

Vaginal Pessary



Type of Vaginal Pessary

Not made with natural rubber latex

DESCRIPTION:

A Pessary is a removable silicon device that fits into the Vagina to provide support of the Uterus, Vagina, Bladder and/or Rectum. Pessaries are commonly used in the management of Pelvic Organ Prolapse (POP) such as Cystocele (Bladder), Rectocele (Rectum) and Stress Urinary Incontinence (Leaking of Urine during Coughing, Straining or Exercising).

All types share similar fundamental features; nevertheless, certain types exhibit distinctive technical specifications

- **Cube Pessary** is available with silicone loop for removal and with or without drainage holes.
- **Ring, Oval, Dish, Ring with Knob, Hodge, Cup and Marland Pessary** are available with and without a support membrane.
- **Gehrung, Hodge and Incontinence Ring Pessary** are malleabl and can be shaped to the specific needs of the patient. These pessary should be removed for an X-ray, ultrasound, or MRI. due to the malleable metal inside.
- **Flexi Shelf Pessary** has an anatomical shape which helps in limiting the possibility of bowel movement complications. Its concave shaped base supports the prolapse and the tapered rigid stem assists a clinician or patient to grip and twist for easy removal.

INDICATIONS:

The flexible silicone pessary is commonly used for a mild first or second-degree uterine prolapse or procidentia.

Pessaries are designed for single patient use and supplied non-sterile.

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

CONTRAINDICATIONS:

Pessaries are contraindicated in acute genital tract infections, pelvic infections, or noncompliant patients.

CAUTION:

1. U.S. Federal law restricts this device to sale by or on the order of a physician.
2. The device should not be used if there is any visible defect (e.g., crack, discoloration).

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.

The physician should decide if estrogen therapy and/or lubricant is suggested prior to the insertion.

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. Each type has a similar method of insertion, however, some types have special methods of insertion into the vagina.

- For **Cube Pessary**, ensure the loop faces outward during insertion.
- For **Shaatz Pessary**, fold it so that the crescent points downward.
- For **Incontinence Ring, Ring with Knob, or Ring Pessary**, fold along the axis, i.e., across the large drainage holes, ensuring the crescent points downward.
- For **Oval Pessary**, fold along its axis in a similar manner.
- For **Marland Pessary**, fold across the large drainage holes with the crescent pointing downward.
- For **Dish and Cup Pessary**, fold so that the elevated section or "porch" faces forward. Slowly move it past the cervix into the posterior fornix.
- For **Donut Pessary**, compress during insertion, and upon passing the introitus, release it to expand.
- For **Gehrung Pessary**, fold before gentle insertion, allowing it to expand after passing the introitus.
- For **Gellhorn/Short-stem Gellhorn Pessary**, involve folding the stem with the knob flat against the disc base.
- For **Hodge Pessary**, require folding with its posterior bar directed toward the cervix.
- For **Flexi Shelf Pessary**, the tapered stem design simplifies holding and removal, streamlining both insertion and extraction processes.

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 insure the patient's comfort and reduce the risk of pressure necrosis. All types are placed in a similar position, but some types have special placement in the uterus.

- For **Ring with Knob and Incontinence Ring Pessary**, carefully place to support the uterus and the urethra knob, ensuring space between the outer rim and the vaginal wall.
- For **Ring Pessary**, rotate a quarter turn to prevent folding or displacement.
- For **Oval Pessary**, adjust by a quarter turn to prevent rotation.
- For **Dish and Cup Pessary**, position to support the uterus, with the "porch" supporting the urethra.
- For **Donut Pessary**, gently move past the cervix into the posterior fornix, supporting the cystocele or rectocele, and the uterus.
- For **Gehrung Pessary**, position to support the cystocele or rectocele.
- For **Gellhorn/Short-stem Gellhorn Pessary**, 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.
- For **Hodge Pessary**, gently move past the cervix into the posterior fornix.
- For **Flexi Shelf Pessary**, gently introduce the base through the introitus, rotate until fully inserted, and ensure the tapered stem points toward the anterior vaginal wall.

- 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. Pessary should be large enough for its indication, yet not cause any undue pressure or discomfort
- The prescribed pessary should be cleaned prior to each insertion and removal, the cleaning steps are especially recommended before your first follow-up visit.
- The Patient should report any discomfort to your doctor immediately.

REMOVAL AND SUGGESTED FOLLOW-UP:

- 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, but some types have special removal methods.
 - 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.

- The pessary should be removed for cleaning every day or two.
- Women often remove their pessary for sexual activity, please contact your physician 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 doctor with any discomfort, irritation, pressure, sensitivity, or unusual discharge.
- Schedule a follow-up visit to communicate with your doctor on the symptoms to maximize the support.

CLEANING:

- Prior to initial use, the Pessary should be washed thoroughly.
- Rinse Pessary with 20 - 40 °C warm water for 30-40 seconds.
- Apply mild pH 5-9 soap to rub the pessary gently back and forth for 10 times to lather well.

- Rinse off Pessary with warm water for 1 minute, repeat and wash if needed.
- Wash again and rinse Pessary thoroughly with distilled water for 1 minute. Ensure all traces of soap are removed to avoid irritation.
- Allow pessary to completely air-dry before reinsertion.

SIZE:

Cube (With Drain / Without Drain)				Ring (With Support / Without Support)				Hodge (With Support / without Support)			
SKU	Length in mm	SKU	Length in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Length in mm	SKU	Length in mm
Cud0	25	CU0	25	Rs0	44	R0	44	HDs0	65	HD0	65
Cud1	29	CU1	29	Rs1	50	R1	50	HDs1	70	HD1	70
Cud2	33	CU2	33	Rs2	57	R2	57	HDs2	75	HD2	75
Cud3	37	CU3	37	Rs3	63	R3	63	HDs3	80	HD3	80
Cud4	41	CU4	41	Rs4	69	R4	69	HDs4	85	HD4	85
Cud5	45	CU5	45	Rs5	75	R5	75	HDs5	90	HD5	90
Cud6	50	CU6	50	Rs6	82	R6	82	HDs6	95	HD6	95
Cud7	56	CU7	56	Rs7	88	R7	88	HDs7	100	HD7	100
Cud8	63	CU8	63	Rs8	95	R8	95	HDs8	105	HD8	105
Cud9	70	CU9	70	Rs9	101	R9	101	HDs9	110	HD9	110
Cud10	75	CU10	75								

Oval (With Support / Without Support)				Ring with Knob (With Support / Without Support)				Dish (With Support / Without Support)			
SKU	Length in mm	SKU	Length in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm
Ovs1	50.5	OV1	50.5	Rks0	44	RK0	44	DSHs0	48.5	DSH0	48.5
Ovs2	57	OV2	57	Rks1	50	RK1	50	DSHs1	53.5	DSH1	53.5
Ovs3	63.5	OV3	63.5	Rks2	57	RK2	57	DSHs2	59	DSH2	59
Ovs4	69.5	OV4	69.5	Rks3	62.5	RK3	62.5	DSHs3	64	DSH3	64
Ovs5	76	OV5	76	Rks4	69	RK4	69	DSHs4	69	DSH4	69
Ovs6	83	OV6	83	Rks5	75	RK5	75	DSHs5	75	DSH5	75
Ovs7	89	OV7	89	Rks6	82	RK6	82	DSHs6	79	DSH6	79
Ovs8	96	OV8	96	Rks7	87.5	RK7	87.5	DSHs7	84	DSH7	84
Ovs9	101	OV9	101								

Cup (With Support / Without Support)				Marland (With Support / Without Support)				Gellhorn			
SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm
CPs0	48.5	CP0	48.5	Ms2	58	M2	58	GD0	38	GD6	76
CPs1	53.5	CP1	53.5	Ms3	64	M3	64	GD1	45	GD7	82
CPs2	59	CP2	59	Ms4	70	M4	70	GD2	51.5	GD8	88
CPs3	64	CP3	64	Ms5	76	M5	76	GD3	57	GD9	95
CPs4	69	CP4	69	Ms6	82	M6	82	GD4	63	GD10	101.6
CPs5	74	CP5	74	Ms7	88	M7	88	GD5	70		
CPs6	79	CP6	79	Ms8	94	M8	94				
CPs7	84	CP7	84								

Short-stem Gellhorn				Incontinence Ring				Gehrung			
SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm
GS0	38	GS5	70	IR0	44	IR5	76	GH0	50	GH5	75
GS1	44	GS6	76	IR1	51	IR6	83	GH1	55	GH6	80
GS2	51	GS7	83	IR2	57	IR7	89	GH2	60	GH7	85
GS3	57	GS8	89	IR3	64	IR8	95	GH3	65	GH8	90
GS4	63.5	GS9	95	IR4	70	IR9	102	GH4	70	GH9	95

Shaatz				Donut				Flexi Shelf			
SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Dimension in mm	SKU	Length in mm	SKU	Length in mm
SH0	38	SH5	70	D0	50	D4	76	FS06	57	FS10	70
SH1	45	SH6	76	D1	59	D5	82	FS08	64	FS12	76
SH2	51.5	SH7	82	D2	65	D6	88				
SH3	57	SH8	88	D3	69	D7	95				
SH4	63	SH9	95								

	Batch code		Warehouse temperature 10~40°C
	Expiry date		Warehouse humidity 30~80%RH.
	Non-Sterile		Consult instructions for use
	Caution		Not Made With Natural Rubber Latex
	Biological risks		Single patient multiple use
	MRI unsafe (Incontinence Ring, Hodge and Gehrung pessaries contain metal and must be removed to MRI, ultrasound and x-ray procedures.)		