

EVALUATING THE FIT:

Patient should be able to stand and bear down slightly without dislodging Pessary. Expulsion or turning of Pessary may indicate that Pessary size is too small. Therefore, the next larger size needs to be evaluated. Patient should be able to comfortably sit, stand and bend with Pessary in place. Pelvic discomfort during these activities may indicate that the Pessary size is too large and that a smaller size should be evaluated. Patient should be able to urinate without difficulty with Pessary in place, otherwise it may indicate an improperly-positioned or incorrectly-sized Pessary. If Pessary is too tight, it may cause discomfort or vaginal wall tissue damage; too loose, it may be easily expelled.

Remove, Clean, and Suggested Follow-Up:

1. To remove Pessary, carefully move Pessary forward toward introitus. When Pessary is within reach, compress Pessary and carefully withdraw.
2. Pessary should be removed for cleaning every day or every other day. Pessary can be cleaned with mild soap and warm water.
3. Discuss with patient the importance of following instructions and the expected length of time for Pessary usage.
4. Schedule follow-up visits to fit the needs of patient.
5. 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
 - Vaginal itching or discharge

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MedGyn Ring Pessary

Device Description: MedGyn Ring Pessary is ring-shaped with a solid core and an indentation on each side. The Ring Pessary size ranges from 51mm to 102mm and is available with support and without support.

INDICATIONS FOR USE:

The Ring Pessary is used for mild first-degree prolapse. Ring Pessary with support can also be used for an accompanying cystocele.

w/ & w/o Support	R#1	R#2	R#3	R#4	R#5
inch	2"	2.2"	2.4"	2.6"	2.9"
mm	51	57	62	68	74
	R#6	R#7	R#8	R#9	
inch	3.2"	3.5"	3.8"	4"	
mm	82	89	96	102	

PREPARATION AND PLACEMENT:

1. This procedure is to be performed by a physician trained thoroughly in obstetrics and gynecology.
2. All instructions to be carefully read prior to use.
3. Instruct patient to empty her bladder.
4. Wear dry gloves.
5. Lubricate entering end of Pessary with tap water, if necessary.
6. Use finger to depress perineum.
7. Compress and guide the Pessary:
For Shaatz- Once the large flat disc is inside the vagina, push pessary upward until resting on cervix
For Gellhorn- Once the large flat disc is past the introitus, push pessary upward until end of the stem shows.
For Dish- Direct the entering end of pessary (opposite side of knob) past cervix into the posterior fornix
For Donut, Dish, Cube, Cerclage, Oval, Ring and Ring with Knob-Allow Pessary to assume shape after it passes introitus
8. Posteriorly guide Pessary rim around cervix and into the posterior fornix.
9. Use the examining finger to turn Pessary one quarter turn so its folding axis is no longer parallel with vaginal canal. This will help prevent Pessary from folding and moving.
10. The patient should be examined 24-48 hours after Pessary insertion.

CONTRAINDICATIONS:

The use of the Pessary is contraindicated with the following:

1. Non compliant Patient
2. Vaginal abrasions



MedGyn Cup Pessary

Device Description: MedGyn Cup Pessary is shaped like a cup with rounded corners. These Cup Pessaries are made of sizes ranging from 63mm to 73mm.

INDICATIONS FOR USE:

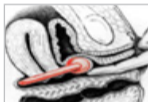
The Cup Pessary is used for first- or a mild second-degree uterine prolapse.

w/ & w/o Support	R#0	R#1	R#2	R#3
inch	1.8"	2"	2.25"	2.5"
mm	48	52	57	63
	R#4	R#5	R#6	R#7
inch	2.7"	2.9"	3"	3.2"
mm	68	73	77	82



MedGyn Ring with Knob Pessary

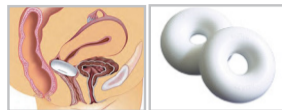
Device Description: MedGyn Pessary Ring with Knob is shaped like a ring with knob on one side of the device. The device diameter ranges from 57mm to 89mm. These pessaries come in Ring with Knob with support and without support.



INDICATIONS FOR USE:

This Pessary is indicated for patients with a mild cystocele accompanying a mild prolapse as well as urinary incontinence.

w/ & w/o Support	R#2	R#3	R#4	R#5	R#6	R#7
inch	2.2"	2.5"	2.8"	3"	3.3"	3.5"
mm	57	63	70	76	83	89



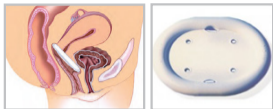
MedGyn Donut Pessary

Device Description: MedGyn Donut Pessary is shaped like a donut and the interior of the donut is hollow. The Donut Pessary is available in sizes ranging from 51mm to 95mm.

INDICATIONS FOR USE:

The Donut Pessary is used for second- to third-degree prolapse as well as cystocele.

Donut	R#0	R#1	R#2	R#3
inch	2"	2.2"	2.5"	2.7"
mm	51	57	64	69
	R#4	R#5	R#6	R#7
inch	3"	3.2"	3.5"	3.7"
mm	76	82	88	95



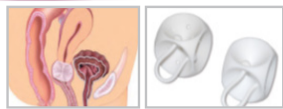
MedGyn Oval Pessary

Device Description: MedGyn Oval Pessary is designed specifically to fit a narrow vaginal vault. These Oval Pessaries are available in sizes from 51mm to 102mm.

INDICATIONS FOR USE:

The Oval Pessary is used for first- to second-degree prolapse. Oval Pessary can also be used for an accompanying cystocele.

w/ & w/o Support	R#1	R#2	R#3	R#4	R#5
inch	2"	2.25"	2.5"	2.7"	3"
mm	51	57	64	69	76
	R#6	R#7	R#8	R#9	
inch	3.25"	3.5"	3.75"	4"	
mm	83	89	95	102	



MedGyn Cube Pessary

Device Description: MedGyn Cube Pessary is shaped like a cube with rounded corners. Each side has a circular suction facet. These Cube Pessaries are available in sizes ranging from 25mm to 74mm. The Cube pessary is available both with or without drainage holes and has a silicone tie to aid in removal.

INDICATIONS FOR USE:

The Cube Pessary is indicated for third-degree prolapse, including procidentia, as well as a cystocele and a rectocele.

w/ & w/o Drain	R#0	R#1	R#2	R#3	R#4	R#5
inch	.98"	1.1"	1.2"	1.4"	1.6"	1.8"
mm	25	29	32	36	40	45
	R#6	R#7	R#8	R#9	R#10	
inch	1.9"	2.2"	2.5"	2.7"	2.9"	
mm	49	55	63	69	74	



MedGyn Gellhorn Pessary

Device Description: MedGyn Gellhorn Pessary is indicated for effective support for cystocele and rectocele. The Gellhorn with drain comes in sizes ranging from 44mm to 82mm.

INDICATIONS FOR USE:

The Gellhorn Pessary is used for second- to third-degree prolapse or procidentia.

Gellhorn	R#1	R#2	R#3	R#4	R#5	R#6	R#7
inch	1.7"	2"	2.2"	2.5"	2.8"	3"	3.2"
mm	44	51	57	63	70	76	82

Stem Height

inch	.87"	.88"	.93"	.89"	1"	1"	1"
mm	21	22	24	23	25	25	25

3. Pelvic Infections/ Pelvic inflammatory disease/Genitourinary tract infections
4. Endometriosis
5. Sexual intercourse would be contraindicated with Pessary in place.

WARNINGS:

The device should be used only if package is dry, and unopened.

CAUTION:

Federal law restricts this device to sale on the order of or for use by a physician.

PRECAUTIONS:

1. This device is to be used by a physician thoroughly trained in operative obstetrics and gynecology.
2. All instructions for the device are to be carefully read prior to its use.
3. Wash hands before handling the Pessary.

ADVERSE REACTIONS:

1. 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.
2. Serious adverse events related to Pessary use include impaction or entrapment of the Pessary requiring surgical removal and infection and/or obstruction.

STERILIZATION:

1. Prior to insertion of Pessary, it is important to thoroughly clean outer surface. It is recommended to wash pessary with mild soap, rinse with water, and dry prior to initial use. Recommended Sterilization before insertion:
 - Pre-vacuum: 270°F - 275°F (132°C-135°C) for 4 minutes
 - Gravity Displacement: 250°F - 255°F (121°C-124°C) for 40 minutes



MedGyn Dish Pessary

Device Description: MedGyn Dish Pessary is shaped like a dish to provide bladder neck support to relieve stress incontinence and minor degrees of prolapse. The Dish Pessaries are made of sizes from 50mm to 85mm.

INDICATIONS FOR USE:

The Dish Pessary is used for first- or second-degree uterine prolapse as well as cystocele. This pessary may also relieve urinary incontinence.

w/ & w/o Support	R#0	R#1	R#2	R#3
inch	2"	2.2"	2.4"	2.5"
mm	50	55	60	63
	R#4	R#5	R#6	R#7
inch	2.7"	2.9"	3.1"	3.3"
mm	68	73	80	85



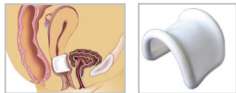
MedGyn Shaatz Pessary

Device Description: MedGyn Shaatz Pessary is circular in shape with a center hole. Shaatz pessaries with drain are available in sizes ranging from 38mm to 88mm.

INDICATIONS FOR USE :

The Shaatz Pessary is indicated for first- to second-degree prolapse as well as cystocele.

w/Drain	R#0	R#1	R#2	R#3	R#4
inch	1.5"	1.75"	2"	2.2"	2.5"
mm	38	44	51	57	64
	R#5	R#6	R#7	R#8	
inch	2.8"	3"	3.2"	3.5"	
mm	70	76	82	88	



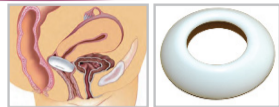
MedGyn Gehrung Pessary

Device Description: MedGyn Gehrung knob with support is for effective support for cystocele and rectocele. They are also more adaptable in cases of procidentia where the uterus tends to herniate when other pessaries are used. The Gehrung Pessaries are made of sizes ranging from 50mm to 90mm.

INDICATIONS FOR USE:

The malleable Gehrung pessary with support membrane is primarily used for a significant cystocele or rectocele and may also provide relief for second or third-degree uterine prolapse.

w/ Support	R#0	R#1	R#2	R#3	R#4
inch	2"	2.2"	2.4"	2.6"	2.8"
mm	50	55	60	65	70
	R#5	R#6	R#7	R#8	
inch	3"	3.2"	3.4"	3.6"	
mm	75	80	85	90	



MedGyn Cerclage Pessary

Device Description: MedGyn Cerclage Pessary is shaped like a bowl and is indicated for mild prolapse. The Cerclage Pessary comes in six sizes with outer diameters 65mm or 70mm, and inner diameter of 32mm or 35mm.

INDICATIONS FOR USE:

The Cerclage Pessary is indicated for mild prolapse.

w/ & w/o Drain	R#1	R#2	R#3	R#4	R#5	R#6
O.D. inch	2.6"	2.8"	2.6"	2.8"	2.6"	2.8"
O.D. mm	65	70	65	70	65	70
I.D. mm	32	32	35	35	35	35
Height mm	21	21	21	21	30	30



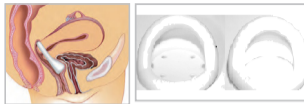
MedGyn Hodge Pessary

Device Description: MedGyn Hodge Pessary is designed for stress urinary incontinence and for women with a small vaginal introitus. The Hodge Pessary is made sizes ranging from 65mm to 110mm. Hodge Pessary comes in with or without support.

INDICATIONS FOR USE:

The Hodge Pessary is commonly used for a first or mild second-degree uterine prolapse and may also relieve a cystocele. A Hodge Pessary with support is also effective in the prevention of exercise incontinence.

w/ & w/o Support	R#0	R#1	R#2	R#3	R#4
inch	2.6"	2.8"	3"	3.2"	3.4"
mm	65	70	75	80	85
	R#5	R#6	R#7	R#8	R#9
inch	3.6"	3.8"	4"	4.2"	4.4"
mm	90	95	100	105	110



MedGyn Marland Pessary

Device Description: MedGyn Marland Pessary is for moderate to extensive cystocele, as well as providing support for the bladder neck in managing stress incontinence. The Marland Pessaries are made of sizes ranging from 57mm to 95mm.

INDICATIONS FOR USE:

The Marland Pessary is available with or without supporting membrane, is used to relieve the symptoms of a second or third-degree uterine prolapse, a cystocele or rectocele.

w/ & w/o Support	R#2	R#3	R#4	R#5	R#6	R#7	R#8
inch	2.25"	2.5"	2.75"	3"	3.25"	3.5"	3.75"
mm	57	63	70	76	83	89	95