Bioteque

Instructions for Use
Vaginal Pessary MD

Description

The vaginal pessary is an invasive, non-sterile, long-term use medical device inserted into the vagina to support the management of POP and relieve associated symptoms. It is made from silicone and is available in various shapes and sizes to suit individual anatomical and clinical needs. The pessary helps maintain the correct positioning of pelvic structures, reducing prolapse and improving patient comfort and quality of life.

This Instructions for Use (IFU) applies to all types of pessaries. All types share similar fundamental features ; nevertheless, certain types exhibit distinctive technical specifications.

- **The Ring**, **Oval**, **Dish**, **Ring with Knob**, **Hodge**, **Cup** and **Marland** Pessary are available with and without a support membrane.
- **The Cube Pessary** is available with a silicone loop for positioning and with or without drainage holes.
- **The Shaatz** Pessary features a rigid disc base to support the prolapse.
- **The Donut** Pessary features a thicker, rounded ring structure that provides strong vault support.
- **The Gehrung**, **Hodge** and **Incontinence Ring** Pessary are malleable and can be shaped to the specific needs of the patient. These pessaries should be removed for an X-ray, ultrasound, or MRI. due to the malleable metal inside.
- **The Flexi Shelf** Pessary features a concave shaped base to support the prolapse, and a tapered rigid stem to assist a healthcare professional or patient to grip and twist for easy removal.
- **The Gellhorn/Short-Stem Gellhorn** Pessary feature a rigid disc base to support the prolapse and a prominent stem with a knob designed for folding flat against the base to facilitate insertion and removal.

Product Model Basic-UDI : 47198944301009G

Vaginal Pessary is available in different types, each identified by shape for easy distinction. The types covered by this instruction are categorized as follows:

Pessaries with a Single Configuration

- **Donut pessary** **D** REF
- **Shaatz pessary** **SH** REF
- **Gellhorn** **GD** REF
- **Short-Stem Gellhorn** **GS** REF
- **Gehrung** **GH** REF
- **Incontinence Ring** **IR** REF
- **Flexi Shelf** **FS** REF

Pessaries Available With or Without a Support Membrane

Type / Model	with support REF	without support REF
Ring	Rs	R
Ring with Knob	RKs	RK
Oval	OVs	OV
Dish	DSHs	DSH
Cup	CPs	CP
Hodge	HDs	HD
Marland	Ms	M

Pessaries Available With or Without a Drain Holes

Type / Model	with drain REF	without drain REF
Cube	CUd	CU

NOTE: Each package contains a single device.

Clinical Benefits

- Provides mechanical support to the pelvic organs in adult women with POP.
- Demonstrates high continuation rates, indicating sustained use and patient tolerability.
- Supports the management of POP and associated symptoms, as measured by reductions in validated patient-reported outcome measures.

Indications for Use

A vaginal pessary is indicated for the conservative management of women with symptomatic pelvic organ prolapse (POP), including uterine, cystocele, rectocele, or vaginal vault prolapse. It is intended for patients who wish to avoid or postpone surgery, or for those who are not suitable candidates for surgical intervention. The device is intended for use by women under the guidance of a qualified healthcare professional.

The suitable indications for the Pessaries are listed as follows:

Type / Symptoms	Prolapse (1-2 Degree)	Prolapse (2-3 Degree)	Cystocele	Rectocele	Stress Incontinence
Ring	O				
Cube		O	O	O	
Donut		O	O	O	
Shaatz	O				
Dish		O	O	O	O
Cup		O	O		O
Oval	O		O		
Ring with Knob	O		O		O
Gellhorn		O	O	O	
Short- stem Gellhorn		O	O	O	
Gehrung		O	O	O	
Marland		O	O		O
Hodge		O			
Incontinence Ring					O
Flexi Shelf		O			

Intended purpose

The Vaginal pessary is a removable silicone device intended for use in adult women for the conservative management of pelvic organ prolapse. The device is intended to be inserted into the vagina to provide mechanical support to the pelvic organs, thereby supporting the management of pelvic organ prolapse and associated symptoms.

Intended patient population

The device is indicated for adult women, typically aged 18 years and older, who have been diagnosed with various grades of pelvic organ prolapse, including uterine prolapse, cystocele, rectocele, and enterocele, and for those experiencing stress urinary incontinence as a result of POP. It is particularly suited for perimenopausal and postmenopausal women experiencing mild to moderate stages of POP, generally classified as Stage I to Stage III.

Intended users

The pessary is intended to be fitted and initially inserted by trained medical practitioners or qualified clinical staff in a clinical setting. Following assessment and instruction by a healthcare professional, the device may also be used,inserted, removed and managed independently by the patient.

Contraindications

Do not use this device in the following conditions

- Acute vaginal infections
- Severe vaginal atrophy
- Unexplained vaginal bleeding
- Known allergy to the device material
- Active pelvic inflammatory disease (PID)
- Patients with significant vaginal scarring or stenosis

Potential Side Effects

- Itching/ burning/ irritation/ discomfort
- Bleeding
- Vaginal odor
- Pain or discomfort
- Uterine leakage
- Infection/ abnormal vaginal discharge
- Vaginal sore or wound

In case of side effects, discontinue the procedure, provide appropriate medical intervention, and report to the manufacturer and the applicable local regulatory authority, as required by local laws and regulations.

Warnings

1. This device must be prescribed, evaluated, and fitted by a trained healthcare professional.
2. Improper sizing or incorrect use may result in complications such as vaginal ulceration, bleeding, infection, urinary retention, or, in rare cases, perforation.
3. Do not leave the pessary in place for prolonged periods without follow-up. Extended use without removal or clinical review may cause serious complications or require surgical intervention.
4. Do not use in patients with known silicone hypersensitivity.
5. Monitor for allergic reactions within 24 to 48 hours after first use and check the vaginal area. If you experience discomfort, irritation, pressure, sensitivity, or unusual discharge, contact your doctor immediately.
6. Incontinence Ring, Hodge and Gehrung pessaries contain metal and must be removed before MRI, ultrasound, and X-ray procedures.

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Cautions

1. After the initial fitting and size confirmation, a short-term follow-up is recommended to assess comfort, urinary flow, and vaginal mucosal condition. Subsequent follow-ups should be conducted as determined by the healthcare professional.
2. If abnormal discharge, unpleasant odor, pain, or difficulty urinating occurs, discontinue use immediately and consult a healthcare professional.
3. Sexual intercourse may be affected while wearing the pessary. If removal is required, follow the healthcare professional's instructions.

Precautions

1. For single-patient reuse only. Remove, clean, and inspect the pessary at regular intervals as directed by the healthcare professional.
2. After insertion, the clinician should confirm that the patient is able to urinate and defecate normally.
3. If slippage, pressure discomfort, or indentation occurs after fitting, reassess the size and model of the pessary.

Instructions for Use

Prior to initial use, the Pessary should be washed thoroughly. Refer to the Cleaning section for the detailed procedure.

Insertion

1. 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. The healthcare professional should decide if estrogen therapy and/or lubricant is suggested prior to the insertion.
2. Perform a normal pelvic examination prior to the fitting 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.
3. 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. Each type has a similar method of insertion.

Specific instructions for the pessaries:

- **Ring**, **Ring with Knob**: Fold along the axis across the large drainage holes, ensuring the crescent points downward.
- **Cube:**Ensure the loop faces outward during insertion to facilitate future removal and avoid mucosal injury.
- **Oval**: Fold along its axis in a similar manner.
- **Shaatz**: Fold it so that the crescent points downward.
- **Marland**: Fold across the large drainage holes with the crescent pointing downward.
- **Dish**: Fold so that the elevated section or "porch" faces forward. Slowly move it past the cervix into the posterior fornix.
- **Donut**: Compress during insertion, and upon passing the introitus, release it to expand.
- **Gellhorn/Short-Stem Gellhorn :** Fold the stem with the knob flat againstthe disc base.
- **Gehrung**: fold before gentle insertion, allowing it to expand after passingthe introitus.
- **Hodge**: Require folding with its posterior bar directed toward the cervix.
- **Flexi Shelf**: The tapered stem design simplifies holding and removal, streamlining both insertion and extraction processes.

4. Gently move the pessary to the cervix to support the cystocele or rectocele and the uterus. When in the correct position, the healthcare professional should be able to insert an examining finger between the outer edge of the pessary and the vaginal wall. This spacing ensures patient comfort and reduces the risk of pressure necrosis. All types are placed in a similar position, but some types have special placement in the uterus.

Specific instructions for the pessaries:

- **Ring with Knob**: Place to support the uterus and the urethra knob, ensuring space between the outer rim and the vaginal wall.
- **Ring**: Rotate a quarter turn to prevent folding or displacement.
- **Oval**: Adjust by a quarter turn to prevent rotation.
- **Dish**: Position to support the uterus, with the "porch" supporting the urethra.
- **Donut**: Gently move past the cervix into the posterior fornix, supporting the cystocele or rectocele, and the uterus.
- **Gellhorn/Short-Stem Gellhorn:** insert the folded pessary past the introitus. After insertion, slowly release the folded pessary so that the base of the disc is supporting the uterus, and the stem with the knob is pointing downward.
- **Gehrung**: Position to support the cystocele or rectocele.
- **Hodge**: Gently move past the cervix into the posterior fornix.
- **Flexi Shelf:** Gently introduce the base through the introitus, rotate until fully inserted, and ensure the tapered stem points toward the anterior vaginal wall.

5. Once in place, the pessary should not dislodge when standing, sitting, squatting, or bearing down. It should not be uncomfortable during these activities. The pessary should be large enough for its indication, yet not cause any undue pressure or discomfort.
6. The prescribed pessary should be cleaned prior to each insertion and removal. The cleaning steps are especially recommended before the first follow-up visit.
7. The patient should report any discomfort to their healthcare professional immediately

Removal

Carefully remove the pessary toward the introitus using the index finger into the vagina to find the rim, pull down and out to allow removal.

All types have similar removal methods.

Specific instructions for the pessaries:

- Locate the **Cube** pessary by the Cube Loop , then carefully use a tool or your finger to remove the pessary.
- To remove **Flexi Shelf** Pessary, carefully break the seal between the disc base and the cervix.Move the pessary forward towards the introitus with the tapered stem protruding first.Once the tapered stem is fully out, twist the pessary so that part of the silicone base moves past the introitus.Gently rotate to remove the entire pessary.

Cleaning

1. Prior to initial use, the Pessary should be washed thoroughly.
2. Rinse Pessary with 20 - 40 °C warm water for 30-40 seconds.
3. Apply mild pH 5-9 soap to rub the pessary gently back and forth for 10 times to lather well.
4. Rinse off Pessary with warm water for 1 minute, repeat and wash if needed.
5. Wash again and rinse Pessary thoroughly with distilled water for 1 minute. Ensure all traces of soap are removed to avoid irritation.
6. Allow pessary to completely air-dry before reinsertion.

Follow-up schedule

- The pessary should be removed for cleaning every day or two.
- Women often remove their pessary for sexual activity, please contact your healthcare professional for questions.
- Discuss with your healthcare provider on how to care for your pessary and expected length of time for pessary use.
- Monitor any allergic reaction within 24 to 48 hours after first fitted. Exam the vagina area, contact your healthcare professional with any discomfort, irritation, pressure, sensitivity, or unusual discharge.
- Schedule a follow-up visit to communicate with your healthcare professional on the symptoms to maximize the support.

Disposal Instructions

- When the pessary becomes damaged, discolored, deformed, or no longer clinically indicated, it should be disposed of in accordance with local regulations for medical waste.
- Used pessaries that have been in contact with bodily fluids should be handled as clinical waste. Place the used device in a sealed plastic bag or container before disposal to minimize contamination.
- If the device has not been in contact with infectious material (e.g., trial-fitted, unused, or clean pessary), it may be discarded as general non-hazardous waste, following hospital or clinic policy.
- Follow institutional and national environmental safety guidelines when discarding the device and its packaging materials.

Storage & Transportation Conditions

- The shelf life of the **Donut** is 5 years, the other devices are 10 years from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

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Size List

Ring (With Support / Without Support)			
SKU	Dimension in mm	SKU	Dimension in mm
Rs0	44	R0	44
Rs1	50	R1	50
Rs2	57	R2	57
Rs3	63	R3	63
Rs4	69	R4	69
Rs5	75	R5	75
Rs6	82	R6	82
Rs7	88	R7	88
Rs8	95	R8	95
Rs9	101	R9	101

Oval (With Support / Without Support)			
SKU	Length in mm	SKU	Length in mm
OVs1	50.5	OV1	50.5
OVs2	57	OV2	57
OVs3	63.5	OV3	63.5
OVs4	69.5	OV4	69.5
OVs5	76	OV5	76
OVs6	83	OV6	83
OVs7	89	OV7	89
OVs8	96	OV8	96
OVs9	101	OV9	101

Dish (With Support / Without Support)			
SKU	Dimension in mm	SKU	Dimension in mm
DSHs0	48.5	DSH0	48.5
DSHs1	53.5	DSH1	53.5
DSHs2	59	DSH2	59
DSHs3	64	DSH3	64
DSHs4	69	DSH4	69
DSHs5	75	DSH5	75
DSHs6	79	DSH6	79
DSHs7	84	DSH7	84

Ring with Knob (With Support / Without Support)			
SKU	Dimension in mm	SKU	Dimension in mm
RKs0	44	RK0	44
RKs1	50	RK1	50
RKs2	57	RK2	57
RKs3	62.5	RK3	62.5
RKs4	69	RK4	69
RKs5	75	RK5	75
RKs6	82	RK6	82
RKs7	87.5	RK7	87.5

Donut			
SKU	Dimension in mm	SKU	Dimension in mm
D0	50	D4	76
D1	59	D5	82
D2	65	D6	88
D3	69	D7	95

Marland (With Support / Without Support)			
SKU	Dimension in mm	SKU	Dimension in mm
Ms2	58	M2	58
Ms3	64	M3	64
Ms4	70	M4	70
Ms5	76	M5	76
Ms6	82	M6	82
Ms7	88	M7	88
Ms8	94	M8	94

Shaatz			
SKU	Dimension in mm	SKU	Dimension in mm
SH0	38	SH5	70
SH1	45	SH6	76
SH2	51.5	SH7	82
SH3	57	SH8	88
SH4	63	SH9	95

Short-Stem Gellhorn			
SKU	Dimension in mm	SKU	Dimension in mm
GS0	38	GS5	70
GS1	44	GS6	76
GS2	51	GS7	83
GS3	57	GS8	89
GS4	63.5	GS9	95

Cube (With Drain / Without Drain)			
SKU	Length in mm	SKU	Length in mm
CUd0	25	CU0	25
CUd1	29	CU1	29
CUd2	33	CU2	33
CUd3	37	CU3	37
CUd4	41	CU4	41
CUd5	45	CU5	45
CUd6	50	CU6	50
CUd7	56	CU7	56
CUd8	63	CU8	63
CUd9	70	CU9	70
CUd10	75	CU10	75

Cup (With Support / Without Support)			
SKU	Dimension in mm	SKU	Dimension in mm
CPs0	48.5	CP0	48.5
CPs1	53.5	CP1	53.5
CPs2	59	CP2	59
CPs3	64	CP3	64
CPs4	69	CP4	69
CPs5	74	CP5	74
CPs6	79	CP6	79
CPs7	84	CP7	84

Gellhorn			
SKU	Dimension in mm	SKU	Dimension in mm
GD0	38	GD6	76
GD1	45	GD7	82
GD2	51.5	GD8	88
GD3	57	GD9	95
GD4	63	GD10	101.6
GD5	70		

Hodge (With Support / without Support)			
SKU	Length in mm	SKU	Length in mm
HDs0	65	HD0	65
HDs1	70	HD1	70
HDs2	75	HD2	75
HDs3	80	HD3	80
HDs4	85	HD4	85
HDs5	90	HD5	90
HDs6	95	HD6	95
HDs7	100	HD7	100
HDs8	105	HD8	105
HDs9	110	HD9	110

Gehrung			
SKU	Dimension in mm	SKU	Dimension in mm
GH0	50	GH5	75
GH1	55	GH6	80
GH2	60	GH7	85
GH3	65	GH8	90
GH4	70	GH9	95

Incontinence Ring			
SKU	Dimension in mm	SKU	Dimension in mm
IR0	44	IR5	76
IR1	51	IR6	83
IR2	57	IR7	89
IR3	64	IR8	95
IR4	70	IR9	102

Flexi Shelf			
SKU	Length in mm	SKU	Length in mm
FS06	57	FS10	70
FS08	64	FS12	76

Glossary of Symbols

- LOT — Batch code
- Manufacturer
- UDI — Unique Device Identifier
- Temperature limit 10-40°C
- Humidity limitation 30-80%RH
- Not made with Natural Rubber Latex
- Single patient multiple use
- Consult instructions for use
- Expiry Date (YYYY/MM/DD)
- Caution
- Do not use if package is damaged and consult instructions for use
- REF — Catalogue number
- MD — Medical device
- MRI unsafe
  (Incontinence Ring, Hodge and Gehrung pessaries cotain metal and must be removed to MRI, ultrasound and x-ray procedures.)

Rx ONLY Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Bioteque Taiwan Ltd. and to the applicable competent authority having jurisdiction in their locale.

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