

SoftBiopsy®+D SFT-1100
Tissue Sampling Debridement Device.
Kylon® Medical Fabric-Based Wound Care

**Device Description**

The **SoftBiopsy®+D** is a single-use brush/curette. The fabric covered tip is designed to dislodge and remove part or all of the debris or necrotic tissue from the wound surface or sample wound-base tissue if needed for analysis. The hooked medical pad employs the patented **Kylon®**, a specialized fabric with individually arranged hooks that gently, frictionally abrade, and collect a potential tissue specimen which is entrapped within the rows of hooks and fabric.

Intended Use

The **SoftBiopsy®+D** is intended to scrape or debride the apparent surface of wounds and collect tissue for histological-based analyses. It is also intended to store tissue samples for transport to a lab for analysis(es).

Indications for Use

The **SoftBiopsy®+D** is indicated for patients with small (no larger than 3 X 3 cm) lesions or non-fibrotic surfaces of wounds requiring debridement in order to remove non-viable tissue and debris. Debridement may stimulate blood flow to encourage tissue regrowth. It is also indicated for scraping or debriding and then transporting tissue requiring histological analyses for further laboratory evaluation regarding identifying biofilm organisms or other pathology.

Contraindications

SoftBiopsy®+D is contraindicated for use in the following patients:

1. Patients with known bleeding disorders or those on anticoagulant therapy.
2. Patients with a medical or surgical condition which is not amenable to debridement or where punch biopsy is preferred for sample collection from wounds (not intact skin).
3. Patients with a known allergy to nylon or acrylic plastic.
4. Pregnancy or suspected pregnancy, when a wound biopsy would not be indicated.

Warnings/Precautions

- **SoftBiopsy®+D** is not designed or intended to debride inside non-visually apparent areas of undermined or tunneling wounds where visualization of the pad surface is obscured. Assure a sample is collected from hair-laden wounds
- Eschar, gross necrotic tissue, or fibrotic solid wound areas should not be debrided with **SoftBiopsy®+D**.
- 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 platform), as this will not improve performance, and may cause mechanical failure of the device.
- The device tip should not require “cleaning” with gauze/sharps when used on small wounds.
- 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+D®** 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.
- Never use a metal instrument to clear tissue out of the **Kylon®** fabric on the **SoftBiopsy®+D**, as this may fracture or damage the integrity of the hooks.
- During any debridement or tissue sampling procedure, including with **SoftBiopsy®+D**, bleeding may occur, and is more likely with deep debridement. In some cases, mild bleeding is pursued to sufficiently clean a wound or prepare it for a graft. Akin to metal curettage, bleeding from debridement is usually self-limiting but may require the user to apply light pressure to resolve.

Instructions for Superficial or Deep Wound Debridement With Optional Tissue Collection For Laboratory Transport and Analysis

Note: When the **SoftBiopsy[®]+D** is used for debridement, the **Kylon[®]** fabric on the device will trap and retain surface debris and devitalized tissue, causing it to appear “full.” This can occasionally affect the efficacy of the device in continuing to debride. Retained tissue in the device tip can be removed, if necessary, by following the steps outlined below (5B).

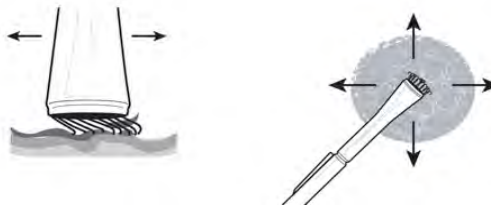
Step 1 - Open the sterile single-use **SoftBiopsy[®]+D** pack by peeling it back no more than halfway. This allows the package cavity to be used as a receptacle for removal of tissue from the **Kylon[®]** pad (see 5B below) or sterile barrier to snap the tip off the device. We recommend using the **SoftBiopsy[®]+D** with two 4X4 sterile **sponges** to wipe dislodged tissue from the wound (standard gauze may be less than optimal due to its tendency to cling to and with repeated traction to possibly weaken the **Kylon[®]** hook integrity).

Step 2 - Open a sterile sponge pack; one could moisten the sterile sponge(s) with a sterile solution if desired.

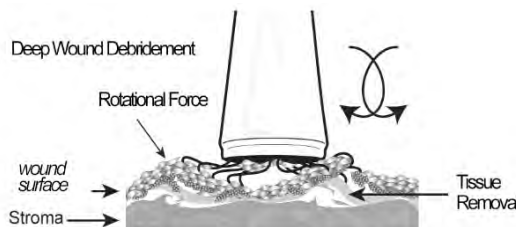
Step 3 - The **SoftBiopsy[®]+D** **Kylon[®]** coated device head can be applied to a wound surface that lies perpendicular to the device handle with mild or moderate pressure depending on the wound condition or desired effect, and pressed onto tissue with **stroking, sweeping, or rotating** (akin to key-turning) motions depending on depth of debridement or sampling desired.

Step 4 - Position and press the trumpet shaped round and hooked fabric coated head of the **SoftBiopsy[®]+D** on the wound.

- a. **Non Selective Mechanical Debridement:** Using light to moderate pressure, lightly press the fabric head of the **SoftBiopsy[®]+D** on the area to debride the wound using back and forth or circular sweeping strokes in a brushing manner until all surface debris and devitalized tissue are detached from the wound base.



- b. **Selective Surgical Debridement:** For hard or thickened areas of the wound, tissue can be excavated by applying pressure akin to moderate toothbrush force directly on the lesion/area while twisting/rotating the **Kylon[®]** fabric head in an alternating clockwise/counterclockwise manner; to dermal or subcutaneous depth as needed. Approaching a non-solid, non-fibrotic firmer target area from the margins to the center will be the most effective method to debride and remove tissue. This will effectively excavate, dislodge, and collect the debris or necrotic tissue from the wound base avoiding removing revitalized healing areas.



Wound Tissue/Debris Removed



Step 5A - One or more opened 4x4 sponges can be used to remove wound tissue by wiping free the excavated debris on the wound surface. The **SoftBiopsy[®]+D** can be used repeatedly to scrape the wound while the sponge is used to sweep the tissue from the surface during continued debridement.

Step 5B - Cleaning the SoftBiopsy[®]+D fabric tip during debridement: Due to the small tip on the device and limitations for use on small wounds, a single device should be able to debride without needing the hook array to be cleaned of debris. **Do not clean the device hook array tip.** Carefully dispose of the device and pouch in biohazard waste when finished with the debridement session.

Step 6 - Use a new **SoftBiopsy[®]+D** single-use sterile device and associated or additional sponge(s) for each separate wound/area to avoid potential cross contamination.

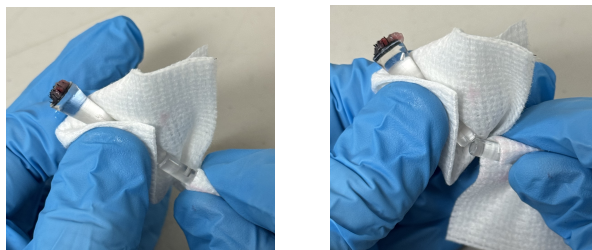
Step 7 - Following facility's best practices, inspect all wound areas which have been debrided or sampled for any remaining debris, dislodged wound tissue, or foreign material. If found or in question, remove all material by thoroughly irrigating the wound with sterile saline, sterile water, or another safe cleaning solution.

Step 8 - Optional Capture and Transfer of Wound Tissue

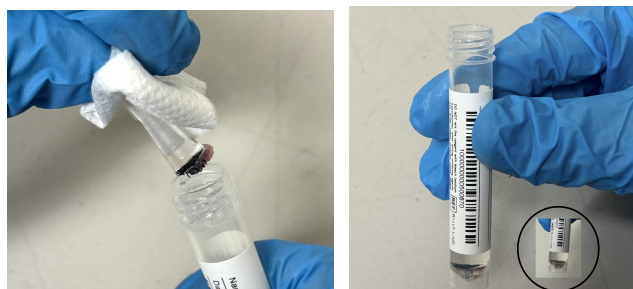
Transfer of the tissue sample for laboratory analysis: It is recommended that a new device be used for wound sampling if culture, molecular testing, or PCR assays are to be ordered from visually apparent wounds. Optimal sampling technique will parallel the debridement instructions outlined in step 4B. 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 tip. Be sure to sample the viable tissue and clear debris prior to sampling. Use force and twist motion to activate the micro-curettes and inspect the hooks for a trapped sample.

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. 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.
3. The **SoftBiopsy[®]+D** 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.
4. 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 bottle that contains histological preservative or culture medium based on the clinical scenario.

- Place the vial with the sample into the bag provided.
- Complete the Pathology Lab Requisition form and include with the specimen.

Step 9 – Clinician or Lab Technologist should dispose of **SoftBiopsy[®]+D** and associated supplies in accordance with biohazardous waste procedures, following facility and local guidelines.

Tissue Sampling and Biopsy Sample Preservation

The tissue samples obtained are true (histological) **tangential biopsy curettings** (vs. Keyes punch biopsy or cytology) samples. Tissue samples obtained with the **SoftBiopsy[®]+D** 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 to be conducted.

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.

Laboratory Histologic Interpretation

The specimen resembles a collection of multiple punch biopsy specimens or curettings but should be evaluated by a pathologist familiar with evaluation of epithelium or wound tissue samples. The single-use, disposable biopsy-brush traps curetting tissue specimens suitable for culture, anatomic pathology with or without special stains, molecular testing, or other tissue-based assays.

Adverse Events:

None known

Clinical Background:

- Han G, Ceilly R. *Chronic Wound Healing: A Review of Current Management and Treatments*. Adv Ther (2017) 34:599–610.
- Smith CM. *Debridement for Surgical Wounds*. Critical Care Nurse (2015) 35:75-76.

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 labelling.

SoftBiopsy[®] and KYLON[®] are trademarks of:
Histologics LLC, 4095 E. La Palma Ave, Suite N, Anaheim, CA – (888) 738-9757
050-0059 Rev. C