



FLOQSwabs®

ENGLISH

FLOQSwabs® in pouch Product Insert & How to Use Guide

INTENDED USE

Copan FLOQSwabs® in pouch are sterile and ready-for-use systems intended for clinical samples drawing. The swab 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 Copan Swab.

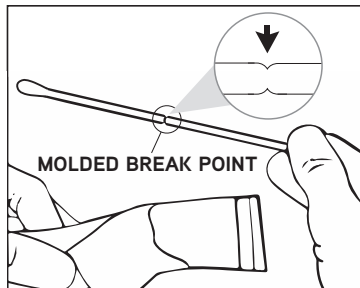
Copan Swabs are available with different size and shape of both shaft and tip for the different body collection sites.

The Copan FLOQSwabs® are packed into medical grade paper pouch.



TECHNICAL NOTES

For this version of sterile single wrapped FLOQswabs® with molded breaking point, **no red marking** is printed onto the plastic stick at the molded breaking point.



The molded breaking point is present and detectable as a **narrowing** of the stick at about 100 mm from the tip.

The absence of red marking does not impact molded breaking point functionality.

Take time to visually locate the position of breaking point onto the stick when using the swab for collecting samples and for subsequent transfer in the transport tube as applicable.

A slight yellowing of the tip is a well-known phenomenon. This could be due to many factors: to the type of raw material, to the product sterilization treatment, to the product 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 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: a longer contact between the swab and the sampling area might cause the fiber to come out.
4. If the swab is submitted to a chemical or physical sterilizing or micro-biostatic process, its intended functioning could be compromised.
5. Product can not be reused or re-sterilized.

STORAGE

Store the Copan Swab devices at 2-30°C. If the product is stored at a different temperature, it would not maintain the stated specifications.

PRODUCT DETERIORATION

The content of the unopened and undamaged units is guaranteed to be sterile.

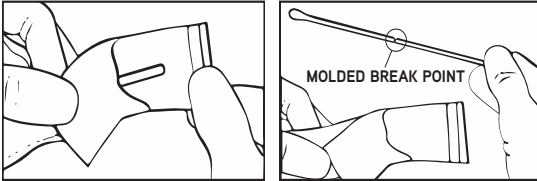
Copan FLOQSwabs® should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the swab package is open or damaged, or (4) there are other signs of deterioration.

DIRECTIONS FOR USE, SPECIMEN COLLECTION

In case the swab is packed in a peel pouch the user's instructions are also printed on each unit, together with the descriptive diagram.

NOTE: Gloves and personal protective equipment proportional to the biological risk should be worn when collecting and handling microbiological specimens.

1. Open the pouch from the side indicated by the arrow and remove the swab taking care not to touch anything with the swab tip
2. Collect the sample. During sampling, the swab tip must only come in contact with the area from which the specimen is to be taken in order to reduce contamination risks.

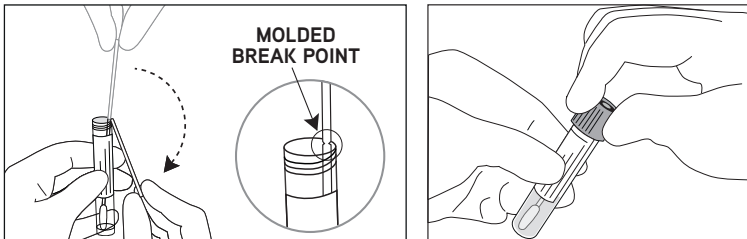


NOTE: Do not Bend or shape the swab before collection. Swab shafts exhibit diameter changes to facilitate sampling procedure. Swab shafts have a molded breakpoint point designed for intentional breakage of the swab into a transport tube. In all circumstances when collecting swabs samples from patients, 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.
4. Send the sample to the laboratory

If the swab needs to be broken in a transport test tube:

1. Check that the test tube and swab sizes are compatible
2. Insert the swab into the test tube by aligning the swab breakpoint, with the edge of the test tube. The molded breaking point is detectable as a narrowing of the stick at about 100 mm from the tip.
3. Gently bend the swab until it breaks
4. Close the test tube by securely screwing on the cap
5. Discard the broken off part of the swab in a dedicated container



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. Copan Swabs 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. The device is ready for use and does not require any preparation for specimen collection.
3. Do not re-sterilize 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 (1) there is evidence of damage (i.e., if the swab tip or swab shaft is broken) or contamination to the product, (2) the expiration date has passed, (3) the swab package is open, or (4) there are other signs of deterioration.
8. Do not bend or shape the swab before collection. 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 unauthorized or unqualified use of the product.
10. To be handled by trained personnel only.
11. It must be assumed that all specimens contain infectious micro-organisms; therefore 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.

INDEX OF SYMBOLS

Symbol	Meaning
	Manufacturer
	Sterilized using ethylene oxide
	Do not reuse
	Catalogue number
	Temperature limitation
	Use by
	Consult Instructions for Use
	Batch code (Lot)
	Contains sufficient for <n> tests
	Do not use if package is damaged
	Country of Manufacture
Rx Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."



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