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Accurette®

Endometrial Biopsy Curette

Do not re-use	Do not re-sterilize	Do not use if package is damaged.	Keep dry	Keep away from sunlight	Temperature limit	Batch code	Use-by date	Unique device identification
Medical Device	Sterilized by Irradiation	Single Sterile barrier system	Manufactured by	Date of manufacture	Country of Manufacturer			

PT/QA/1195:05
 Effective Date - 04/10/2024

INSTRUCTIONS FOR USE

ACCURETTE®- ENDOMETRIAL BIOPSY CURETTE

Slim flexible device collects diagnostically adequate endometrial sample's

INTENDED USE

The Accurette® Endometrial Biopsy Curette is intended for the removal of endometrial tissue for biopsy sample.

INTENDED USER

Accurette® should be used by healthcare professionals / Gynaecologist only

PATIENT POPULATION

Endometrial biopsies are typically done on women over the age of 35. It cannot be done on pregnant women. Sometimes a biopsy will be done on a woman who is having trouble getting pregnant to see if the infertility is linked to a problem with the endometrium.

INDICATIONS FOR USE

The device is indicated for use to remove material from the uterus and from the mucosal lining to obtain tissue for histological Biopsy or sample extraction of uterine menstrual content for any of the following:

- Primary or secondary infertility
- Abnormal uterine bleeding
- Amenorrhoea
- Hyperplasia
- Chronic endometrial infections

CONTRAINDICATIONS

1. Pregnancy or suspicion of pregnancy.
2. Acute pelvic inflammatory disease (PID) or recent treatment for PID.
3. Untreated acute cervicitis, chronic cervicitis, or vaginitis, in case of bacterial vaginosis or suspected vaginosis, the endometrial biopsy should be delayed until infection is controlled
4. Cervical cancer

STORAGE AND HANDLING:

Store the Accurette® Endometrial Biopsy Curette at temperature 15°C - 30°C.

WARNINGS

1. Accurette® should not be used to obtain an endometrial biopsy in patients with amenorrhoea unless a laboratory test has confirmed the absence of detectable circulating HCG levels. The procedure should not be done without emergency backup for women with a history of blood dyscrasia because of the risk of haemorrhage.
2. Accurette® is meant for single use only.
3. Do not use the device or re-sterilize the device if you find the sterile packaging is damaged or unintentionally opened before use.
4. A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PRECAUTIONS

Prior to insertion of Accurette®, the uterus should be carefully sounded to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. If resistance is felt at any time in the procedure, the device should never be forced. When cervical stenosis is present, dilation may be required. Slight lubrication of Accurette® with a water-soluble gel may aid the insertion.

ADVERSE REACTIONS

Endometrial curetting is a procedure that involves minimal trauma to the uterus and cervix. However, in a small percentage of cases, one or more of the following complications may occur uterine or cervical perforation, hypotension, vasovagal reaction, pelvic infection, or air embolism.

EXAMINATION AND ASSESSMENT

Pre-procedure screening of patients should include a complete history, physical examination, and laboratory tests as indicated. In postmenopausal women, cervical stenosis may make as the procedure more difficult. If the working diagnosis is infertility, the patient should be in the premenstrual (luteal) phase of her cycle. It is preferable to perform endometrial biopsy when the patient is not bleeding.

BIMANUAL PELVIC EXAMINATION

Prior to the bimanual exam, explain the purpose of the examination to the patient. She should empty her bladder and assume the lithotomy position on an examination table. Drape the patient to protect her privacy. The practitioner should wear clean, undamaged examination gloves. As the purpose of the pelvic examination is to establish the size, consistency, and position of the uterus, and to check for adnexal tenderness or other signs of infection. Careful assessment of the uterus and cervix is essential to the procedure.

DIRECTIONS FOR USE

1. Prepare the vagina and cervix using as the currently accepted antiseptic techniques for intrauterine procedures, use of aseptic technique during the entire procedure is essential. Observe a No-Touch Technique throughout the procedure: do not contaminate the uterine sound or curette or allow the tip to touch objects or surface before being inserted through the cervical canal
2. With a speculum in place, note any abnormal discharge. Check for sign of cervical infection sexually transmitted diseases (STD) and pelvic inflammatory disease (PID). Any suspected infection should be treated before aspiration. If no pathology found, gently insert a sterile uterine sound to determine the depth and direction of the uterine canal. It may be advisable to use a vulsellum or a tenaculum to correct the angulation and stabilize the cervix.

3. After sounding the uterus, the depth and direction of the uterine canal should be noted. With the piston fully engaged in device, the curette / device is gently inserted through the cervical canal into the uterine cavity until it just touches the fundus as shown in Fig 1.

If resistance is encountered, no attempt should be made to force the insertion. Note the uterine depth by the dots visible on the curette. The dot nearest the tip of the cannula is 5 cm from the tip, and the other dots are at 1cm intervals. After measuring the uterine size, withdraw the cannula slightly.

In patients with an extremely dry or narrow cervical canal, slight lubrication of the curette with a water-soluble gel may aid the insertion.

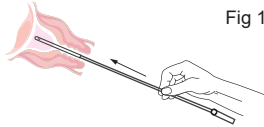


Fig 1.

4. When Accurette® is positioned as per the measured depth in the uterine cavity, the piston should be pulled back as far as possible with one hand while the curette is held in position with the other hand as shown in Fig 2. A quick and steady motion will create the maximum negative pressure within the collection tube/device and result in an optimal tissue sample.

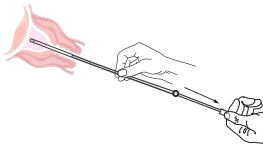


Fig 2.

5. After pulling back the piston, Accurette® should be rolled between the fingers while simultaneously moving it laterally as well a back and forth inside the uterus 3 to 4 times for comprehensive sampling. It is important not to withdraw the curette beyond the cervical os during the procedure.as shown in Fig.3

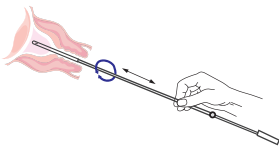


Fig 3.

6. Accurette® should be removed gently from the patient. as shown in the Fig.4

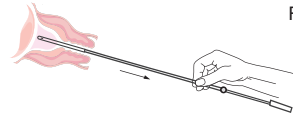


Fig 4.

7. The distal tip of the device should be examined for the presence of a uterine mucosa sample.

8. To expel the sample into the transport container, the piston is pushed forward into the curette as shown in Fig 5.

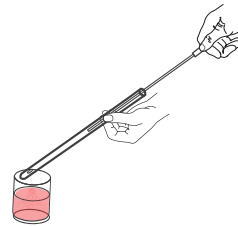


Fig 5.

9. Accurette® must be safely discarded after use.

INSTRUCTION FOR DISPOSAL

On completion of shelf life or on removal after use, dispose the items as per the local regulations governing as the disposal of non recyclable waste/medical waste.

RISK OF RE-USE

Loss of sterility & corresponding risk of infections.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Gynaecology Instrument Endometrial Biopsy Curette comply with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the essential requirements. The Clinical evidence is demonstrated with the relevant essential requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of EN ISO 14971:2019/A11:2021.

PERFORMANCE CHARACTERISTICS OF THE DEVICE

The clinical Performance of the product was evaluated by taking the rating (scale 1 to 5, where 5 being excellent and 1 being poor) of following parameters of Accurette Endometrial Biopsy Curette:

- Sturdiness
- Flexibility
- Sample Collection
- Suction and Vacuum

The overall rating given for using Accurette Endometrial Biopsy Curette is 4.