

PRO VAC Endometrial Biopsy Sampler

Description:

PRO VAC Endometrial Biopsy Sampler

Configuration:

See brochure

Intended Use:

PRO VAC Endometrial Biopsy Sampler:
Used for obtaining endometrial tissue.

Indications for Use:

PRO VAC Endometrial Biopsy Sampler is indicated when precise diagnostic information is needed on the status of endometrium.

Clinical Benefit:

The PRO-VAC biopsy tool helps to find problems in the lining of the uterus early. It does this with a gentler way of taking a tissue sample than some other methods. This procedure is also safer with a lower chance of issues. Because it allows for earlier detection and a safer procedure, it can ultimately lead to better overall health for patients.

Patient Target Group:

The device is intended for Adults women.

Contraindications:

- Pregnancy
- Acute pelvic inflammatory disease
- Clotting disorders (coagulopathy)
- Acute cervical or vaginal infections
- Cervical cancers

Complications:

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

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

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

Storage:

The device should be stored in a clean, dry area. Do not expose to organic solvents, ionizing radiation or ultraviolet light. The devices must be used prior to the sterilization expiration date on package.

How Supplied:

The Uteral Stent is provided sterile by ethylene oxide and is intended for single use only. Do not resterilize, reuse or reprocess.

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 Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.
Consult Instruction for use	Do not use if Packing is damaged	Caution	Keep out of sunlight	Keep Dry	MD Medical Device	STERILE	Sterilized using ethylene oxide Not made with natural rubber latex Temperature Limit




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