

Innovatek Cervical Scraper/Spatula

INTENDED USE

The Innovatek Cervical Scraper/Spatula is a blunt wooden instrument intended for scraping, removing and collecting of cervical cells at different locations of lesions (endocervical lesions, ectocervical lesion, synchronous ecto- and endocervical lesions) of the cervix or vagina for Pap smear analysis. For professional use only.

This product is available in three different styles: (1) Ayres, (2) Double end, and (3) Lerner style.

SUMMARY AND EXPLANATION

Introduced in 1941, the Pap smear is an inexpensive yet effective method of screening women for invasive, but clinical occult, carcinoma of the cervix. The systemic use of Pap smears has led to a steady reduction in cervical mortality.

The experience of the sampler, the method of sampling, and the age of the patient affect the reliability of obtaining smears. The most frequently used instruments for the Pap smear were the cervical scraper/spatulas.

The surface area of the ectocervix, the diameter and the length of the cervical canal differ between the nullipara and parous woman. Therefore a variety of cervical scrapers / spatulas were designed from which one of suitable size and shape may be chosen according to individual requirement. Since spontaneously exfoliated cells are not always representative of the whole lesion, rendering the surface of each spatula roughly allows removal of parakeratotic, hyperkeratotic and necrotic layers and ensures sampling of the underlying neoplastic cells.

Most dysplastic epithelial abnormalities are believed to arise in or near the squamocolumnar junction, and most authorities feel that smears lacking endocervical cells are inadequate for reliable interpretation. The elongated "tongue" of the spatula can be used for scraping the endocervical canal. Some studies indicated that the use of cytology brushes is better for collecting endocervical canal sample for cytology studies.

WARNING AND PRECAUTION

1. For professional use only.
2. The cervical scraper/spatula is not sterile.
3. The cervical scraper/spatula is not intended for use in pregnant woman.
4. Do not reuse the scraper/spatula.
5. Contact bleeding is known to occur.
6. Prolonged storage in arid condition may result in slight warping and splitting. Do not use the split scraper / spatula.
7. Do not use scraper/spatula with sharp or rough edges.

STORAGE

Store at any temperature in the box provided. Do not place near heaters.

INSTRUCTION AND PROCEDURE

For Pap Smears:

Patients should not douche or have sexual intercourse for at least 24 hours prior to examination and should not be menstruating. Collect sample with scraper first before collecting endocervical canal sample with cytology brush.

1. After insertion of the speculum the surface of the ectocervix is cleansed with a cotton swab or gauze to remove mucus and debris.
2. The correct style of scraper/spatula is chosen for the individual.
3. Scrape the entire circumference of the external cervical os area.
4. With light but firm pressure, rotate the spatula one complete turn in a clockwise direction.
5. Spread the specimen on a glass slide along its long axis, parallel to its edges. If the distribution of the cellular material is uneven, the same spatula may be used for re-spreading.
6. Fix immediately with a cytology fixative.
7. Collect endocervical canal sample with cytology brush, if required. (Cytology brushes available from Innovatek Medical.)

LIMITATIONS

Pap smear:

1. Contact bleeding in 2-3 % of cases may interfere with subsequent colposcopic examination.
2. Cytology specimen must be fixed immediately with proper cytofixative to avoid air drying artifact. (Cytology spray fixative is available from Innovatek Medical.)

DISPOSAL

All materials that have been in contact with the patient are potentially infectious. Follow each clinic/laboratory's established procedure for proper handling and disposal.

REFERENCE

1. Koss LG. Diagnostic Cytology and its Histopathologic Bases, J.B. Lippincott Co.. 1979.
2. L. Szalay Wilhelm Maudrich : Cytology of the uterine cervix. Medical Publishers Wien-Miincheu-Bern. 1990.
3. Schuman J, O'Connor DM. Pap Smear Collection Devices. Diagn Cytopathol. 1992.
4. Hoffman MS, Cavanagh D. Cervical Cancer: Screening and Prevention of Invasive Disease. Cancer Control Journal. 2:6, 1998.
5. Aaen V, Ferry L. Can Cervical Cancer Screening be Improved. Federal Practitioner. 1998.

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