

Procedure for Wound Care Treatment Using ACell Vet[®] Scaffold

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or properly licensed practitioner. This product is not for human use. These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Always read product IFU before use.

DEVICE DESCRIPTION

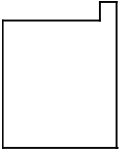
The ACell Vet Scaffold is derived from porcine urinary bladder. It is a naturally occurring extracellular matrix that maintains and supports a healing environment for wound management.

INDICATIONS

The ACell Vet Scaffold is indicated for use in the management of wounds, including but not limited to: partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds (donor sites/grafts, post laser surgery wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears), de-gloving injuries, urinary augmentation, periodontal, general soft tissue/organ repair and tissue reinforcement. This device is intended for one-time use only.

DEVICE APPLICATION

External Use

1. Discontinue the use of all topical medications at the wound site 48 hours prior to the application or use of the ACell Vet Scaffold.
 2. Clean the wound bed. Remove all necrotic and/or scar tissue, and gently remove or irrigate any exudates. Obtain fresh tissue edges, and control bleeding.
 3. Aseptically prepare the site, rinsing thoroughly with sterile saline to remove any residues left from cleaning agents before applying the ACell Vet Scaffold.
 4. Remove the ACell Vet Scaffold from the sterile packaging using standard aseptic/sterile technique. The device can be cut or sized at this time (it is recommended that the sheet be slightly larger than the area to be covered).
 5. The ACell Vet Scaffold can be rehydrated on the wound or soaked in sterile saline for 2 to 3 minutes before being placed. The ACell Vet Scaffold should be placed on the wound bed with the basement membrane side facing up. Match the device exactly to the diagram on the right to determine the sidedness of the device. If placed on the wound dry, moisten with sterile saline by gentle lavage.
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6. In large wounds, more than one sheet of ACell Vet Scaffold may be necessary to obtain complete coverage. Overlap the edges slightly to ensure coverage of the entire wound.
 7. Cover the ACell Vet Scaffold with sterile saline soaked non-adhering gauze followed by your standard bandaging procedure. The material and the wound bed should be kept moist.
 8. If no adverse reactions occur, the wound should be inspected after 3 to 4 days and exudates removed. Do not remove material that is intact on the wound surface. Gently irrigate the wound to remove any colored exudates. Reapply the sterile saline soaked non-adhering gauze followed by your standard bandaging procedure.

9. Repeat this process every 4 to 5 days until the wound is re-epithelialized. A second application of ACell Vet material should be considered 2 to 3 weeks following the initial treatment, if not applied during a previous change of dressing. Attention should be given to the tissues surrounding the edges of the wound. As wound healing occurs, redness and swelling will decrease, and drainage will become less. These are signs of wound healing and are often seen before new epithelium is obvious.
10. Re-application of an ACell Vet Scaffold can be applied until the desired effect is achieved.

DEVICE APPLICATION

Internal Use

1. Remove the ACell Vet Scaffold from the sterile packaging using standard aseptic/sterile technique. The device can be cut or sized at this time (it is recommended that the sheet be slightly larger than the area to be covered).
2. The ACell Vet Scaffold can be rehydrated by soaking the ACell Vet Scaffold in sterile saline for 2 to 3 minutes before being placed. Use the indicator as shown in step 5 to place the device properly. If the wound where the ACell Vet Scaffold is being placed has an epithelial or endothelial surface, then for best results the luminal side of the ACell Vet Scaffold should be placed so that it serves as a continuation of the wound's epithelial or endothelial surface. If no epithelial or endothelial surface is present in the wound, then the ACell Vet Scaffold can be placed in or on the wound without regard to the orientation of the luminal and abluminal sides of the device.
3. Using standard surgical technique, suture the ACell Vet Scaffold into place avoiding excessive tension along the suture line.