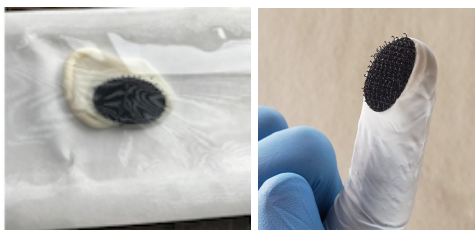


Soft K-Cot® SFT-4200 Instructions for Use

Finger-Controlled Hooked Brush Array for Wound Hygiene



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 can be used gently to frictionally abrade slough and semi-solid necrotic non-viable tissue from a wound mechanically. For wound hygiene non-debridement purposes very light stroking pressure insufficient to press the hook shafts flat will be used as a hooked “brush” to clean wounds systematically.

Intended Use

The **Soft K-Cot®** is intended to wipe off, scrape, and gently clean the apparent non-solid slough or necrosis on the surface of chronic wounds intermittently possibly between dressing changes by any level provider caring for chronic wounds.

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 in order to remove non-viable tissue and debris. These instructions limit the use to gentle brushing of the wound surface and not debridement or biopsy that is performed by Advanced Wound Care trained or certified providers.

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 frictional brushing of the wound surface.
3. Patients with a known allergy to nylon or nitrile.

Warnings/Precautions

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

- Inside crevices or tubular shaped wound channels where visualization of the pad surface is obscured.
- Eschar, gross necrotic tissue, or dry crusted wound areas.
- Non-visually apparent areas of undermined or tunneling wounds.
- Any wound that contains semi-solid or solid debris and wound require sharp or frictional mechanical curettage/selective debridement to properly clean the wound.

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 wound hygiene procedure, including with **Soft K-Cot®**, minimal micro-punctate bleeding may occur. In rare cases, mild bleeding may require the user to apply light pressure to resolve.

Instructions for Superficial Cleansing – Eye Protection During Procedure(s) is Advised.

Note: If debridement is required to remove solid, or semi-solid necrotic tissue on the wound surface and the provider is licensed or certified to perform deeper mechanical or surgical (selective) debridement, please refer to the alternative instructions for use of the Soft K-Cot® for debridement or biopsy sampling. This instructions for use is for clinicians who do not perform non-selective (mechanical) or selective (surgical) debridement or surgical biopsy of wounds.

When the **Soft K-Cot®** is used for wound hygienic cleansing, the **Kylon®** fabric on the device will trap and retain surface debris and devitalized tissue, occasionally causing it to appear “full.” This can potentially affect the efficacy of the device in continuing to clean the wound base. 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 customary for your practice, a topical antiseptic or anesthetic can be applied prior to Step 4. **If the fit of the cot is not snug, the thumb can be used to press grip under the base of the fabric for additional stability.**



Thumb Anchoring Pad

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

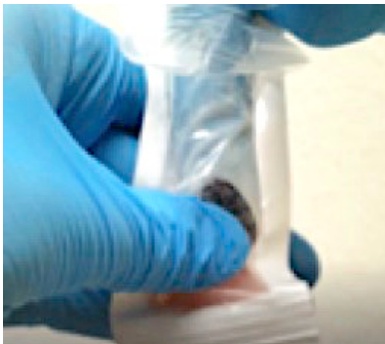
Wound Hygiene: Applying the cot hooks with **light pressure (the hooks remain upright and are not pressed or flattened into the fabric pile surface preventing a curettage effect)** and stroking the wound with linear “paint-brushing” strokes lighter than what is customary for tooth brushing. This will 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.

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.



Soft K-Cot on index finger wiping away non-solid, non-fibrous crusted wound slough

Step 5B - Cleaning the finger cot hook pad array during a wound care session: 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 trapped 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 - Following facility's best practices, inspect all wound areas which have been cleaned 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. This is a very rare potential event.

Step 8 – Clinician should dispose of **Soft K-Cot®** and associated supplies in accordance with biohazardous waste procedures, following facility and local guidelines.

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.

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