

Product Insert and User guide Individually Packed Specimen Collection Flocked Swab

PRODUCT INSERT FOR :

Nasopharyngeal and Oropharyngeal Flocked Swab	Part no. 4051 – UDI 05745000445004
Nasopharyngeal and Oropharyngeal Flocked Swab	Part no. 4052 – UDI 05745000445240
Nasopharyngeal and Oropharyngeal Flocked Swab	Part no. 4053 – UDI 05745000445035
Nasopharyngeal and Oropharyngeal Flocked Swab	Part no. 4054 – UDI 05745000445066
Nasopharyngeal Flocked Swab	Part no. 4055 – UDI 05745000445189

INTENDED USE:

Sterile Specimen Collection Flocked Swab for collection of nasopharyngeal and oropharyngeal swab samples or sputum, saliva, urine, and faeces.

The intended user is trained personnel in a controlled environment.

SUMMARY AND PRINCIPLES:

Proper specimen collection is critical for rapid and accurate diagnosis of clinical specimens. Meditec Specimen Collection Flocked Swab are used for nasal and oral collection of clinical samples. Meditec provides different variations of the same Flocked Swab with various placement of the moulded breakpoints and a variant without any breakpoint. For sterilisation, each swab is individually packed in Impermeable PET/PE foil that are E-Beam and gamma sterilisation compatible. In accordance with hygienic principles for prevention of cross- contamination and infections. Do not re-use.

PRECAUTIONS:

- Follow directions for use as demonstrated below.
- For single use only. Do not re-use.
- The swabs are sterilised using irradiation.
- Do not re-pack or re-sterilise.
- Do not apply excessive force using the swab during specimen collection sampling from patients. It could result in unintended breakage of the swab handle.
- All clinical specimens should be handled with proper care.
- Swabs should not be used if peel pouch is damaged or if expiration date printed on label has passed.

STORAGE:

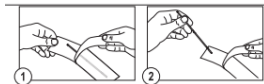
Store Meditec Specimen Collection Flocked Swab between 4–25°C.

User Environment:

Trained Personnel, Professional Users. Hospitals and Clinics.

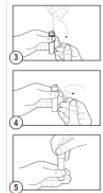
Instruction of use:

1. Peel to open the sterile package from the end indicated with an arrow and remove the swab without anything touching the swab tip.



2. Collect oral specimen and ensure the swab tip is only in contact with the area the sample is to be taken from.

3. Process the Swab according to internal laboratory instructions. Swab may be placed in a sterile tube and transferred to laboratory for microbiological analysis.



4. Disposal of swabs according to laboratory regulations for biohazard waste.

Product_insert - A5_Specimen Collection Flocked Swab_UK_rev.05



LIMITATIONS:

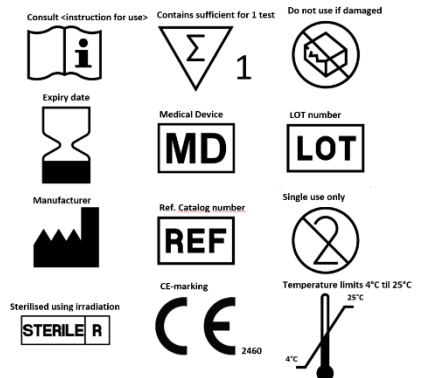
- Reliable specimen collection depends on many factors including collection and handling technique, specimen conditions and timing. Best results are achieved when specimens are processed shortly after the time of collection. If delays are anticipated, Swab specimens are recommended to be stored in a suitable buffered preservative until it is processed.
- In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Pay attention to Biosafety recommendations when handling or analysing specimen samples.
- Storage temperature outside of recommended range should be avoided.
- Specimen Collection Flocked Swab are not intended to remain on skin or mucosal membrane for an extended period (contact duration ≤ 24 hours).

WARNINGS:

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. The device is ready for use and does not require any preparation for specimen collection.
3. Do not re-sterilise unused swabs.
4. Do not re-pack.
5. Not suitable for any other application than intended use.
6. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
7. Do not use if:
 - There is any evidence of damage.
 - The swab tip or swab shaft is broken.
 - Product is contaminated.
 - The expiration date has passed.
 - The swab package is open.
 - There are other signs of deterioration.
8. Swab shafts have a moulded breakpoint point designed for intentional breakage of the swab into a transport tube. 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.
9. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorised or unqualified use of the product.
10. To be handled by trained personnel only.
11. All specimens must be handled and disposed with appropriate precautions. WASTE DISPOSAL Unused swabs may be considered as non-hazardous waste and be disposed of accordingly. The swabs used for collection must be disposed of according to the procedures for biological risk materials.
12. A notice to the user and/or patient; if any serious incident that occur in relation to the device should be reported to Meditec and The Danish Medicines Agency. For further information use below Meditec contact information.



Meditec A/S
 Fabrikvej 17C
 3000 Helsingør
 Phone: +45 48 48 36 36
 E-Mail: QA@meditec.dk



This Product Insert was updated February 2023