allwin® Medical Devices

THE SAMPLER ENDOMETRIAL BIOPSY CATHETER

Description:
ENDOMETRIAL BIOPSY SAMPLING SYSTEM

Intended use:
Used for histological biopsy of the uterine mucosal lining or sample extraction of uterine menstrual contents.

Indication:
Endometrial biopsy is indicated when precise diagnostic information is needed on the status of endometrium.

Contraindications:
- Pregnancy
- Acute pelvic inflammatory disease.
- Clotting disorders (coagulopathy).
- Acute cervical or vaginal infections
- Cervical cancer

Complications:
Some possible complications may include, but are not limited to, the following:
- Bleeding
- Pelvic infection
- Perforation of uterine wall

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 5ºC to 30ºC.

Instruction for Use:
- The endometrial biopsy catheter tip is inserted into the cervix, avoiding contamination with nearby tissues.
- The catheter tip is then inserted into the uterus and advanced till the uterine fundus or until resistance is felt.
- Once the catheter is in the uterine cavity, the suction shaft in the catheter is fully withdrawn, creating suction at the catheter tip.
- The catheter tip is moved with an in and out motion, ensuring that the tip does not exit the endometrial cavity through the cervix, which maintains the vacuum effect.
- Use 360° twisting motion to move the catheter between the uterine fundus and the internal cervical os. Make at least four up and down excursions to ensure that adequate tissue is in the catheter.
- Once the catheter is filled with tissue, it is withdrawn and the sample is removed from the catheter by gently reinserting the shaft, tracing the tissue out of the catheter tip.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization 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.

REF Catalogue Number | LOT 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

allwin® Medical Devices
Allwin Medical Devices, Inc.
3305 E. Miraloma Ave., Suite 176 Anaheim, CA 92806 (USA)
Tel. : +1 714-572-1709
E-mail : info@allwinmedical.com | www.allwinmedical.com