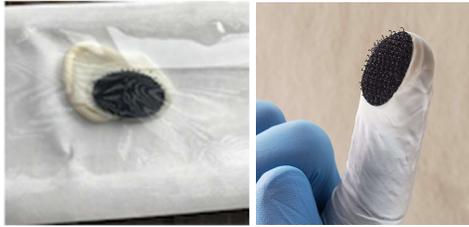


**Soft K-Cot® SFT-4200**  
**Instructions for Use**  
**Finger-Controlled Brush Curette for Tissue Debridement and Specimen Collection**



### Device Description

The **Soft K-Cot®** is a single-use, nitrile, finger cot, brush/curette, which is placed over an already gloved finger. The index finger is usually used, and in some cases the middle finger can also be used (two cots per case for larger wounds). The oval-shaped fabric covered fingertip 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. Only moderate force sufficient to press the hook shafts flat to the surface expose the stiffest aspect of the hook which can frictionally curettage soft or semi-solid wound tissue.

### Intended Use

The **Soft K-Cot®** is intended to wipe off, scrape, or debride the apparent surface of wounds and optionally 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 **Soft K-Cot®** is indicated for patients with small to moderate sized (no larger than 6 X 6 cm), non-fibrotic surfaces of wounds requiring cleaning or debridement in order to remove non-viable tissue and debris. Debridement may stimulate blood flow to encourage tissue regrowth. It is also indicated for trapping and transporting tissue requiring histological analyses for further laboratory evaluation regarding infection or other pathology.

### Contraindications

**Soft K-Cot®** 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 debridement.
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

**Soft K-Cot®** is not designed or intended to debride:

- Inside crevices or tubular shaped wound channels where visualization of the pad surface is obscured.
- Eschar, gross necrotic tissue, or dry crusted wound areas which can damage the hook material.
- Non-visually apparent areas of undermined or tunneling wounds.
- Eye protection is advised during debridement due to potential airborne tissue during any frictional debridement.

Never use a metal instrument to clear tissue out of the **Kylon®** fabric on the **Soft K-Cot®**, as this may fracture or damage the integrity of the hooks.

During any debridement or tissue sampling procedure, including with **Soft K-Cot®**, 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 Cleansing, Moderate, or Deep Wound Debridement with Optional Tissue Collection for Laboratory Transport and Analysis – Eye Protection During Procedure(s) is Advised.

**Note:** When the **Soft K-Cot®** 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 **Soft K-Cot®** 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). We recommend using the **Soft K-Cot®** 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.

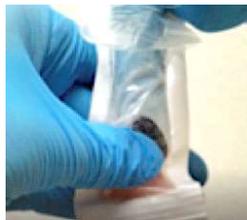
**Step 3** – Mount the **Soft K-Cot®** on the index finger of the gloved dominant hand and unroll the entire length of the cot onto the finger, ensuring the black **Kylon®** pad is positioned over the fingertip. **If the fit of the cot is not snug, the thumb can be used to grip the base of the cot for additional stability.**

**Step 4** - Position and press the hooked fabric fingertip pad of the **Soft K-Cot®** on the wound.

- a. **Wound Hygiene:** Applying the cot hooks with **light pressure** and stroking the wound with linear “paint-brushing” strokes will dislodge slough and surface necrotic tissue without significant frictional excision effects and will avoid bleeding. The dislodged tissue can be simply wiped from the wound with sterile gauze.
- b. **Conservative Debridement:** Using **light to moderate pressure** insufficient to flatten the hooks shafts, lightly press the fabric tipped finger on the area to debride the wound, using back and forth or circular sweeping strokes in a brushing manner until all surface debris and necrotic tissue is detached from the wound base.
- c. **Excisional 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, flattening the hook shafts to the fabric pile, while twisting/rotating the Kylon® fabric head** in an alternating clockwise/counterclockwise manner. Approaching a firmer target area from the softer margins to the firmer 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.

**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 **Soft K-Cot®** 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 finger cot hook pad array during debridement:** Add up to **2 ml of sterile saline or water** into the pouch (created by partially peeling the device package) and immerse the cot-covered fingertip inside. Using the opposite gloved hand, rub the immersed pad frictionally to release the debrided tissue into solution. This avoids any particulate spray. Carefully dispose of the pouch in biohazard waste when finished. Only one cleaning episode is advised per device debridement session.



**Step 6** - Use a new **Soft K-Cot®** single-use sterile device and associated or additional sponge(s) for each separate wound site to avoid potential cross contamination.

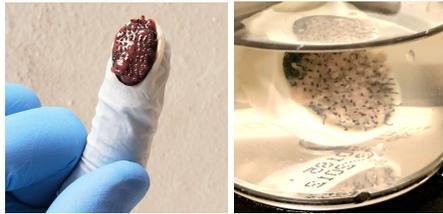
**Step 7** - Inspect all wound areas which have been debrided or sampled for any remaining debris, dislodged wound tissue, foreign, or in rare cases black nylon hook material. If found or in question, remove all necrotic tissue or material by thoroughly wiping it off or irrigating the wound with sterile saline, sterile water, or another safe cleaning solution.

### **Step 8 – Instructions for Optional Tissue Sampling Use**

**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 a Collected Tissue Sample to the Preservative Vial**

1. Inspect the finger cot pad for adequate tissue trapped between the hook rows.
2. The tissue-filled **Soft K-Cot®** should be removed from the index finger and placed into a specimen vial for transport with the pad visible as shown in the photo below (do not turn cot inside out when removing from finger).



**Soft K-Cot®** tissue-filled finger cot 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.
2. Place the vial with the sample into the bag provided.
3. Complete the Pathology Lab Requisition form and include with the specimen.

**Step 9** – Clinician or Lab Technologist should dispose of **Soft K-Cot®** 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) curetting (vs. Keyes punch biopsy or cytology) samples. Tissue samples obtained with the **Soft K-Cot®** 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. With any tissue manipulation tissue particulate matter may become airborne and eye protection is advisable.

### **Clinical Background**

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

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**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.