



GIMA

PROFESSIONAL MEDICAL PRODUCTS

**PESSARY
PESSARIO
PESSAIRE
PESSAR
PESSÁRIO
ΠΕΣΣΟΣ
ПЕСАР
PESAR**

**PESAR
NIJE STERILNO
PESSZÁRIUM
PEŠĀRIJS
PESSARIUM
PESSAR
PESAR VAGINAL
PESAR**

فَرْجَة

**GIMA 30030 - 30031 - 30032 - 30033 - 30034 - 30035 - 30036 -
30037 30038 30039 - 30040 - 30041 - 30042 - 30044 - 30045 - 30046
30047 30048 - 30049 - 30053 - 30054 - 30055 - 30056 - 30057 -
30071 - 30072 - 30073 - 30074 - 30075 - 30043**



Guangzhou Fame Medical Co., Ltd.

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Made in China



0123



REF PER00 - PER01 - PER02 - PER03 - PER04 - PER05 - PER06 - PER07 - PER08
PER09 - PERS00 - PERS01 - PERS02 - PERS04 - PERS05 - PERS06 - PERS07
PERS08 - PERS09 - PEGLO3 - PEGLO4 - PEGLO5 - PEGLO6 - PEGLO7
PECUD00 - PECUD01 - PECUD02 - PECUD03 - PECUD04 - PERSO3



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M-30030M-Rev.0.01.25

Instructions For Use

The flexible silicone pessary is commonly used for a mild first or second degree uterine prolapse or procidentia. The pessaries are made from 100% medical grade silicone. Pessaries are designed for single patient use.

CAUTION

Federal law requires that a physician prescribe the device.

CONTRAINDICATIONS

Pessaries are contraindicated in acute genital tract infections, pelvic infections, or non-compliant patients.

PROCEDURES

Fitting usually requires a trial of various sizes to determine the proper pessary size. The Pessary Fitting Set is a valuable aid in selecting the correct pessary. A vaginal lubricant may be required for the patient's comfort before insertion of the pessary. The physician may suggest K-Y jelly®, or equivalent.

The physician should determine if the patient requires oestrogen therapy before prescribing a pessary.

1. Perform a normal pelvic examination prior to the fitting and introduction of a pessary. A pelvic exam helps determine the appropriate size. The pessary will easily fold across the largest drainage holes to simplify insertion and removal. The pessary should be large enough for its indication, yet not cause any undue pressure or discomfort.
2. Compress the pessary and gently insert the pessary through the introitus. Once the pessary has passed the introitus, release the compressed pessary so that it expands to its normal shape.
3. Gently move the pessary to the cervix to support the cystocele or rectocele and the uterus. When in the correct position, the physician should be able to insert an examining finger between the outer edge of the pessary and the vaginal wall. This spacing will ensure the patient's comfort and reduce the risk of pressure necrosis.
4. Once in place, the pessary should not dislodge when standing, sitting, squatting or bearing down. It should not be uncomfortable for the patient during any of these routine activities.
5. If the patient is to care for the pessary, please be sure to instruct on its cleaning, insertion and removal.
6. Tell the patient to report any discomfort or difficulty in urinating or defecating immediately.

















REMOVAL, CLEANING AND SUGGESTED FOLLOW UP

1. To remove the pessary, carefully move the pessary forward towards the introitus. When the pessary is within reach, compress the pessary and carefully withdraw.
2. The pessary can be cleaned with mild soap and warm water. The use life of the pessary is limited. Examine pessary for signs of deterioration.
3. Sexual intercourse would be contraindicated with pessary in place.
4. Discuss with patient the importance of following instructions and the expected length of time for pessary usage.
5. Within 24 to 48 hours, ensure the patient is not allergic to the pessary. Examine the vagina and ask the patient if there has been any discomfort, irritation, pressure, sensitivity, or unusual vaginal discharge. Also determine if there has been any improvement in her personal symptoms.
6. Schedule follow-up visits to fit the needs of the patient and in accordance with local policy.

GIMA WARRANTY TERMS

The Gima -12month standard B2B warranty applies.

SYMBOLS - DESCRIPTION

	Keep in a cool, dry place		Lot number
	Manufacturer		Product code
	Date of manufacture		Keep in a cool, dry place
	Medical Device complies with Directive 93/42/EEC		Keep away from sunlight
	Caution: read instructions (warnings) carefully		Don't use if package is damaged
	Authorized representative in the European community		Latex free
	Expiration date		Non-sterile
	Disposable device, do not re-use		Imported by