

PRO VAC Endometrial Biopsy Sampler

Description:

PRO VAC Endometrial Biopsy Sampler

Intended Use:

Used for obtaining endometrial tissue.

Contraindications:

- Pregnancy or suspected pregnancy
- Acute pelvic inflammatory disease.
- Acute cervical or vaginal infections

Warning / Precaution:

- Do not use if package is opened or damaged
- This device is supplied sterile and intended for single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Only experienced surgeon should use this device
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation
- Storage temperature between 5°C to 30°C.

NOTE: Endometrial tissue is very hygroscopic and should be placed in a fixative to maintain tissue in satisfactory condition for pathologist

Instruction to use:

- Prepare the cervical and vaginal area for intrauterine procedure using antiseptic techniques.
- Place a vaginal speculum to expose the cervical canal. Tenaculum is required to straighten the cervical canal for inserting the uterine sound for examining the depth of uterine cavity.
- After examining, if cervical canal is dry, lubricate tip of the sampler with sterile water soluble gel for smooth passage. Gently insert the sampler.
- Connect syringe with adapter of sampler, hold adapter with one hand and pull piston with other hand rapidly to create negative suction pressure and lock the syringe.
- For additional vacuum unlock the mechanism and detach syringe from adapter, empty it for refilling.
- After completing the procedure gently withdraw the sampler from the uterus and discharge the tissue in container.
- Allow patient to rest for 10-20 minutes.

Potential Complications / Adverse Events:

Some possible complications may include, but are not limited to, the following:














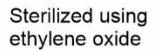

- Unusual Weakness
- Cramping
- Perforation of uterine wall
- Uterine spasm

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & reesterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

 Catalogue Number	 Batch Code	 Date of Manufacture	 Use By	 Do not re-use	 Do not Re-Sterilize	 Rx only	Caution : Federal (USA) law restricts device to sale by or on the order of a physician.
 Consult Instruction for use	 Do not use if Packing is damaged	 Caution	 Keep out of sunlight	 Keep Dry	 STERILE EO	 Sterilized using ethylene oxide	 Temperature Limit



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