

Soft K-Rette®-V VT-4500
Kylon® Veterinary Fabric-Based Biopsy and Debridement Device
For Veterinary Use Only

Device Description
The **Soft K-Rette®- V** single-use disposable device is designed to be used once to debride and sample a visually apparent wound crevice at a single wound site. The **Soft K-Rette®- V** head is a tapered-tip paddle shaped device with a diamond shaped **Kylon®** fabric pad on one surface, that is easily directed to the wound surface crevice contour and maintained on a specific target area. **Kylon®** is a specialized fabric with individually arranged hooks that gently, frictionally abrade and collect the specimen within the rows of hooks and fabric. The diamond shaped head of the **Soft K-Rette®-V** is uniform and of optimal size for application to a fine wound target, or to brush a slightly larger area for debridement, or sample wound-base tissue if needed for analysis.

Intended Use
The **Soft K-Rette®-V**device is intended to scrape or debride the apparent surface of creviced or inter-digitary 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 **Soft K-Rette®-V** is indicated for animals with small to moderate sized (no larger than 3 X 3 cm), non-fibrotic surfaces of creviced or inter-digitary 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 infection or other pathology.

Contraindications

Soft K-Rette®-V is contraindicated for use in the following patients:

1. Animals with known bleeding disorders or those on anticoagulant therapy.
2. Animals with an acute wound infection or condition which is **not amenable** to debridement.
3. Animals 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-Rette®-V is not designed or intended to debride:

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

Never use a metal instrument to clear tissue out of the Kylon® fabric on the **Soft K-Rette®-V** as this may fracture or damage the integrity of the hooks. In rare cases where black nylon hook material is noted following debridement, wipe or irrigate the wound tissue to remove any foreign or necrotic material.
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.
Soft K-Rette®-V is not designed or intended to perform debridement in flat wounds parallel to the skin surface (flat ulcers, wounds). If wound debridement or sampling is needed for complete diagnostic work-up of a non-tunneling wound, use a suitable instrument such as the Soft K-Cot®.

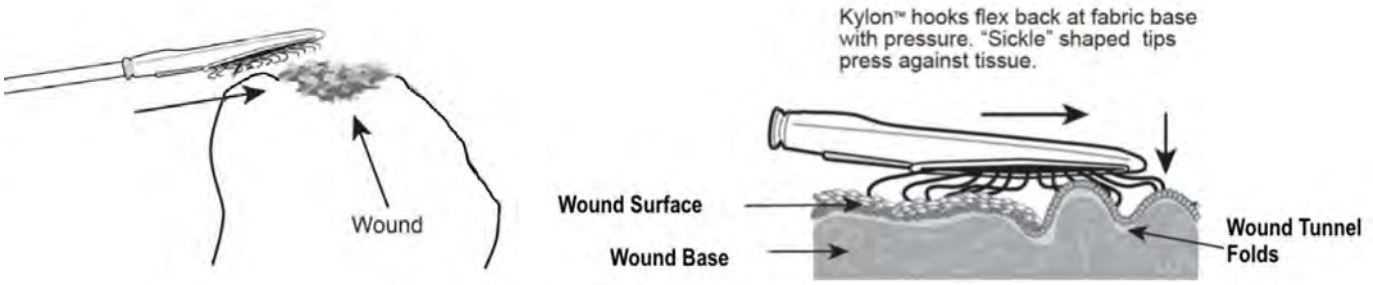
Instructions for Wound Debridement With Tissue Collection For Laboratory Transport and Analysis

Step 1 - Open the sterile single-use **Soft K-Rette®-V** Kylon® fabric-based debridement/curettage/tissue collection pack. Use the **Soft K-Rette®-V** Kylon® debridement brush, with sterile sponges available to sweep for wound debris.

Step 2 - The **Soft K-Rette®-V** Kylon® coated device head can be applied into a wound crevice that is visually apparent such as the inter-digitary toe space, oriented parallel to the handle of the device, onto a wound surface with mild or moderate pressure depending on the wound condition or desired effect. It should be pressed onto tissue with **stroking, sweeping, or rotating** (akin to key-turning motions) depending on the depth desired for sampling or debridement. The **Soft K-Rette®-V** brush device can be used to collect tissue

from the wound surface for transport to the laboratory for analysis.

DO NOT INSERT Soft K-Rette® INTO ANY WOUND TUNNEL WHERE VISUALIZATION OF THE HOOKED TIP IS COMPROMISED.



Step 3 - Position and press the diamond shaped tapered device hooked fabric coated head of the Soft K-Rette®-V on the crevice and firmly press on the wound surface to be sampled or debrided. ***Take care NOT to insert the tapered tip into the wound too forcefully to avoid "spearing" with puncture of the surface.***

Debridement/Curettage:

a. Peel the sterile pack on the handle side halfway and remove the **Soft K-Rette®-V** device. Using light to moderate pressure, lightly curette the wound/skin with the Kylon fabric head using sweeping strokes in a brushing manner, or insert gently, and rotate into tight wound channels in a keyturning motion until all surface debris and devitalized tissue are detached from the wound base**.**

b. Add up to 4 ml of sterile saline or water into the pouch (created by partially peeling the device package) and immerse the Kylon covered tip of the **Soft K-Rette®-V** inside. Using the opposite gloved hand, rub the immersed pad frictionally to release the debrided tissue into solution. Carefully dispose of the pouch in biohazard waste when finished. **The device can be cleaned once during a debridement session.**

c. Open a sterile sponge pack; One could moisten the sterile sponge with a sterile solution if desired. The sponge can be used to remove wound tissue by wiping free the excavated debris on the wound surface into one or more sponges. The Soft K-Rette®-V can be used repeatedly to scrape the wound while the sponge is used to sweep the tissue from the surface during continued debridement.

Step 4 - Use a new **Soft K-Rette®-V** single-use sterile device and associated or additional sponge(s) for each separate wound area to avoid potential cross contamination.

Step 5 - Use of A New Sterile Device For Wound Base Biopsy Sampling

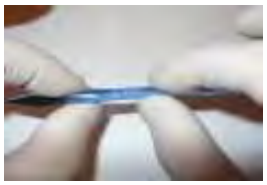
Capture and Transfer of the tissue sample for laboratory analysis: Apply a new device to the debrided wound base and with pressure and key turning motion, rake tissue to be collected between the rows of hooks, which also serve as a basket for transport to the lab. Inspect the black fabric pad before placing in a sample vial of fixative (anatomic or molecular pathology) or culture medium (culture or molecular testing). Inspect the device tip to be sure the fabric pad is filled with an adequate sample of tissue prior to detaching the tip from the handle of the device.

Step 6 - 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.

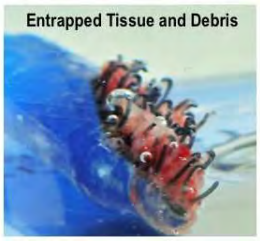
Step 7- Clinician or Lab Technologist should dispose of **Soft K-Rette®-V** and associated supplies in accordance with biohazardous waste procedures, following facility and local guidelines. The remaining handle, post detachment of the tip may be considered for medical plastic waste recycling.

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.

1. The **Soft K-Rette®-V** head will separate from handle by bending firmly. The handle of the device may be discarded.



Snap and Detach - Device Head from Handle.



Soft K-Rette®-V Tissue filled head in 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.

Case Example

Ferrel Cat Wound Pre-Debridement

Wound Poxst-Debridement – Healed

Transfer of the Sample to the Preservative Vial and Prepare for Transport

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-Rette®-V** 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.

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 resterilize	Indicates a medical device that is not to be resterilized.	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
R_x ONLY	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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