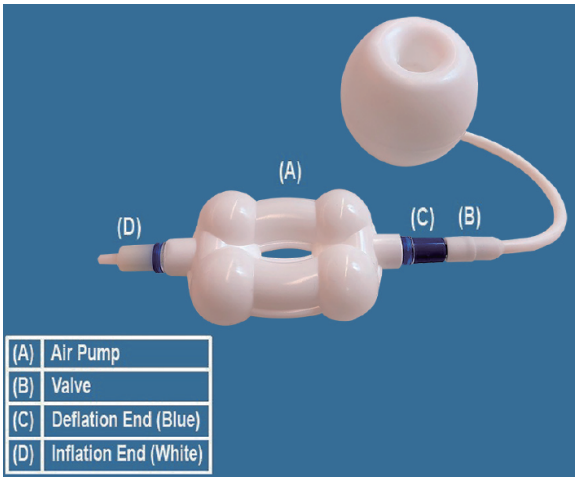
Instructions for Use
Silicone Inflatable Donut Pessary MD



Description
Inflatable Donut Pessaries are constructed of a compression molded silicone rubber with white pigment rubber colorant. They are non-toxicity, and the colorant is mainly made up of titanium dioxide. It is subject to specific FDA regulation, and the ratio of the addition is complied with regulation.
Inflatable Donut Pessary is for single-patient use silicone pessary for mild cystocle and/or rectocele associated with POP. They are four different size available shown below. It is necessary to have available a minimum of two size.

Product Model

SKU	ID2 REF	ID3 REF	ID4 REF	ID5 REF
Size	51mm	57mm	64mm	70mm
Suggested Number of Squeezes	1	2	3	4

IMPORTANT
DO NOT OVER INFLATE. See suggested number of squeezes. Overinflation will weaken silicone. If your pessary "Balloon" out, it is an indication that it has been overinflated and you need a large size Inflatable Donut Pessary.

Clinical Benefits
- Provides mechanical support to the pelvic organs in adult women with POP.
- Demonstrates high continuation rates, indicating sustained use and patient tolerability.
- Supports the management of POP and associated symptoms, as measured by reductions in validated patient-reported outcome measures.

INDICATIONS:
1. The Inflatable Donut Pessary is effective suppport in second- or third-degree prolapsed, and also effective in patients with mild cytocele or recocele associated with a procidentia/prolapsed.
2. Support of Inflatable Donut Pessary can be adjusted based on the its inflation level.

Note:
(1) Experience has shown that in order to properly fit an Inflatable Donut Pessary, you should have at least one of two most commonly used sizes of this pessary (size 57 (ID3) and 64 (ID4)).
(2) The physician may suggest K-Y jelly ®, Replens® or equivalent, if you need to use lubricant.

Intended purpose
The Inflatable Donut Pessary is a removable silicone device intended for use in adult women for the conservative management of pelvic organ prolapse.
The device is intended to be inserted into the vagina to provide mechanical support to the pelvic organs, thereby supporting the management of pelvic organ prolapse and associated symptoms.

Intended patient population
The device is indicated for adult women, typically aged 18 years and older, who have been diagnosed with various grades of pelvic organ prolapse, including uterine prolapse, cystocele, rectocele, and enterocele, and for those experiencing stress urinary incontinence as a result of POP. It is particularly suited for perimenopausal and postmenopausal women experiencing mild to moderate stages of POP, generally classified as Stage I to Stage III.

Intended users
The pessary is intended to be fitted and initially inserted by trained medical practitioners or qualified clinical staff in a clinical setting.
Following assessment and instruction by a healthcare professional, the device may also be used,inserted, removed and managed independently by the patient.

Contraindications
1. Do not use during pregnancy because of the risk of air embolism.
2. Inflatable Donut Pessary is contraindicated in endometriosis, or non-compliant patients.
3. Do not use this device in the following conditions
   - Acute vaginal infections
   - Severe vaginal atrophy
   - Unexplained vaginal bleeding
   - Known allergy to the device material
   - Active pelvic inflammatory disease (PID)
   - Patients with significant vaginal scarring or stenosis

Potential Side Effects
- Itching/ burning/ irritation/ discomfort
- Bleeding
- Vaginal odor
- Pain or discomfort
- Uterine leakage
- Infection/ abnormal vaginal discharge
- Vaginal sore or wound

In case of side effects, discontinue the procedure, provide appropriate medical intervention, and report to the manufacturer and the applicable local regulatory authority, as required by local laws and regulations.

Cautions
1. After the initial fitting and size confirmation, a short-term follow-up is recommended to assess comfort, urinary flow, and vaginal mucosal condition. Subsequent follow-ups should be conducted as determined by the healthcare professional.
2. If abnormal discharge, unpleasant odor, pain, or difficulty urinating occurs, discontinue use immediately and consult a healthcare professional.
3. Sexual intercourse may be affected while wearing the pessary. If removal is required, follow the healthcare professional's instructions.

Warnings
1. This device must be prescribed, evaluated, and fitted by a trained healthcare professional.
2. Improper sizing or incorrect use may result in complications such as vaginal ulceration, bleeding, infection, urinary retention, or, in rare cases, perforation.
3. Do not leave the pessary in place for prolonged periods without follow-up. Extended use without removal or clinical review may cause serious complications or require surgical intervention.
4. Do not use in patients with known silicone hypersensitivity.
5. Monitor for allergic reactions within 24 to 48 hours after first use and check the vaginal area. If you experience discomfort, irritation, pressure, sensitivity, or unusual discharge, contact your doctor immediately.

Instructions for Use
Silicone Inflatable Donut Pessary MD

Precautions

1. For single-patient reuse only. Remove, clean, and inspect the pessary at regular intervals as directed by the healthcare professional.
2. After insertion, the clinician should confirm that the patient is able to urinate and defecate normally.
3. If slippage, pressure discomfort, or indentation occurs after fitting, reassess the size and model of the pessary.

Instructions for Use

Prior to initial use, the Pessary should be washed thoroughly. Refer to the Cleaning section for the detailed procedure.

Fitting Instructions For The Physicaina

1. Inflatable Donut Pessary is fitted by trial and error. There are no mechanical devices available that can accurately determine the size your patient requires to obtain the desired results.
2. Fitting diaphragms should not be used to measure the size pessary a patient need.
3. Even before fitting a pessary, the patient should be informed that it is not uncommon to have to change the size more than once after being originally fitted. This is why it is so important that your patient be instructed to return within 24 hours of the initial fitting and again in 72 hours. Thereafter, re-examination every few months is recommended to ensure a proper fit is maintained as long as the patient is wearing the pessary.
4. At each visit the pessary should be removed and the vaginal vault inspected for signs of allergic reaction or undue pressure.
5. At the physician's discretion, the patient can be instructed in the proper removal, cleaning and reinsertion techniques for her own pessary. This process can be performed nightly by patient under ideal condition.
6. A noncomplian patient should not be fitted with Inflatable Donut Pessary. It is essential that your patient understands the importance of these frequent follow-up visits and that she fully cooperates with you to ensure the desired results.

Prior to Fitting

1. Have the patient empty her bladder before fitting the pessary.
2. Ulcerations and erosions frequency occur in cases of complete prolapsed due to irritation of the exteriorized cervix. Whenever possible, reducing the mass and treating the irritation are primary steps before using a pessary.
3. The Inflatable Donut Pessary is designed for ease of insertion and removal by the patient. The pessary is inserted Deflated.
4. Perform a normal pelevic examination before inserting or fitting of the pessary. A first approximation of size can be made by using fingers to determine the approximate width of the vaginal vault. This will generally get you within size or two of proper pessary.

Note:
If necessary, irrigate the vagina prior to insertion of the pessary. This will cleanse the vagina of excess discharge and secretions.

Insertion

1. Deflate the air inside the Pessary completely before insertion. (See Figure 1)
   Step (1) Attach Deflation End (C) to Valve (B) .
   Step (2) Press the Air Pump (A) to deflate the air inside the device.

Figure 1

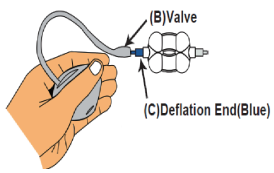
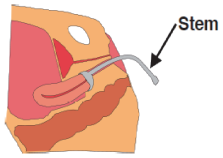


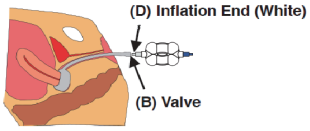
Figure 2



2. Gently insert the clean device into the posterior vagina beneath the cervix. The stem should protrude outside the vagina. (See Figure 2)
3. Attach the Inflation End (D) to the Valve (B) to inflate the Inflatable Donut Pessary with sufficient air as needed. (Figure 3)

Warning : DO NOT over inflate the Inflatable Donut Pessary to avoid causing any damage or/ and pain to the vagina.

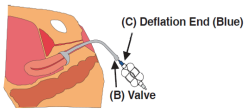
Figure 3



4. Detach the Inflation End (D) from the Valve (B). Gently place the stem into the vaginal vault.
5. If the patient is fitted using the physician's fingers and a ruler, and the patient returns after a day or more of use and complains the pessary either falls out (too small) or is painful and difficult to place (too large), the patient should be advised to use another pessary of different size.
6. Once in place, the patient sit, stand and bear down. Examine the patient while she is in the standing position to ensure the pessary has not shifted position. The pessary should not to be too loose as it may turn or be expelled, and it should not be too tight as it may caused discomfort.
7. The physician should be able to sweep on finger between the pessary and vaginal walls. It there is not enough space to do this, the next smaller pessary should be tired. If excessive space exists, the pessary will not be effective and may rotate or even be expelled.
8. It is sometimes necessary to refit the patient with a differnt size after period of time. Check the fitting to ensure continued patient comfort and relief of symptoms. Examine frequently for aigns of deterioration.
   DO NOT assume that replacement will always be the same size as the previous one.

Removal

Figure 4



1. To remove the pessary, slip stem of pessary out of vagina. Attach the Deflation End (C) to Valve (B) (See Figure 4). Squeeze as suggestion then grasp the deflaed pessary and withdraw.
   WARNING: DO NOT pull the stem directly to remove the device from patient's vagina; this action may rupture the device.
2. During each vist, the vagina should be carefully inspected for evidence of pressure or any reaction. The patient should be questioned concerning discharge, disturbance of bowel function or urination. It may be necessary to fit another size.
3. At each checkup, the pessary is removed and cleaned.

Cleaning

1. Prior to initial use, the Pessary should be washed thoroughly.
2. Rinse Pessary with 20 - 40 °C warm water for 30-40 seconds.
3. Apply mild pH 5-9 soap to rub the pessary gently back and forth for 10 times to lather well.
4. Rinse off Pessary with warm water for 1 minute, repeat and wash if needed.
5. Wash again and rinse Pessary thoroughly with distilled water for 1 minute. Ensure all traces of soap are removed to avoid irritation.
6. Allow pessary to completely air-dry before reinsertion.

Instructions for Use
Silicone Inflatable Donut Pessary MD

NOTE:

1. The Inflatable Donut Pessary should be periodically check for deep cracks or discoloration that make adequates cleaning impossible.
2. Do not immerse air pump of Inflatable Donut Pessary in water or any solutions to avoid malfunction.

Follow-up schedule

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

Disposal Instructions

- When the pessary becomes damaged, discolored, deformed, or no longer clinically indicated, it should be disposed of in accordance with local regulations for medical waste.
- Used pessaries that have been in contact with bodily fluids should be handled as clinical waste. Place the used device in a sealed plastic bag or container before disposal to minimize contamination.
- If the device has not been in contact with infectious material (e.g., trial-fitted, unused, or clean pessary), it may be discarded as general non-hazardous waste, following hospital or clinic policy.
- Follow institutional and national environmental safety guidelines when discarding the device and its packaging materials.

Storage & Transportation Conditions

- The shelf life is **3 years** from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

Glossary of Symbols

LOT	Batch code
	Manufacturer
	Temperature limit 10-40°C
	Humidity limitation 30-80%RH
	Not made with Natural Rubber Latex
	Single patient multiple use
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
REF	Catalogue number
MD	Medical device

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Bioteque Taiwan Ltd. and to the applicable competent authority having jurisdiction in their locale.

Bioteque Taiwan Ltd.
7 F., No. 431, 433, Baozhang Rd., Xizhi Dist., New Taipei City 221036, Taiwan.
Info@bioteque.com

For further assistance, please contact Bioteque Taiwan Ltd.