Instructions for Use: Medifil™ II Particles

Availability

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Detailed Instructions for Use
(Instructions are also available on each unit and each box)

A. Preparation of wound bed:
1. Remove and dispose of old dressing following manufacturer's recommendations.
2. Gently irrigate the wound with sterile water or saline until it is free of debris (necrotic tissue, slough, etc.) Use enough irrigation pressure to enhance wound cleansing without causing trauma to the wound bed. Safe and effective irrigation pressures range from 4 to 15 pounds per square inch (psi). An irrigation pressure of 8 psi effectively cleanses the wound and reduces the risk of trauma and wound infection. Certain concentrations of povidine iodine, hydrogen peroxide, sodium hypochlorite, etc. are cytotoxic and should not be used to cleanse the wound.
3. Gently blot wound edges dry.
4. An ointment or cream may be applied to the wound margin if desired to protect the area.
5. If a topical medication is ordered, apply to the wound bed.

B. Application of Medifil™ II Particles
1) Apply Medifil™ II Particles to cover the wound surface:
   a) Minimally Draining Wounds- Lightly sprinkle just enough to completely cover the surface of the wound bed.
   b) Moderately Draining Wounds- Cover wound surface with Medifil™ II Particles ¼ to ⅛ inches deep.
   c) Heavily Draining Wounds- Cover wound surface with Medifil™ II Particles ⅛ inch deep.
   NOTE: DO NOT PACK THE WOUND TIGHTLY WITH MEDIFIL PARTICLES! Medifil™II Particles are highly absorbent and need room for expansion. If packed tightly into a wound, there may be increased pressure on surrounding tissue as the particles expand which may affect healing. If there is a “dead space,” gently fill the wound with dressing of choice to prevent premature closure of wound. DO NOT PACK Tightly! Always maintain a moist wound environment.

2) Apply secondary dressing:
   a. Cover with a non-adherent, absorbent dressing (conventional gauze/abdominal pads, specialty absorptive, etc.). Dressings should be changed when saturated (or as recommended by manufacturer) until excessive drainage is resolved.
   b. Always maintain a moist (not wet) wound environment. (Please continue on next page)
   c. When necessary, gently secure wound cover dressing with surgical netting or tape.
C. Other Considerations

1) If the wound is infected:
   a. If a topical medication is ordered, apply the topical agent to the wound first and sprinkle the Medifil™ II Particles to completely cover the topical agent.
   - Change Medifil™ II Particles daily until infection is resolved (or more often, depending on the amount of drainage).

2) If the wound is contaminated:
   a. Change Medifil™ II Particles after each occurrence of contamination.
   b. May use semi-permeable film over secondary dressing to protect wound from contamination.

3) If the wound is undermined and/or tunneled:
   a. Medifil™ II Particles can be mixed with sterile normal saline to make a thick solution.
   - Combine Medifil™ II Particles with sterile normal saline and mix (in a sterile receptacle) to a thick liquid consistency.
   - Draw mixture into syringe (DO NOT USE A NEEDLE) and apply to tunneled or undermined areas.
   - Gently pack the wound with gauze or dressing of choice to eliminate dead space and prevent premature closure of the wound. Medifil™ II Particles paste may be applied to packing material before application to the wound.

D. Removal of Medifil™ II Particles

1) Change the secondary (cover) dressing daily or as indicated by the amount of drainage.
2) Remove the secondary dressing. If secondary dressing is adhered to the wound,
3) Irrigate with sterile normal saline until dressing loosens. Lift gently.
4) Irrigate wound with saline solution to cleanse the area thoroughly to remove all traces of these materials and any foreign bodies present in the wound bed.
5) If after irrigating the wound with sterile normal saline, Medifil™ II Particles adhere to wound, do not attempt to remove because this can cause trauma to the new granulation bed.
6) Frequency of dressing changes is determined by wound characteristics and amount of drainage:
   a. **Minimally Draining Wounds**- Dressings may be changed every 2-3 days until wound is healed. It is very important to keep the wound bed moist.
   b. **Moderately or Heavily Draining Wounds**- Dressings should be changed when saturated until excessive drainage is resolved. Once drainage subsides, dressing changes may be reduced to every 2-3 days until wound is healed.
   c. **Undermined or Tunneling Wounds**- Wounds should be flushed daily with sterile normal saline and Medifil™ II Particles re-applied.

**Precautions and Comments:**

- **Normal reactions:** Wounds may appear larger during the first several days of treatment due to the reduction of edema and the removal of necrotic tissue and/or slough. An increase in drainage (which may or may not have an odor) may be seen in the first several days of treatment.
- **Allergic reaction:** Medifil™ II Particles are of bovine origin. Signs and symptoms of local allergic reaction are pain (to the wound site) and localized redness that may extend beyond the perimeters of the wound. Irrigate the wound with sterile normal saline to remove the product and the symptoms should disappear. Do not use Kollagen products if patient is sensitive to materials of bovine origin.

For Clinician Use only. Not for distribution to patients
• **Wound debridement:** Wet to dry gauze dressings should not be used in conjunction with Medifil™ II Particles. Although this procedure will remove necrotic tissue and slough, it can also damage new granulation tissue.

  A collagenase enzymatic debriding agent should not be used in conjunction with Medifil™ II Particles. Other enzymatic debriding agents may be used in conjunction with or prior to utilization of Medifil™ II Particles.

  **WARNING:** Discontinue the use of Medifil™ II Particles and notify your doctor if excessive redness, pain, swelling or blistering occurs

  **WARNING:** Potential risk of loss of sterility and infection if opened and re-used.

Secondary wound dressings that may be used with Medifil™ II Particles:

1. Gauze roll dressings
2. Gauze (impregnated and non-impregnated)
3. Non-adherent
4. Specialty absorptive
5. Hydrocolloids
6. Hydrogels
7. Semi-permeable film
8. Semi-permeable foam