

SoftBiopsy® - SFT-1000
Instructions for Use for Wound Biopsy
Biopsy Brush Surgical Curettage for Tissue Sampling and Specimen Collection

**Intended Use**

SoftBiopsy® is intended to be used for the histologic sampling of visually apparent wounds at the wound base, or wound-associated lesions in clinical situations where brush-biopsy curettage specimens would be desired in contrast to a deep, single punch biopsy specimen(s) or fluid collection or cytological swab sampling for anatomic, culture, or molecular pathologic testing.

Indications For Use

During the care of an external skin wound, biopsy of the wound bed post-debridement or areas of the wound suspicious for pathology where tangential curettage specimens would be diagnostic using anatomic, microbiologic, or molecular pathologic technologies.

SoftBiopsy® is not recommended for use:

- To debride wounds because the *Kylon® fabric on SoftBiopsy® is not optimally conditioned to withstand prolonged frictional tissue manipulation*. Instead, the *Soft K-Bride® (SFT-4000) should be considered because it is conditioned to withstand a longer more frictional debridement procedure over a larger surface area*.
- To biopsy non visually apparent surface wounds, e.g. tunneled or undermined wounds.
- To biopsy hardened or hyperkeratotic wound tissue.

Contraindications

SoftBiopsy® is contraindicated for use in the following patients:

1. Patients with known bleeding disorders or those on anticoagulant therapy.
2. Patients with an acute wound infection or condition which is not amenable to wound biopsy.
3. Patients with a known allergy to nylon or acrylic plastic.
4. Pregnancy or suspected pregnancy, when a wound biopsy would not otherwise be indicated.

Warnings/Precautions

- Avoid contact with alcohol or alcohol containing solutions, as they may adversely affect the integrity of the pad adhesion to the plastic tip of the device.
- Avoid application of pressure beyond full compression of the Kylon fabric as seen visually (visually apparent flattening of the hooks until they lay parallel to the base of the of platform), as this will not improve performance, and may cause mechanical failure of the device.
- If the tip or fabric pad separates from the device during a procedure, the device should be disposed of and a new device should be used.
- With vigorous frictional pressure on the wound surface, hooked bristles may in rare instances fracture or separate from the fabric pad of the device, and should be removed along with dislodged tissue following biopsy.
- The use of SoftBiopsy® on pregnant patients has not been studied.
- Although unlikely, snap off of the tissue filled tip can potentially release airborne particulate and covering the tip, eye aversion, or eye protection during snap off is advised.

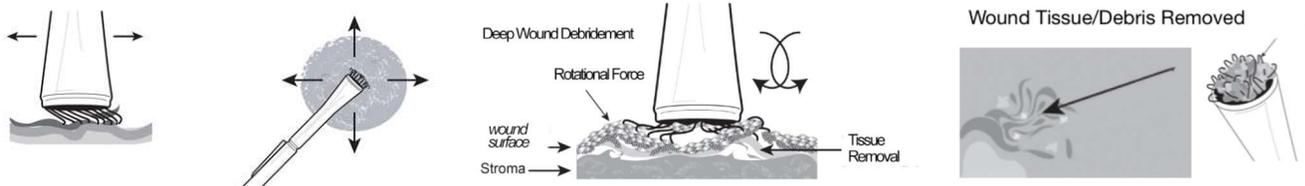
Tissue Sampling Instructions

Peel open the sterile single use SoftBiopsy® package at the handle side.

Tissue Capture:

Any lesion on a wound can be directly sampled for histological evidence as tangential curettings. For wound biome analysis, after a wound has been cleaned and debrided with your device and method of choice, select the desired area for sampling and apply the SoftBiopsy® to it using pressure akin to moderate tooth brushing force (that depresses the hooks onto the surface) while rotating the Kylon® fabric head (with a twist of the wrist) in an alternating clockwise/counterclockwise manner. This will excavate, dislodge and collect (within the hook array) devitalized or viable tissue from the wound bed. A light pressure swab-like paint brushing application over the entire wound base could precede any focal biopsy if desired to survey the entire wound and enrich the histologic sample.

1. Wipe Across the Wound Base 2. Biopsy Focal Areas with Press/Rotation 3. Inspect the Tip for Tissue



Note: Following facility's best practices, inspect all wound areas which have been sampled for any remaining debris, dislodged wound tissue, or foreign material. If found, remove them by thoroughly irrigating the wound with sterile saline, sterile water, or another safe cleaning solution.

Capture and Transfer of Wound Tissue Sample for Lab Analysis: The wound debris and tissue raked into and collected between the rows of hooks, which serve as a basket for transport to the lab, can be transported within the device.

Transfer of the Sample to the Preservative Vial

1. Place your index and thumb on the handle/shaft of the device with the scored mark between the fingers of the right and left hand. A sterile gauze is used to guard against contamination on the specimen side of the scored mark. Gauze covering of the device tip, or eye protection from potential release of tissue during the snap-off procedure should be performed.
2. The SoftBiopsy® head will separate from handle by bending firmly at the scored mark. The handle of the device may be discarded or medically recycled as acrylic plastic. If sterile method is needed, use sterile gloves or gauze to snap the head from the handle.
3. Carefully place the tip into the vial or container for transport to the lab.



Device tip being separated from handle



Tissue-filled head placed into a vial

Transport to the Laboratory

1. Clearly mark the first and last name, date, and patient identification number on the specimen vial that contains histological preservative or culture medium based on the clinical scenario.
2. Place the vial with the sample into the bag provided.
3. Complete the Pathology Lab Requisition form and include with the specimen.

Device Disposal

Clinician or Lab Technologist should dispose of SoftBiopsy® and associated supplies in accordance with biohazardous waste procedures, following facility and local guidelines. The remaining handle, post detachment of the tip may be considered for medical plastic waste recycling.

Tissue Sampling and Biopsy Sample Preservation

The tissue samples obtained are true (histological) curetting (vs. Keyes punch biopsy or cytology) samples. Tissue samples obtained with the SoftBiopsy® device may be paired with vials filled with; fixative for anatomic sampling, culture medium for bacterial or viral culture, or other medium if molecular or PCR testing is being pursued. Evidence provided in the Clinical Background show tissue provides the highest standard for evaluation of organisms in wounds.

Laboratory Processing

Samples of tissue should be carefully removed completely from the Kylon® fabric in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen resembles a collection of multiple punch biopsy specimens or curettings but should be evaluated by a pathologist familiar with evaluation of wound tissue samples.

Laboratory Histologic Interpretation

The single-use, disposable biopsy-brush traps curetting specimens suitable for tissue culture, anatomic pathology with or without special stains, molecular testing, or other tissue-based assays.

Adverse Events: None known

Clinical Background:

1. Bowler PG, Duerden BI, Armstrong DG. Wound microbiology and associated approaches to wound management. *Clin Microbio Rev*, April 2001, p. 244-269.
2. Copeland-Halperin LR, Kaminsky AJ, Bluefield N, Miraliakbari R. Sample procurement for cultures of infected wounds: a systematic review. *J Wound Care, North American Supplement Vol25 (4)*, April 2016, p. S4-S10.
3. Huang Y, Cao Y, Zou M, et al. A Comparison of Tissue versus Swab Culturing of Infected Diabetic Foot Wounds. *Int J Endocrinology*, Volume 2016, Article ID 8198714, p1-6.
4. Pallua N, Fuchs PC, Hafemann B, et al. A new technique for quantitative bacterial assessment on burn wounds by modified dermabrasion. *Journal of Hospital Infection* (1999) 42: 329–337.
5. Melendez JH, Frankel YM, A. T. An AT, et al. Real-time PCR assays compared to culture-based approaches for identification of aerobic bacteria in chronic wounds. *Clinical Microbiology and Infection*, Volume 16 Number 12, December 2010, p 1762-69.
6. Rondas A, Schols JM, Ruud J.G. et al. Swabs versus biopsy for the diagnosis of chronic infected wounds. *ADVANCES IN SKIN & WOUND CARE*, MAY 2013, p 211-219.
7. Attinger C, Wolcott R. Clinically addressing biofilm in chronic wounds. *ADVANCES IN WOUND CARE*, VOLUME 1, NUMBER 3 , 2012, p 127-132.

Glossary of Symbols

Symbol	Symbol # and Title	Explanatory Text	Standard Title
	2794 Packaging unit	To indicate the number of pieces in the package. Note: A number is inserted in the symbol to indicate the number of pieces in the package.	IEC 60417:2002 DB Graphical Symbols For Use on Equipment
	5.1.4 Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.4 Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.6 Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.8 Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.2 Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.4 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician.	21 CFR 801.15 (c)(1)(i)(F) Medical devices; prominence of required label statements; use of symbols in labeling.

050-0048 Rev. A

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