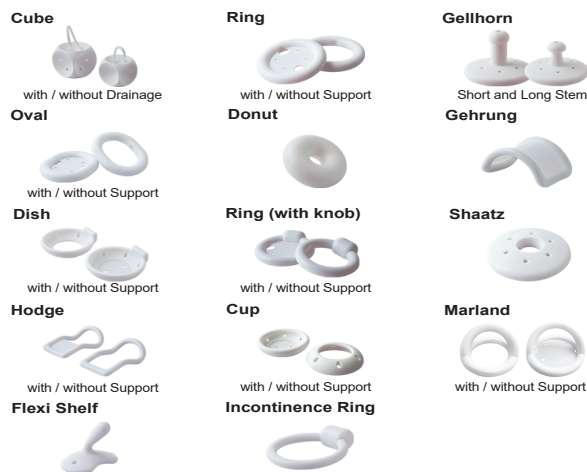




Type of Vaginal Pessary

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 malleable 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				

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).

Vaginal Pessary



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CONTRAINDICATIONS:

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

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.

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.

Pessary should be large enough for its indication, yet not cause any undue pressure or discomfort

5. The prescribed pessary should be cleaned prior to each insertion and removal, the cleaning steps are especially recommended before your first follow-up visit.

6. The Patient should report any discomfort to your doctor immediately.

REMOVAL AND SUGGESTED FOLLOW-UP:

1. 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)			
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
CUd91	75	CU91	75

Oval (With Support / Without Support)			
SKU	Length in mm	SKU	Length in mm
OVs1	59.5	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

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

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

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

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

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

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

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

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

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

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

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		

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

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



Batch code



Expiry date



Non-Sterile



Caution



Biological risks



MRI unsafe
(Incontinence Ring, Hodge and Gehrung pessaries contain metal and must be removed to MRI, ultrasound and x-ray procedures.)



Warehouse temperature 10~40°C



Warehouse humidity 30~80%RH.



Consult instructions for use



Not Made With Natural Rubber Latex



Single patient multiple use