Puritan Individually Wrapped Swabs

PRODUCT INSERT: Puritan Traditional Spun Fiber, Foam, HydraFlock® and PurFlock Ultra® Flocked Swabs Individually Wrapped.

INTENDED USE: Individually wrapped Puritan traditional, foam, HydraFlock® and PurFlock Ultra® swabs are sterile, ready-to-use devices for the collection of clinical samples.

SUMMARY AND PRINCIPLES: Proper specimen collection is critical for rapid and accurate diagnosis of clinical specimens. Puritan traditional, foam, HydraFlock® and PurFlock Ultra® swabs are used for the collection of clinical samples. Puritan Medical Products LLC provides a variety of swab tip sizes and various shaped handles for specific applications. For sterilization, each swab is individually wrapped in medical paper pouches that are gamma or EO compatible. Gamma or EO sterilization is marked on the product labels.

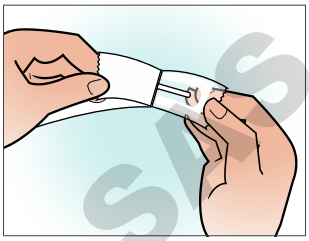


Fig. 1

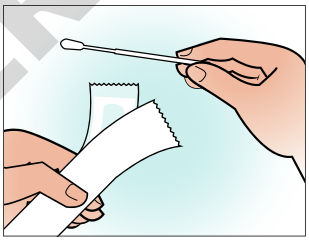


Fig. 2

PRECAUTIONS:

- For single use only, re-use may cause a risk of infection and/or inaccurate results.
- Do not re-pack or re-sterilize.
- The use of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.
- Do not apply excessive force when collecting swab samples from patients as it may result in unintended breakage of the swab handle.
- To be handled by trained personnel only. Follow directions for use as demonstrated below, the manufacturer cannot be held responsible for any unauthorized use of the product.
- All clinical specimens may contain infectious microorganisms and should be handled with care. Appropriate protective equipment should be worn. Laboratory and biosafety guidelines should be followed when handling a clinical specimen.
- Swabs should not be used if peel pouch is damaged or if expiration date printed on label has passed.

STORAGE: Store Puritan traditional, foam, HydraFlock® and PurFlock Ultra® swabs at 2–30°C.

DIRECTIONS FOR USE:

1. Peel open sterile pouch. *(Fig. 1)*
2. Remove swab applicator and collect specimen. Ensure applicator tip only touches the suspected infectious area to minimize potential contamination. *(Fig. 2)*
3. Swab should be processed immediately according to internal laboratory instructions. Alternatively, swab may be placed in a sterile tube marked with patient information and transferred to laboratory for microbiological analysis.
4. Disposal of tubes and swabs must be done according to laboratory regulations for biohazard waste.

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. Refer to corresponding reference standard and procedure for optimum collection techniques.[1,2]
- Storage temperature outside of recommended range should be avoided.
- Swabs are intended to collect specimens and not to remain on skin or mucosal membrane for an extended period of time (contact duration ≤ 24 hours).

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REFERENCES:

[1] Miller, J.M. 1999. A guide to specimen management in clinical microbiology. American Society for Microbiology. Washington, DC

[2] "Media Transport Systems." *Puritan Medical Products.* Puritan Medical Products LLC, n.d. Web. 17 Apr. 2014. <http://www.puritanmedproducts.com/>.

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207-876-3311 • puritanmedproducts.com
sales@puritanmedproducts.com
Puritan Diagnostics LLC, An affiliate of Puritan Medical Products Co.
31 School Street, Guilford, Maine 04443-0149 USA
ISO 9001:2008 ISO 13485:2003 CE

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