



HallmarkSurgical™

Pessary Instructions of Use

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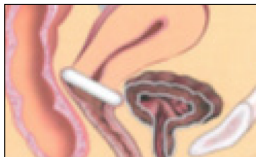
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Ring Pessary



Device Description

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.

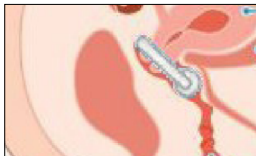
Indications For Use

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

	inch	mm
#1	2"	51
#2	2.2"	57
#3	2.4"	62
#4	2.75"	70
#5	2.9"	74
#6	3.2"	82
#7	3.5"	89
#8	3.8"	96
#9	4"	102

Ring with Knob Pessary



Device Description

Pessary Ring with Knob is shaped like a ring with knob on one side of the device. The device diameter ranges from 51mm to 89mm. These pessaries are available 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	inch	mm
#1	2"	51
#2	2.2"	57
#3	2.5"	63
#4	2.8"	70
#5	3"	76
#6	3.3"	83
#7	3.5"	89

Modified Cup Pessary



Device Description

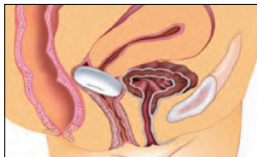
Modified Cup Pessary is shaped like a bowl and is indicated for mild prolapse. The Pessary comes in six sizes with outer diameters 65mm or 70mm, and inner diameter of 32mm or 35mm.

Indications For Use

The Modified Cup Pessary is indicated for mild prolapse.

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

Cerclage Pessary



Device Description

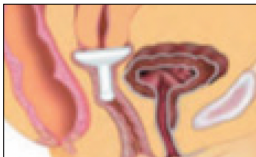
Cerclage Pessary is shaped like a bowl and is indicated for mild prolapse. The Pessary comes in six sizes with outer diameters 65mm or 70mm, and inner diameter of 32mm or 35mm.

Indications For Use

The Cerclage Pessary is indicated for mild prolapse.

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

Gellhorn Pessary



Device Description

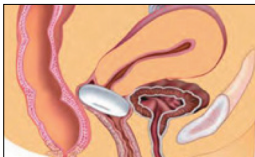
Gellhorn Pessary is indicated for effective support for cystocele and rectocele. The Gellhorn pessary with drain available in sizes ranging from 44mm to 89mm.

Indications For Use

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

Diameter	inch	mm
#1	1.7"	44
#2	2"	51
#3	2.2"	57
#4	2.5"	63
#5	2.8"	70
#6	3"	76
#7	3.2"	82
#8	3.5	89

Donut Pessary



Device Description

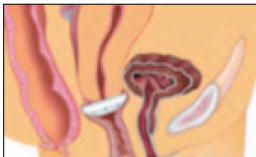
Donut Pessary is shaped like a donut and the interior of the donut is hollow. The Donut Pessary is available in sizes ranging from 51mm to 95mm.

Indications For Use

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

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

Shaatz Pessary



Device Description

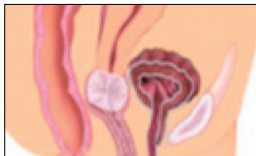
Shaatz Pessary is circular in shape with a center hole. Shaatz pessaries with drain are available in sizes ranging from 38mm to 88mm.

Indications For Use

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

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

Cube Pessary



Device Description

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.

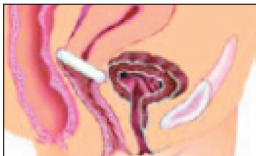
Indications For Use

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

w/ & w/o Drain

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

Cup Pessary



Device Description

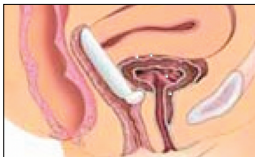
Cup Pessary is shaped like a cup with rounded corners. These Cup Pessaries are available of sizes ranging from 48mm to 82mm.

Indications For Use

The Modified Cup Pessary is indicated for mild prolapse.

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

Dish Pessary



Device Description

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 available sizes from 50mm to 85mm.

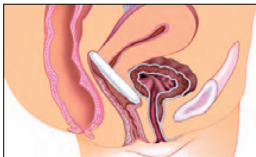
Indications For Use

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

Oval Pessary



Device Description

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	O.D. inch	O.D. mm
#1	2"	51
#2	2.25"	57
#3	2.5"	64
#4	2.7"	69
#5	3"	76
#6	3.25"	83
#7	3.5"	89
#8	3.75"	95
#9	4"	102

Marland Pessary



Device Description

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 available in sizes ranging from 57mm to 95mm.

Indications For Use

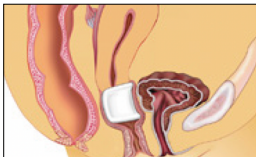
The Marland Pessary is available with or without supporting membrane, is used to relieve the symptoms

of a second or third-degree uterine prolapse, a cystocele or a rectocele.

w/ & w/o Support

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

Gehrung Pessary



Device Description

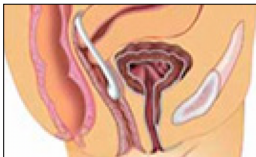
Modified Cup Pessary is shaped like a bowl and is indicated for mild prolapse. The Pessary comes in six sizes with outer diameters 65mm or 70mm, and inner diameter of 32mm or 35mm.

Indications For Use

The Modified Cup Pessary is indicated for mild prolapse.

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

Hodge Pessary



Device Description

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	O.D. inch	O.D. mm
#0	2.6"	65
#1	2.8"	70
#2	3"	75
#3	3.2"	80
#4	3.4"	85
#5	3.6"	90
#6	3.8"	95
#7	4"	100
#8	4.2"	105
#9	4.4"	110

Preparation & Placement

1. This procedure is to be performed by a physician trained thoroughly in obstetrics and gynecology. The physician is to train the patient on reinsertion and removal of pessary based on patient's condition and anatomy.
2. All instructions to be carefully read prior to use.
3. Please clean before use.
4. Instruct patient to empty her bladder.
5. Wear dry gloves.
6. Lubricate entering end of Pessary with tap water, if necessary.
7. Use finger to depress perineum.
8. 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, Modified Cup Pessary, Oval, Ring and Ring with Knob-Allow Pessary to assume shape after it passes introitus.
9. Posteriorly guide Pessary rim around cervix and into the posterior fornix.
10. 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.

11. 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
3. Pelvic Infections/ Pelvic inflammatory disease/ Genitourinary tract infections
4. Endometriosis
5. Sexual intercourse is 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, or on instructions by physician.
2. All instructions for the device are to be carefully read prior to its use.
3. Wash hands before handling the Pessary.
4. There are no precautions in disposal of the device. It is safe to dispose.

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.
2. fully submerge the device.
 2. Soak and Scrub
 - a. Soak the device in the container of prepared soap solution for a minimum of 5 minutes.
 - b. Following the 5-minute soak period, scrub the device for a minimum of 15 seconds with a soft-bristled brush, such as a toothbrush and/or pipe brush. Scrub device below water line to prevent aerosolization of contaminants.
 - c. Following scrub, inspect device for visible soil residue.

Recommended cleaning instructions

1. Prepare a cleaning solution by mixing a mild soap (such as Dawn or equivalent) with tap water using the soap's manufacturer's recommended concentration. Prepare this solution in a container large enough to
3. Rinse
 - a. Remove the device from the soap solution and thoroughly rinse under flowing tap water for a minimum of 30 seconds.
 - b. Allow the device to dry.

*New pessaries are powdered with food-grade powder.

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. Do not pull the string on cube pessary. The string is for marking/locating prior to removal.
3. Pessary should be removed for cleaning every day or every other day. Pessary can be cleaned with mild soap and warm water. Discuss with patient how and when to place pessary after cleaning.

4. Discuss with patient the importance of following instructions and the expected length of time for Pessary usage up to 29 days.
5. Schedule follow-up visits to fit the needs of patient.
6. Instruct patient to immediately report any of the following: Discomfort, Spontaneous expulsion, Any changes in colour, amount, consistency, or odour of vaginal discharge, difficulty with elimination.

Storage

Pessaries are stored at room temperature around 0 to 30°C (32 to 86 °F).

See product label for



Manufacturer

CE
1304



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Catalog number



Date of manufacturer



Batch number



Use by date



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