

INSTRUCTIONS FOR USE

OROPHARYNGEAL SPECIMEN COLLECTION

SUPER BRUSH COLLECTION SWABS

PRODUCT TITLE: Super Brush Collection Swabs: Part Numbers 53-0100-TFS, 53-0101-TFS, 53-0103-TFS, 53-4582-TFS

PURPOSE STATEMENT: This document provides guidance on the use of Super Brush Collection Swabs.

PRODUCT DESCRIPTION: Super Brush collection swabs are individually packaged electron beam sterilized swabs. They are made with a polypropylene handle and polyurethane foam in a paper-on-film thermoform package.

INTENDED USE: The Super Brush Collection Swabs are single use, sterile devices that are suitable for oropharyngeal specimen collection. They are suitable for short duration contact with the human body and should be used by trained professionals as directed in this instruction or according to the instructions from the laboratory or test kit manufacturer.

MATERIALS PROVIDED: One of the individually packaged Super Brush collection swabs shown below is provided for specimen collection. Images are enlarged to show details thus not reflecting the actual size of the swabs.

53-0100-TFS 6-INCH 50MM BREAKPOINT SWAB



53-0101-TFS 6-INCH 80MM BREAKPOINT SWAB



53-0103-TFS 6-INCH 55MM BREAKPOINT SWAB



53-4582-TFS 6-INCH SWAB



MATERIALS NOT PROVIDED: Tongue depressor, transport tube, testing kit or personal protective equipment are not provided.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

1. Read the package insert carefully before collecting. Failure to follow directions may produce invalid specimen.
2. Keep this product out of the reach of children.
3. This product is to be used by a trained healthcare or laboratory professional.
4. Do not use on anyone under 3 years of age.
5. Do not use if:
 - i. Package is open or damaged
 - ii. Foam tip is detached from handle
 - iii. Swab handle is broken
 - iv. Foam tip is deformed
 - v. Foreign matter visible on swab
6. Each swab is for single use, do not re-use. There are risks of specimen contamination and/or cross-infection if re-used.
7. Do not use excessive force or pressure when collecting specimen as the swab handle could break.
8. For swab handle that has a breakpoint, hold it gently to avoid it breaking during collection.
9. Do not touch the swab foam tip when handling the swab.
10. Please consult a healthcare provider before use on people who have had facial or head injuries or surgery recently.
11. Always read the laboratory or the test kit manufacturer's package insert for specific instructions regarding specimen collection and transport.
12. Incorrect test results may occur if a specimen is incorrectly collected or handled.
13. The specimen collected by this product could be further used for clinical research, diagnostic test, or other medical purposes. Proper validations are needed before such applications.
14. Specimens may contain infectious microorganisms. Wear appropriate protective equipment and follow laboratory and biosafety guidelines when handling and disposing of specimens.
15. Seek medical attention if a seriously ill or allergic reaction occurs. In case of emergency, contact local emergency services.

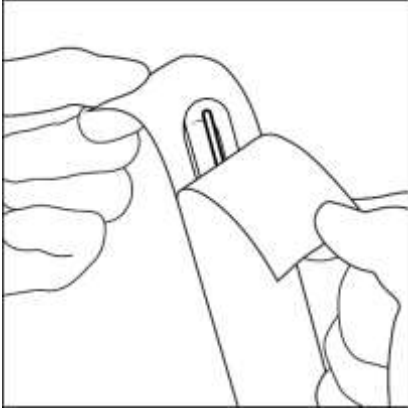
PREPARATION

1. Wash hands before specimen collection.
2. Wear appropriate personal protective equipment.
3. Read the instructions.
4. Check the swab packaging and the expiration date on the pouch. Do not use if expired or the pouch is damaged or open.

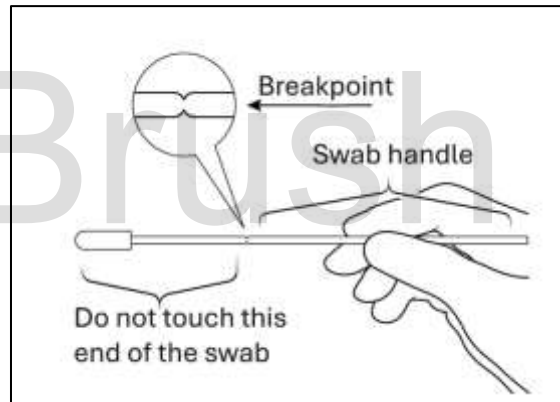
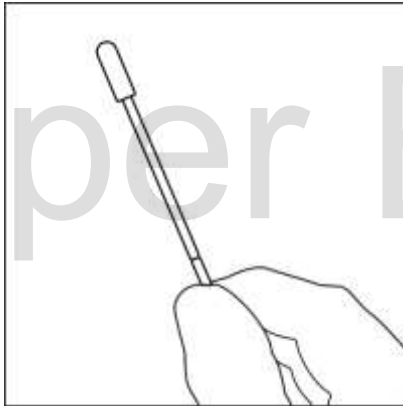
5. For swab handle that has a breakpoint, do not use if the handle is broken.

SPECIMEN COLLECTION PROCEDURE

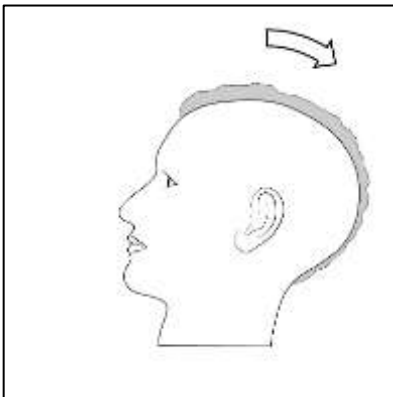
1. Peel the pouch in the direction indicated by the PEEL icon. Remove the swab from the pouch. Do not touch the swab foam tip.



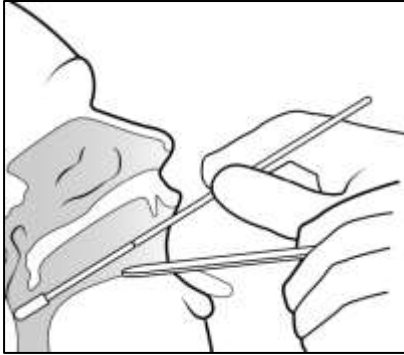
2. For swab handle with a breakpoint, hold the handle above the breakpoint.



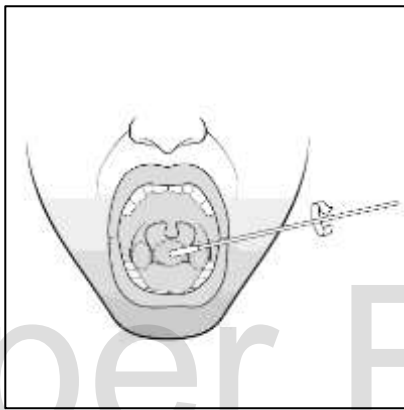
3. Position the head slightly back.



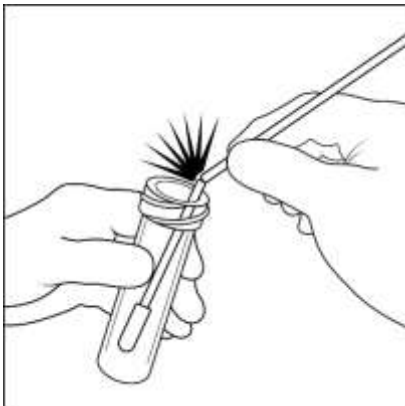
4. Insert the swab into the mouth with care to avoid the tongue and teeth.



5. Rub swab over both tonsillar pillars and posterior oropharynx.



6. Once the specimen is taken, follow the laboratory or the test kit manufacturer's instructions for further action.
7. For breakpoint swab, insert the swab into a compatible transport tube and break the handle at the breakpoint. Do not touch the swab handle below the breakpoint.



8. Wash hands and properly dispose of waste.

STORAGE INSTRUCTIONS

Store swabs in their original containers at 2°C~30°C (36°F ~86°F) away from UV light and propane exhaust fumes. Swabs are stable until the expiration date printed on the pouch. Do not use beyond the expiration date.

DISPOSAL

Dispose of in accordance with applicable regulations.

ADDITIONAL INFORMATION

Instructions for use and product information can also be found online at www.superbrush.com.

For questions, comments, or to report a serious adverse event related to the use of this device, please contact the manufacturer at:

Super Brush LLC











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Symbol Glossary for Symbols used on labeling.

Symbol	ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer	
	REF. NO. and Title	Description
	5.1.1 Manufacturer	Indicates the medical device manufacturer as defined in applicable medical device regulations
	5.1.4 Use-by date	Indicates the date after which the medical device is not to be used
	5.1.5 Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	5.1.6 Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.2.4 Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only
	5.4.3 Consult instructions for use or consult Electronic instructions for use	Indicates the need for the user to consult the instructions for use
	5.4.4 Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	5.7.7 Medical Device	Indicates the item is a medical device
	5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information

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