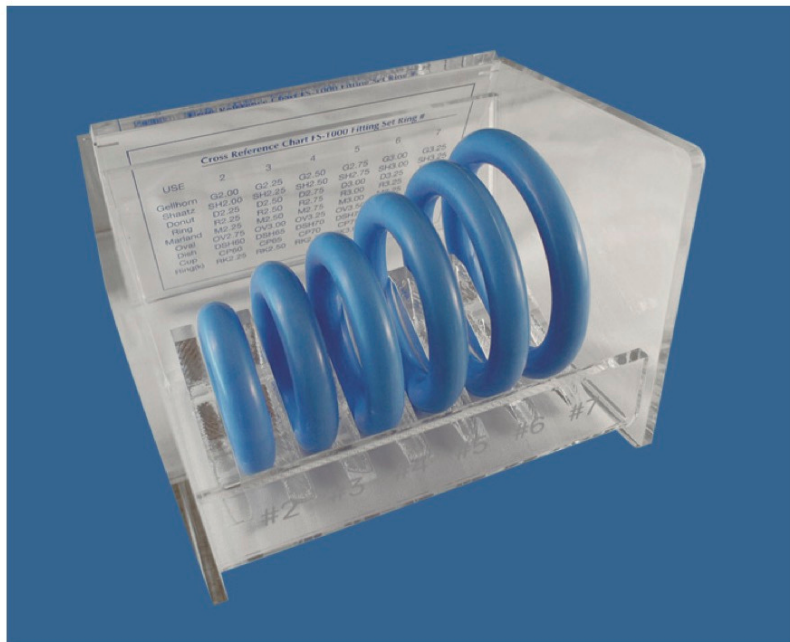


Pessary Fitting Set for Healthcare Professional



Pessary Fitting Set / Ring Type

DEVICE DESCRIPTION

A Pessary Fitting Set is designed for a physician to determine the proper size and type of pessary for the patient before prescription. It is fitted by trial and error. The fitting pessary is to be used as a fitting device within the clinic environment.

SPECIFICATION

TYPE	PRODUCT CODE, SKU
Ring	FS 1000
Cube	FS 2000
Dish with Support	FS 3000
Oval with Support	FS 4000
Gellhorn	FS 5000
Ring with Support	FS 6000
Ring w/Knob with Support	FS 7000
Marland with Support	FS 8000
Cup	FS 9000
Flexi Shelf	FS 1100
All are BLUE color	

CAUTION

Federal law restricts this device to be sold by or on the order of a physician.

CONTRAINDICATIONS

A Pessary Fitting Set is contraindicated in acute genital tract infections, pelvic infections, or noncompliant patients.

Visit our website:

www.biotequeeurope.com

Tel: +3 (531) 522-7778



Panpac Medical Corporation
2~6F, No. 58, Nanxing Rd.,
Shi-Chih Dist., New Taipei City,
Taiwan.



Wellkang Ltd
The Black Church, St. Mary's Place,
Dublin 7, D07P4AX, Ireland.

Not made with natural rubber latex

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. If 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.

RECOMMENDED CLEANING, HIGH LEVEL DISINFECTION AND STERILIZATION INSTRUCTIONS

CLEANING

1. Prepare enough enzymatic solution to fully submerge the device and follow the solution cleaning instructions.
2. Rinse
 - (a) Remove the device from the solution and thoroughly rinse (be sure to follow manufacturer's instruction).
 - (b) Allow the device to dry.

HIGH LEVEL DISINFECTION

1. Use a High Level Disinfection Solution (HLD) following the HLD manufacturers guidelines. Examples of high level disinfectants are CIDEX OPA® and Revital-Ox™ RESERT®. Prepare the high level disinfectant in a container, enough to fully submerge the device and follow manufacturer's instruction for use.
2. Rinse the device thoroughly in sterile water.
3. Place the cleaned/disinfected device in an appropriate clean and dry storage area.

STERILIZATION

Sterilization Process	Exposure Temperature	Exposure Time
Pre-Vacuum Autoclave	132 °C	4 minutes
Gravity Steam Autoclave	121 °C	30 minutes
	132°C~135 °C	10 minutes

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, high level disinfection /sterilizing procedure.
3. The fitting pessary is past its use by date/shelf life.



NON STERILE



BATCH CODE



EXPIRY DATE