64	70	76	83	89	95

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions for Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in serious injury to the patient and/or clinician.

DESCRIPTION:

The Balance Gellhorn Pessary is a medical device made from a medical grade clear silicone. This flexible silicone pessary fits into the vagina to help support the uterus, bladder and/or rectum.

INDICATIONS FOR USE:

The flexible Gellhorn pessary is commonly used effective support of third-degree prolapse or procidentia. The cervix rests behind the flat base of the pessary and only the stem shows in the vaginal entrance when the patient does a Valsalva maneuver. The Gellhorn pessary requires a relatively capacious vagina and an intact perineum.

CONTRAINDICATIONS:

Pessaries are contraindicated in:

- The presence of pelvic infections or lacerations
- A non-compliant patient
- Acute genital tract infections
- Endometriosis
- Pregnant patient
- Patients allergic to silicone
- Severe atrophy of the vaginal tissue

WARNINGS:

- The device should be used only if package is dry and unopened.
- Do not leave pessaries in place for long periods of time, as serious complications can occur which may require surgical intervention.
- Do not use these pessaries on a patient with a known silicone allergy.
- Chemicals in various vaginal preparations can interact with the pessary material, resulting in discoloration or deterioration of the pessary.
- Sexual intercourse would be contraindicated with pessary in place. The pessary should be removed before sexual intercourse.
- In pregnant patients, the Clinician may need to exercise clinical judgment to detect and guard against preterm labor, premature rupture of membranes, and infection.
- In patients who have undergone prior placement of surgical mesh in the vagina, the Clinician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against potential mesh erosion or displacement.
- In cases of acute inflammation, the Clinician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against exacerbated inflammation.
- In cases of bleeding, other than menstrual bleeding, the Clinician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against exacerbated bleeding.

PRECAUTIONS:

- Insertion and removal of Pessaries should only be performed by competent trained medical personnel/clinician.
- Clinicians must consider a patient as being under their active care as long as the patient wears a pessary.
- If the patient is not able to remove the pessary on their own for cleaning and inspection, more frequent healthcare visits are required.
- After removal of the Pessary an inspection of the vagina should be performed to check for ulceration, bleeding or infection.

STORAGE CONDITIONS:

- When in the package, store in a dry, dark place.

PATIENT INSTRUCTIONS FOR PESSARY USE

CAUTIONS:

IT IS RECOMMENDED THAT PESSARIES TO BE INSERTED AND REMOVED BY THE PHYSICIAN OR OTHER HEALTHCARE PROFESSIONAL UNLESS OTHERWISE DIRECTED.

- To ensure the desired correction of your condition, your healthcare professional needs your full cooperation.
- It is essential that your healthcare professional inspects your vagina at frequent intervals for evidence of pressure and/or allergic reaction.
- A gradual increase in the interval of inspection may be considered at the discretion of the treating practitioner.

REPORT ANY OF THE FOLLOWING SYMPTOMS TO YOUR PHYSICIAN:

- Any difficulty in urinating
- Any discomfort
- Any changes in the color or consistency of vaginal discharge
- Any increase in the amount of vaginal discharge or vaginal bleeding
- Any foul odor associated with vaginal discharge
- Vaginal itching
- If the pessary falls out

For medical emergencies and for all medically related advice, consult your healthcare professional.

FOR THE PHYSICIAN / HEALTHCARE PROFESSIONAL

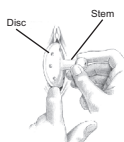


Figure 1



Figure 2



Figure 3

Review these instructions with the patient to establish use regimen.

INSTRUCTIONS:

Fitting usually requires a trial of various sizes to determine the proper pessary size. A vaginal lubricant like EasyLube Lubricating Jelly may be required for the patient's comfort before insertion of a pessary.

1. Wear sterile gloves. When necessary, lubricate only the entering end of the pessary with EasyLube Lubricating gel. Hold the pessary as shown in Figure 1.
2. Use one finger to depress the perineum. Guide the pessary, inserting it edgewise almost parallel to the introitus (see Figure 1), avoiding the urethral opening while the perineum is strongly pushed downward. Use a corkscrew motion while introducing the GELLHORN into the vagina.
3. Once the large flat disc is past the introitus, push the pessary upward until only the end of the stem shows in the vaginal entrance. The cervix rests behind the flat disc (see Figure 2).
4. Ask the patient to sit, stand and bear down slightly. If there is no leakage and the patient is comfortable with the pessary in position, have her empty her bladder.
5. If the patient can void without difficulty and the pessary remains in position upon re-examination and the patient is comfortable with the pessary in place, this is a good indication that the correct size

may have been selected. Patient experience may vary.

Note: If the patient is unable to urinate with the pessary in position, remove it and fit her with the next smaller size. Repeat as necessary.

6. Examine the patient while she is in the standing position to ensure the pessary has not shifted position. The patient should not feel the pessary once it is in position. The pessary should not be too loose as it may turn or be expelled and it should not be too tight as it may cause discomfort.
7. The healthcare professional should be able to sweep one finger between the pessary and the vaginal walls. If there is not enough space to do this, the next smaller size should be tried. If excessive space exists, the pessary will not be effective and may rotate or even be expelled.
8. It is sometimes necessary to refit the patient with a different size or type of pessary after a period of time. Do not assume that a replacement will always be the same size as the previous one. Check the fitting to ensure continued patient comfort and relief of symptoms. The useful life of a pessary is limited. Examine frequently eg. two or three months for signs of deterioration (such as cracks or breaks in silicone outer surface). A pessary should be replaced if damaged.
9. Ulcerations and erosions frequently occur in cases of complete prolapse due to irritation of the exteriorized cervix or vaginal wall. Whenever possible, reducing the mass and treating the irritation are primary steps before using a pessary. Prolapse reduction may resolve cervical vaginal irritation. Verification of cervical cytology (pap) and or biopsy as clinically indicated.
10. During each visit, the vagina should be carefully inspected for evidence of pressure or allergic reaction. The patient should be questioned concerning douching, discharge, disturbance of bowel function or urination. It may be necessary to fit another size or an entirely different type of pessary.
11. At the clinician's discretion, the patient can be instructed in the proper removal, cleaning and reinsertion techniques for her own pessary. This process can be performed nightly or even weekly by the patient under ideal circumstances.

TO REMOVE:

- Use one finger to depress the perineum.
- Use other hand to grasp the "knob," pulling the pessary away from the cervix, turning the pessary so that the disc is almost parallel to the introitus. Using corkscrew motion ease the pessary out. See Figure 3.
- Removal may be facilitated by passing a finger along the stem and behind the disk and folding in against the stem for removal

RECOMMENDED FOLLOW-UP:

Discuss with patient the importance of following instructions and the expected length of time for Pessary usage. Schedule follow-up visits to fit the needs of the patient and in accordance with local guideline/policy or have a suggested following schedule:

- Have patient return within 24 hours for first examination.
- Have patient return for second examination within 3 days.
- Have patient return for examination every few months.(i.e. 2-3 months)

Note: The above schedule of follow-up examinations may be altered to fit the needs of the individual patient at the discretion of the healthcare provider.

Instruct patient to immediately report any of the following: Discomfort, Spontaneous expulsion, Any changes in color, amount, consistency or odor of vaginal discharge, Difficulty with elimination.

ADVERSE REACTIONS:

- While mild and/or transient symptoms appear to be fairly common during Pessary use, rare serious adverse effects may also occur, particularly if Pessary care is neglected.
- Serious adverse events related to Pessary use include impaction or entrapment of the Pessary requiring surgical removal and infection and/or obstruction.

RECOMMENDED CLEANING INSTRUCTIONS:

1. Prepare a cleaning solution by mixing a mild soap with tap water using the soap. Prepare this solution in a container large enough to fully submerge the device.

2. Soak and Scrub

- a. Soak the device in the container of prepared soap solution for a minimum of 5 minutes.
- b. Following the 5-minute soak period, scrub the device for a minimum of 15 seconds with a soft-bristled brush, such as a tooth brush and/or pipe brush. Scrub device below water line to prevent aerosolization of contaminants.
- c. Following scrub, inspect device for visible soil residue.

3. Rinse

- a. Remove the device from the soap solution and thoroughly rinse under flowing tap water for a minimum of 30 seconds.
- b. Allow the device to dry.

Recommended Replacement Interval: If there are no complications, as a guide & best practice, the maximum time for changing and replacing the Balance Gellhorn Pessary with a new one is once every 5 years or earlier if it shows signs of cracking, loss of shape or flexibility. A pessary should be replaced if damaged

DISPOSAL OF DEVICE

This device must be handled and disposed of as healthcare medical waste in accordance with hospital procedures and applicable regulations.

Any device that has been contaminated with potentially infectious substances of human origin (such as bodily fluids) must be handled according to hospital protocol for infectious medical waste.

ADDITIONAL INFORMATION:

If you require any further information regarding this product, please contact us at: info@trionpharma.co.uk



EXPLANATION OF SYMBOLS

	Catalogue number
	Batch code
	Use-by date
	Consult instructions for use
	Not made with natural rubber latex
	Authorized Representative in the European community
	Product complies with requirement of directive 93/42/EEC for medical device
	Caution
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Medical Device
	Non-sterile
	Single patient-multiple use



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