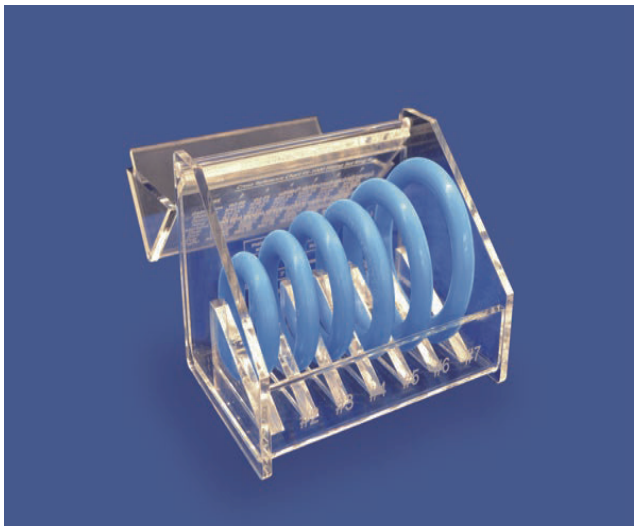
Biotegue

Instructions for Use
Pessary Fitting Set

MD



Not made with natural rubber latex

Description:

The Pessary Fitting Set is specifically designed for healthcare professionals to assist in determining the most appropriate size and type of pessary for individual patients. This product is intended for use in clinical settings, where physicians can perform repeated fitting and evaluation procedures to ensure optimal anatomical compatibility and patient comfort.
This fitting set is for clinical trial fitting purposes only and is not intended for long-term implantation.

Specification:

TYPE	Product Code, SKU
Ring	FS1000 REF
Cube	FS2000 REF
Dish with Support	FS3000 REF
Oval with Support	FS4000 REF
Gellhorn	FS5000 REF
Ring with Support	FS6000 REF
Ring w/Knob with Support	FS7000 REF
Marland with Support	FS8000 REF
Cup	FS9000 REF
Flexi Shelf	FS1100 REF
All are **Blue** color	

Indications for Use:

The Pessary Fitting Set is designed for the physician to determine the proper size and type of pessary for the patient before prescription is written.

Caution:

1. Federal law restricts this device to be sold 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).

Contraindications:

A Pessary Fitting Set is 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. Pessary Fitting Set is a valuable aid in selecting the correct pessary. A vaginal lubricant (e.g. K-Y® jelly, Replens® or equivalent) may be required for the patients comfort before insertion of a pessary.
The physician should determine if the patient requires estrogen therapy before prescribing a pessary.

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 will insure the patients comfort and reduce the risk of pressure necrosis.
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 patients comfort and reduce the risk of pressure necrosis.
4. Once in place, have the patient sit, stand and bear down. Examine the patient whilst she is in the standing position to ensure the pessary has not shifted position. The pessary should not be too loose as it may turn or be expelled, and it should not be too tight as it may cause discomfort.
5. The physician should be able to place one finger between the pessary and vaginal walls. It there is not enough space to do this, the next smaller pessary should be tried. If excessive space exists, the pessary will not be effective and may rotate or even be expelled.
6. To remove the pessary, carefully move the pessary forward toward the introitus. When the pessary is within reach, compress the pessary and withdrew gently with caution.

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Recommended Cleaning, Disinfection and Sterilization Instructions

※Clean and sterilize the device prior to first use.
※The Pessary Fitting Set must be cleaned and sterilized before being returned to the acrylic case to prevent contamination of other size pessaries.
※It is recommended that after cleaning, the physician can perform a High Level Disfinfection or Sterlization

Option 1- Cleaning followed by High-Level Disinfection

1. Cleaning

Medical Enzyme DetergentOPASTER' ANIOS

1. **Prepare enzymatic cleaning solution:**

Prepare an adequate volume of enzyme solution by diluting it with sterile or filtered water at a ratio of 1:250. Ensure that the product is fully submerged in the solution and soaked for 15 minutes. All cleaning steps must be performed manually while wearing gloves. The recommended water temperature is 25°C.

2. **Rinse:**

Remove the product from the solution and rinse thoroughly with sterile water or filtered water.

3. **Dry:**

Dry the product with a disposable paper towel or towel, or place it on a sterile drying table to dry.

2. High Level Disinfection

OPASTER' ANIOS

1. This disinfectant should be used directly; do not dilute it. The product should be thoroughly cleaned before disinfection.
2. Place the product in a soaking box and then pour the disinfectant (OPA) into the soaking box. Ensure the product is completely submerged in the liquid to achieve a thorough disinfection.
3. The soaking time should be 5 minutes.
4. After soaking, rinse the product thoroughly with sterile or filtered water, ensuring that no OPA residue remains on the surface.
5. Dry the product with a disposable paper towel or towel, or place it on a sterile drying table to dry.

Option 2- Cleaning followed by Sterilization

1. Cleaning

Follow the same procedure as described in Option 1 – Section 1: Cleaning.

2. **Sterilization**

Sterilization Process	Exposure Temperature	Exposure Time
Pre-Vacuum	132℃	4 Mins
Gravity Steam	121℃	30 Mins
	135℃	10 Mins

PATIENT FOLLOW-UP

Have the patient:

1. Once a physician has chosen the appropriate pessary and size, the patient will now use a single patient use pessary, normally white.
2. The patient should return to the clinic if there is discomfort or difficulty caused by their pessary.

WHEN TO REPLACE

A fitting pessary should be replaced if:

1. There is any deterioration or damage whatsoever to the fitting pessary.
2. The Pessary Fitting Set is past its 150 cycles of cleaning, sterilizing procedure.
3. The fitting pessary is past its use by date/shelf life.

WARNINGS

• Dispose of medical waste properly in accordance with regulations after using.

Glossary of Symbols

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

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.

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