MedSchenker® CavSwab™ Oropharyngeal in Pouch

Product Insert & How-to-Use Guide

INTENDED USE

MedSchenker® CavSwab™ Oropharyngeal in pouch is sterile and ready-for-use system intended for clinical samples drawing. The CavSwab™ is suitable for short contact with the human body. Product should be used as directed.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections involves the collection of swab samples.

This can be accomplished using the MedSchenker® CavSwab™. CavSwabs™ are available with different size and shape shaft and tip for the two types of body collection sites. CavSwabs are made from nylon and are packed into a medical grade paper pouch. CavSwabs™ are electron beam sterile. The sterilization type is indicated on the product labels (pouch, carton and/or box labels.)

TECHNICAL NOTES

A slight yellowing of the tip is a well-known phenomenon. This could be due to many factors: the type of raw material, the product sterilization treatment, or the products natural aging. Therefore, product yellowing is not necessarily indicative of product deterioration.

PRECAUTIONS

1. Carefully follow the instructions for use.
2. When using a device with plastic or wooden stick, the pressure applied during sampling shall be light since the stick material is breakable.
3. The fiber adhesion to the stick is tested for instantaneous sampling: longer contact between the swab and the sampling area might cause the fibers to come out.
4. If the swab is submitted to a chemical or physical sterilization or microbiostatic process, its intended functioning could be compromised.
5. Product cannot be reused or re-sterilized.

STORAGE

Store the MedSchenker® CavSwab™ device at 2 - 25°C. If the product is stored at a different temperature, it would not maintain the stated specifications.

Shelf Life

The MedSchenker® CavSwab™ device has a shelf life of 36 months after the date of manufacture and should not be used after the listed expiration date.
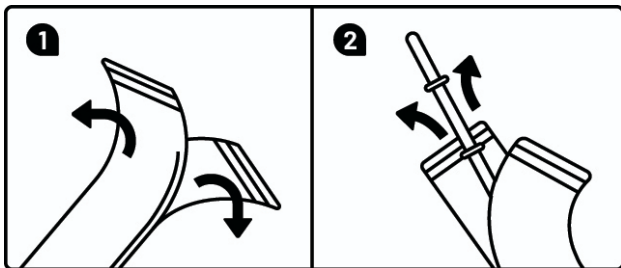
PRODUCT DETERIORATION

The content of the unopened and undamaged units is guaranteed to be sterile. MedSchenker® CavSwabs™ should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the swab package is open or damaged, or (4) there are other signs of deterioration.

DIRECTIONS FOR USE, SPECIMEN COLLECTION

NOTE: Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens
1. Open the peel pouch and extract the swab.
2. Collect the sample. During sampling, the swab end (tip) shall only come in contact with the suspected infection, so as to reduce contamination risks.

NOTE: Do not use excessive force, pressure or bending when collecting swab samples from patients as this

may result in accidental breakage of the swab shaft

Swab shafts often exhibit diameter changes to facilitate different sampling requirements. Swab shafts may also have a molded breakpoint point designed for intentional breakage of the swab into a transport tube. In all circumstances when collecting swab samples from patients, do not use excessive force, pressure or bending of the swab as this may result in accidental breakage of the swab shaft.

3. Process the swab according to internal laboratory procedure. Alternatively put the swab in the transport test tube.
4. Send the sample to the laboratory for immediate testing.

Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines. Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with internal guidelines of the institution.

LIMITATIONS

1. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe Biosafety recommendations when handling or analyzing patient samples.
2. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. MedSchenker® CavSwabs™ must be used by skilled personnel only.

WARNINGS

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. Do not resterilize unused swabs.
3. Do not re-pack.
4. Not suitable for any other application than intended use.
5. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
6. Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is broken).
7. Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft.
8. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
9. To be handled by trained personnel only.
10. It must be assumed that all specimens contain infectious microorganisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

WASTE DISPOSAL

Unused swabs may be considered as nonhazardous waste and disposed of accordingly. Dispose of used swabs as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

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