

## PART 2

# Pessaries for POP and SUI: Their fitting, care, and effectiveness in various disorders

A refresher on how to fit a pessary, instructions for patients, goals for pessary aftercare visits, and the various conditions for which pessaries may or may not be effective

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In Part 1 of this article in the December 2020 issue of *OBG Management*, I discussed the reasons that pessaries are an effective treatment option for many women with pelvic organ prolapse (POP) and stress urinary incontinence (SUI) and provided details on the types of pessaries available.

In this article, I highlight the steps in fitting a pessary, pessary aftercare, and potential complications associated with pessary use. In addition, I discuss the effectiveness of pessary treatment for POP and SUI as well as for preterm labor prevention and defecatory disorders.

### The pessary fitting process

For a given patient, the best size pessary is the smallest one that will not fall out. The only “rule” for fitting a pessary is that a woman’s internal vaginal caliber should be wider than her introitus.

When fitting a pessary, goals include that the selected pessary:

- should be comfortable for the patient to wear
- is not easily expelled
- does not interfere with urination or defecation
- does not cause vaginal irritation.

The presence or absence of a cervix or uterus does not affect pessary choice.

Most experts agree that the process for fitting the right size pessary is one of trial and error. As with fitting a contraceptive diaphragm, the clinician should perform a manual examination to estimate the integrity and width of the perineum and the depth of the vagina to roughly approximate the pessary size that might best fit. Using a set of “fitting pessaries,” a pessary of the estimated size should be placed into the vagina and the fit evaluated as to whether the device is too big, too small, or appropriate. If the pessary is easily expelled, larger sizes should be tried until the pessary remains in place or the patient is uncomfortable. Once the pessary is in place, the clinician should be able to run his or her finger around the entire pessary; if this is not possible, the pessary is too tight. In addition, the pessary should remain more than one finger breadth above the introitus when the patient is standing or bearing down.

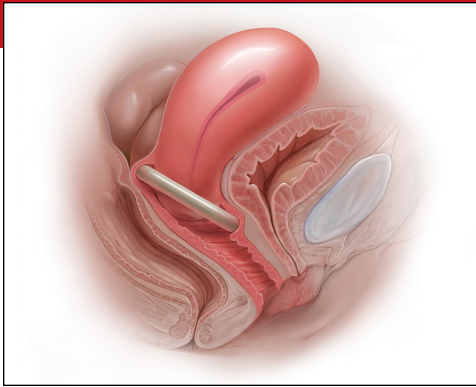
Since many patients who require a pessary are elderly, their perineal skin and

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vaginal mucosa may be atrophic and fragile. Inserting a pessary can be uncomfortable and can cause abrasions or tears. Successfully fitting a pessary may require extra care under these circumstances. The following steps may help alleviate these difficulties:

- Explain the fitting process to the patient in detail.
- Employ lubrication liberally.
- Enlarge the introitus by applying gentle digital pressure on the posterior fourchette.
- Apply 2% lidocaine ointment several minutes prior to pessary fitting to help decrease patient discomfort.
- Treat the patient for several weeks with vaginal estrogen cream before attempting to fit a pessary if severe vulvovaginal atrophy is present.

Once the type and size of the pessary are selected and a pessary is inserted, evaluate the patient with the pessary in place. Assess for the following:

**Discomfort.** Ask the patient if she feels discomfort with the pessary in position. A patient with a properly fitting pessary should not feel that it is in place. If she does feel discomfort initially, the discomfort will only increase with time and the issue should be addressed at that time.

**Expulsion.** Test to make certain that the pessary is not easily expelled from the vagina. Have the patient walk, cough, squat, and even jump if possible.

**Urination.** Have the patient urinate with the pessary in place. This tests for her ability to void while wearing the pessary and shows whether the contraction of pelvic muscles during voiding results in expulsion of the pessary. (Experience shows that it is best to do this with a plastic “hat” over the toilet so

that if the pessary is expelled, it does not drop into the bowl.)

**Re-examination.** After these provocative tests, examine the patient again to ensure that the pessary has not slid out of place.

Depending on whether or not your office stocks pessaries, at this point the patient is either given the correct type and size of pessary or it is ordered for her. If the former, the patient should try placing it herself; if she is unable to, the clinician should place it for her. In either event, its position should be checked. If the pessary has to be ordered, the patient must schedule an appointment to return for pessary insertion.

Whether the pessary is supplied by the office or ordered, instruct the patient on how to insert and remove the pessary, how frequently to remove it for cleansing (see below), and signs to watch for, such as vaginal bleeding, inability to void or defecate, or pelvic pain.

It is advisable to schedule a subsequent visit for 2 to 3 weeks after initial pessary placement to assess how the patient is doing and to address any issues that have developed.

### Special circumstances

It is safe for a patient with a pessary in place to undergo magnetic resonance imaging.<sup>1</sup> Patients should be informed, however, that full body scans, such as at airports, will detect pessaries. Patients may need to obtain a physician’s note to document that the pessary is a medical device.

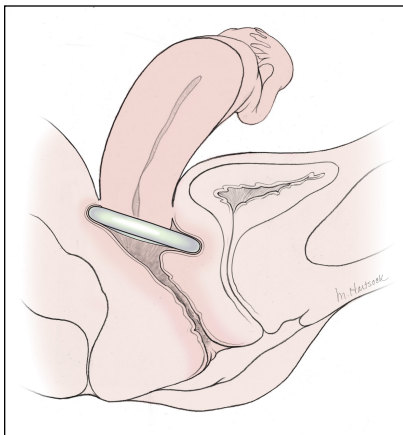
Finally, several factors may prevent successful pessary fitting. These include prior pelvic surgery, obesity, short vaginal length (less than 6–7 cm), and a vaginal introitus width of greater than 4 finger breadths.

### FAST TRACK

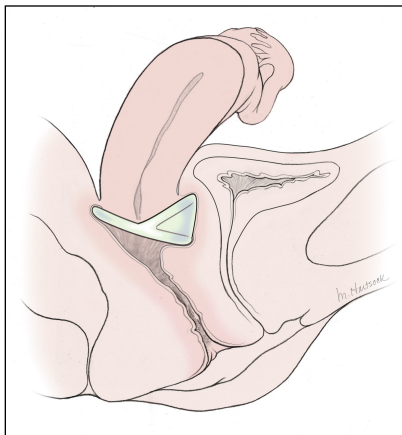
*Evaluate the patient with the pessary in place for discomfort, expulsion, and urination, and then re-examine to ensure that the pessary has not slid out of place*

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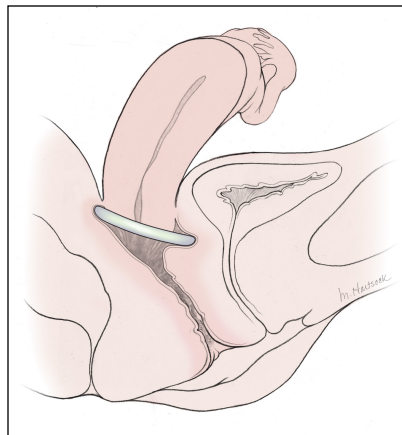
Ring pessary



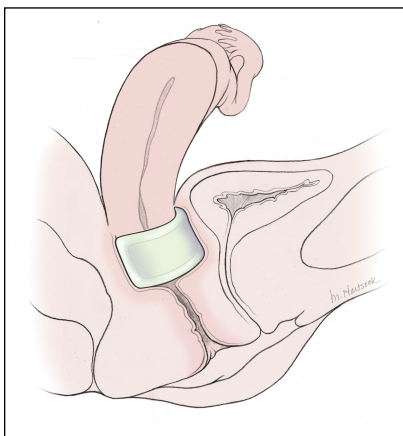
Marland pessary



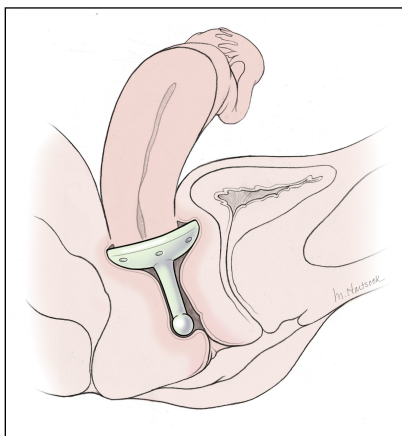
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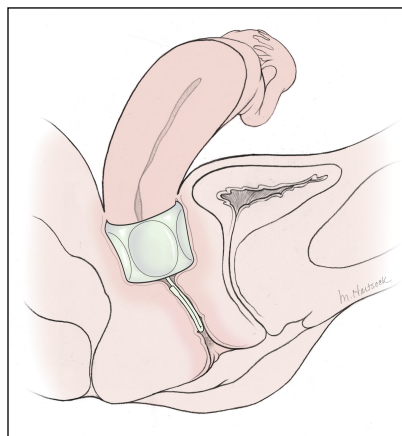
Gehring pessary



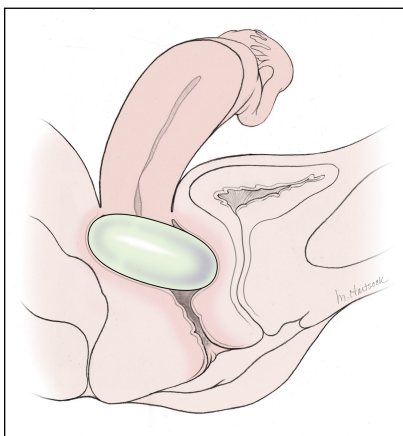
Gellhorn pessary



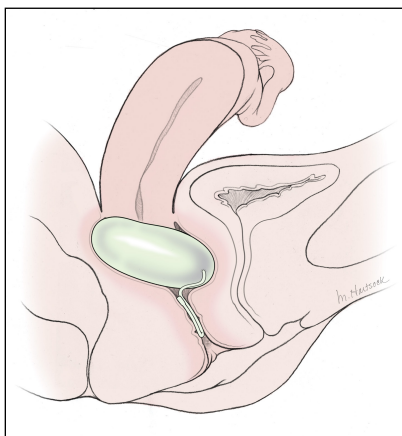
Cube pessary



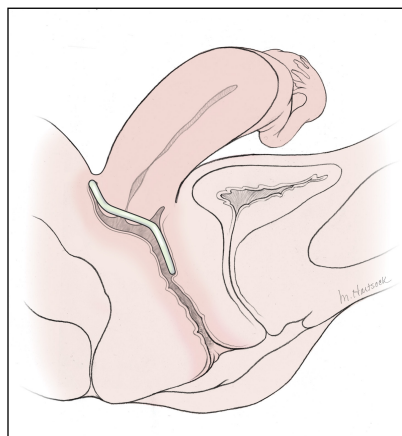
Donut pessary



Inflatable pessary



Lever pessary



ILLUSTRATIONS: MARCIA HARTSOCK FOR OBG MANAGEMENT

## Necessary pessary aftercare

Once a pessary is in place and the patient is comfortable with it, the only maintenance necessary is the pessary's intermittent removal for cleansing and for evaluation of the vaginal mucosa for erosion and ulcerations. How frequently this should be done varies based on the type of pessary, the amount of discharge that a woman produces, whether or not an odor develops after prolonged wearing of the pessary, and whether or not the patient's vaginal mucosa has been abraded.

### The question of timing for pessary cleaning

Although there are many opinions about how often pessaries should be removed and cleaned, no data in the literature support any specific interval. Pessaries that are easily removed by women themselves can be cleaned as frequently as desired, often on a weekly basis. The patient simply removes the pessary, washes it with soap and water, and reinserts it. For pessaries that are difficult to remove (such as the Gellhorn, cube, or donut) or for women who are physically unable to remove their own ring pessary, the clinician should remove and clean the pessary in the office every 3 to 6 months. It has been shown that there is no difference in complications from pessary use with either of these intervals.<sup>2</sup>

Prior to any vaginal surgical procedure, patients must be instructed to remove their pessary 10 to 14 days beforehand so that the surgeon can see the full extent of prolapse when making decisions about reconstruction and so that any vaginal mucosal erosions or abrasions have time to heal.

### Office visits for follow-up care

The pessary "cleaning visit" has several goals, including to:

- see if the pessary is meeting the patient's needs in terms of resolving symptoms of prolapse and/or restoring urinary continence
- discuss with the patient any problems she may be having, such as pelvic discomfort or pressure, difficulty voiding or defecating, excessive vaginal discharge, or vaginal odor
- check for vaginal mucosal erosion or ulceration; such vaginal lesions often can be prevented by the prophylactic use of either estrogen vaginal cream twice weekly or the continuous use of an estradiol vaginal ring in addition to the pessary
- evaluate the condition of the pessary itself and clean it with soap and water.

## Potential complications of pessary use

The most common complications experienced by pessary users are:

**Odor or excessive discharge.** Bacterial vaginosis (BV) occurs more frequently in women who use pessaries. The symptoms of BV can be minimized—but unfortunately not totally eliminated—by the prophylactic use of antiseptic vaginal creams or gels, such as metronidazole, clindamycin, Trimo-San (oxyquinoline sulfate and sodium lauryl sulfate), and others. Inserting the gel vaginally once a week can significantly reduce discharge and odor.<sup>3</sup>

**Vaginal mucosal erosion and ulceration.** These are treated by removing the pessary for 2 weeks during which time estrogen cream is applied daily or an estradiol vaginal ring is put in place. If no resolution occurs after 2 weeks, the nonhealing vaginal mucosa should be biopsied.

**Pressure on the rectum or bladder.** If the pessary causes significant discomfort or interferes with voiding function, then either a different size or a different type pessary should be tried

Patients may discontinue pessary use for a variety of reasons. Among these are:

- discomfort
- inadequate improvement of POP or incontinence symptoms
- expulsion of the pessary during daily activities
- the patient's desire for surgery instead
- worsening of urine leakage
- difficulty inserting or removing the pessary
- damage to the vaginal mucosa
- pain during removal of the pessary in the office.

## FAST TRACK

*For difficult-to-remove pessaries or for women physically unable to remove their own ring pessary, the clinician should remove and clean the pessary in the office every 3 to 6 months*

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**TABLE 1** Percentage of women with relief of POP symptoms with pessary use<sup>4-13</sup>

Study	No. of women	Outcome	Percentage
Wu, 1997 <sup>4</sup>	81	Continued pessary use 12 months	66
Bai, 2005 <sup>5</sup>	104	“Satisfied” with pessary use	70
Clemons, 2004 <sup>6</sup>	72	“Satisfaction” after pessary use for 2 months	92
Hanson, 2006 <sup>7</sup>	661	Relief of POP symptoms	83
Fernando, 2006 <sup>8</sup>	97	Success maintaining pessary for 4 months	48
Cundiff, 2007 <sup>9</sup>	134	Relief of symptoms of protrusion and voiding dysfunction at 6 months	57
Komesu, 2007 <sup>10</sup>	64	Continued use 6–12 months	56
Yang, 2018 <sup>11</sup>	162	“Satisfied” after pessary use for 1 year	79
Mao, 2018 <sup>12</sup>	142	Successful use of pessary 17 months	69
Duenas, 2018 <sup>13</sup>	94	Continuous use, average 27 months	80.8

Abbreviation: POP, pelvic organ prolapse.

**TABLE 2** Percentage of women with relief of SUI symptoms with pessary use<sup>6,8,14-17</sup>

Study	No. of women	Outcome	Percentage
Clemons, 2004 <sup>6</sup>	73	SUI improvement after 2 months	45
Farrell, 2004 <sup>14</sup>	97	Complete or partial decrease in SUI symptoms at 11 months	61
Donnelly, 2004 <sup>15</sup>	101	SUI improvement after 6 months	50
Fernando, 2006 <sup>8</sup>	97	SUI improvement after 4 months	77
Richter, 2010 <sup>16</sup>	149	SUI improvement after 3 months	40
Ding, 2016 <sup>17</sup>	31	SUI improvement after 3 months	58

Abbreviation: SUI, stress urinary incontinence.

### Pessary effectiveness for POP and SUI symptoms

As might be expected with a device that is available in so many forms and is used to treat varied types of POP and SUI, the data concerning the success rates of pessary use vary considerably. These rates depend on the definition of success, that is, complete or partial control of prolapse and/or incontinence; which devices are being evaluated; and the nature and severity of the POP and/or SUI being treated.

That being said, a review of the literature reveals that the rates of prolapse symptom

relief vary from 48% to 92% (TABLE 1).<sup>4-13</sup>

As for success in relieving symptoms of incontinence, studies show improvements in from 40% to 77% of patients (TABLE 2).<sup>6,8,14-17</sup>

In addition, some studies show a 50% improvement in bowel symptoms (urgency, obstruction, and anal incontinence) with the use of a pessary.<sup>9,18</sup>

### How pessaries compare with surgery

While surgery has the advantage of being a one-time fix with a very high rate of initial success in correcting both POP and incontinence, surgery also has potential drawbacks:

- It is an invasive procedure with the discomfort and risk of complications any surgery entails.
- There is a relatively high rate of prolapse recurrence.
- It exposes the patient to the possibility of mesh erosion if mesh is employed either for POP support or incontinence treatment.

Pessaries, on the other hand, are inexpensive, nonsurgical, removable, and allow for immediate correction of symptoms. Moreover, if the pessary is tried and is found to be unsatisfactory, surgery always can be performed subsequently.

Drawbacks of pessary treatment compared with surgery include the:

- ongoing need to wear an artificial internal device
- need for intermittent pessary removal and cleansing
- inability to have sexual intercourse with certain kinds of pessaries in place
- possible accumulation of vaginal discharge and odor.

### Sexual activity and pessaries

Studies by Fernando, Meriwether, and Kuhn concur that for a substantial number of pessary users who are sexually active, both frequency and satisfaction with sexual intercourse are increased.<sup>8,19,20</sup> Kuhn further showed that desire, orgasm, and lubrication improved with the use of pessaries.<sup>20</sup> While some types of pessaries do require removal for intercourse, Clemons reported that issues involving sexual activity are not associated with pessary discontinuation.<sup>21</sup>

### Using a pessary to predict a surgical outcome

Because a pessary elevates the pelvic organs, supports the vaginal walls, and lifts the bladder and urethra into a position that simulates the results of surgical repair, trial placement of a pessary can be used as a fairly accurate predictive tool to model what pelvic support and continence status will be after a proposed surgical procedure.<sup>22,23</sup> This is especially

important because a significant number of patients with POP will have their occult stress incontinence unmasked following a reparative procedure.<sup>24</sup> A brief pessary trial prior to surgery, therefore, can be a useful tool for both patient and surgeon.

### Pessaries for prevention of preterm labor

Almost 1 in 10 births in the United States occurs before 37 completed weeks of gestation.<sup>25</sup> Obstetricians have long thought that in women at risk for preterm delivery, the use of a pessary might help reduce the pressure of the growing uterus on the cervix and thus help prevent premature cervical dilation. It also has been thought that use of a pessary would be a safer and less invasive alternative to cervical cerclage. Many studies have evaluated the use of pessaries for the prevention of preterm labor with a mixture of positive (TABLE 3, page 26)<sup>26-29</sup> and negative results (TABLE 4, page 26).<sup>30-33</sup>

From these data, it is reasonable to conclude that:

- The final answer concerning the effectiveness or lack thereof of pessary use in preventing preterm delivery is not yet in.
- Any advantage there might be to using pessaries to prevent preterm delivery cannot be too significant if multiple studies show as many negative outcomes as positive ones.

### Pessary effectiveness in defecatory disorders

Vaginal birth has the potential to create multiple anatomic injuries in the anus, lower pelvis, and perineum that can affect defecation and bowel control. Tears of the anal sphincter, whether obvious or occult, may heal incompletely or be repaired inadequately.<sup>34</sup> Nerve innervation of the perianal and perineal areas can be interrupted or damaged by stretching, tearing, or prolonged compression. Of healthy parous adult women, 7% to 16% admit incontinence of gas or feces.<sup>35,36</sup>

In addition, when a rectocele is present,

### FAST TRACK

*Trial placement of a pessary can be used as a fairly accurate predictive tool to model what pelvic support and continence status will be after a proposed surgical procedure*

**TABLE 3 Effectiveness of pessaries to prevent preterm labor**<sup>26-29</sup>

Study	No. of women	Effectiveness
Goya, 2012 <sup>26</sup>	385	4.5-fold lower rate of preterm delivery with pessary use (6%) vs expectant management (27%)
Di Tommaso, 2016 <sup>27</sup>	40	30% less likely to deliver before 36 weeks with use of pessary in twins, cervical length <2.5 cm between 21 and 31 weeks
Saccone, 2017 <sup>28</sup>	300	2-fold lower preterm delivery rate with pessary use and progesterone (7.3%) vs progesterone alone (15%)
Perez-Lopez, 2019 <sup>29</sup>	1,612	Reduced the rate of spontaneous preterm birth both at 34 and at 37 weeks (risk ratio, 0.33)

**TABLE 4 Lack of effectiveness of pessaries to prevent preterm labor**<sup>30-33</sup>

Study	No. of women	Effectiveness
Hui, 2013 <sup>30</sup>	108	Higher rate of preterm delivery in the pessary group (9.4%) than in the control group (5.5%)
Nicolaides, 2016 <sup>31</sup>	931	No difference in preventing preterm labor: use of the pessary (12%) vs expectant management (10.8%)
Saccone, 2017 <sup>32</sup>	1,420	Use of a vaginal pessary did not reduce the rate of spontaneous preterm delivery or improve perinatal outcomes
Conde-Agudelo, 2020 <sup>33</sup>	4,687 (12 studies)	No significant differences between the pessary and no-pessary groups in the risk of spontaneous preterm birth <34 weeks

**TABLE 5 Pessary CPT codes**<sup>38</sup>

Diagnosis	CPT code	Notes
Pessary fitting	57160	Fitting and insertion of pessary
Pessary device	A4562	
Evaluation, management—Existing patient	99211-99215	Depending on complexity and length of visit
Evaluation, management—New patient	99201-99205	Depending on complexity and length of visit
Return visit for follow-up/cleaning	99213	E & M only

Abbreviations: CPT, Current Procedural Terminology; E & M, evaluation and management.

stool in the lower rectum may cause bulging of the anterior rectal wall into the vagina, preventing stool from passing out of the anus. This sometimes requires women to digitally press their posterior vaginal walls during defecation to evacuate stool successfully. The question thus arises as to whether or not pessary placement and subsequent relief of rectoceles might facilitate bowel move-

ments and decrease or eliminate defecatory dysfunction.

As with the issue of pessary use for prevention of preterm delivery, the answer is mixed. For instance, while Brazell<sup>18</sup> showed that there was an overall improvement in bowel symptoms in pessary users, a study by Komesu<sup>10</sup> did not demonstrate improvement.

There is, however, a relatively new device specifically designed to control defecatory problems: the vaginal bowel control system (Eclipse; Pelvalon). The silicon device is placed intravaginally as one does a pessary. After insertion, it is inflated via a valve and syringe. It works by putting pressure on and reversibly closing the lower rectum, thus blocking the uncontrolled passage of stool and gas. It can be worn continuously or intermittently, but it does need to be deflated for normal bowel movements. One trial of this device demonstrated a 50% reduction in incontinence episodes with a patient satisfaction rate of 84% at 3 months.<sup>37</sup> This device may well prove to be a valuable nonsurgical approach to the treatment of fecal incontinence. Unfortunately, the device is relatively expensive and usually is not covered by insurance as third-party payers do not consider it to be a pessary (which generally is covered).

## Practice management particulars

Useful information on Current Procedural Terminology codes for pessaries, diagnostic codes, and the cost of various pessaries is provided in **TABLE 5**,<sup>38</sup> **TABLE 6**,<sup>39</sup> and **TABLE 7**.<sup>40-42</sup>

## A contemporary device used since antiquity

Pessaries, considered “old-fashioned” by many gynecologists, are actually a very cost-effective and useful tool for the correction of POP and SUI. It behooves all who provide

**TABLE 6 Diagnostic codes supporting medical necessity for pessary**<sup>39</sup>

Diagnosis	CPT codes
Complete uterovaginal prolapse	N81.3
Cystocele	N81.10
Rectocele	N81.6
Stress incontinence	N39.3
Enterocoele	N81.5
Other female genital prolapse	N81.9

Abbreviation: CPT, Current Procedural Terminology.

**TABLE 7 Cost of various pessaries**<sup>40-42</sup>

Type of pessary	Source	Cost
Ring	Milex	\$131
Ring	CooperSurgical	\$123
Ring	Online	\$30
Inflatable	Milex	\$129
Cube	Milex	\$116
Cube	CooperSurgical	\$166
Cube	Online	\$45-\$60
Gellhorn	CooperSurgical/Milex	\$152
Gellhorn	Online	\$30-\$55

medical care to women to be familiar with them, to know when they might be useful, and to know how to fit and prescribe them. ●

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