

LeFlap™ by Monarch Labs (formerly 'Creature Comforts II')

Dual-layer, pre-assembled maggot confinement dressing, for use with Medical Maggots™

Description -

The **LeFlap™** Dual-layer maggot confinement dressing is a 2-layered, pre-assembled maggot therapy dressing. It is similar to **Creature Comforts™** (woven polyester with a pore size of 160u), but is already affixed to a hydrocolloid foundation to facilitate quick and simple application of the maggot confinement dressing.

Mechanisms of Action -

The polyester mesh (pore size: 160u) prevents the escape of medicinal maggots; the hydrocolloid base provides a safe and effective foundation with which to affix the dressing to the healthy per-wound skin. The adhesive lining affixing the polyester mesh to the hydrocolloid pad eliminates the need to use glues and other messy adhesives to adhere the mesh to the wound dressing.

[See **Medical Maggots™ package insert** for discussion of the maggots' mechanisms of action]

Clinical Indications -

LeFlap™ is to be used to confine medicinal maggots on the wound bed. For indications for using medicinal maggots, please refer to their labeling. **Medical Maggots™** brand of medicinal maggots are indicated for debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post surgical -wounds.

Storage & Handling -

LeFlap™ by Monarch Labs may be stored at room temperature (60-80°F) until the posted expiration date.

Warnings -

- Do not use with patients allergic to hydrocolloid.
- Do not use if packaging or product appears damaged.
- Remember always to familiarize yourself with all instructions and package labeling before using this or any other medical device. Call Monarch Labs immediately if you have any

questions or concerns about the use or quality of this item.

- Remember always to wash hands before handling patients or patient care items.
- See also **Warnings and Contraindications for Medical Maggots™** or whatever brand of medicinal maggots you are using.

Instructions for Use -

Remember always to familiarize yourself with all instructions and package labeling before using this or any other medical device. Remember always to wash hands before handling patients or patient care items.

LeFlap™ is sterile if packaging is unopened and undamaged. However, it is not necessary to handle this item with sterile gloves. Follow institutional guidelines regarding handling of "sterile" vs "clean" wound dressing care. If not using gloves to handle this device, be sure to put on gloves before touching patient or wound to avoid spread of infection.

Dressing Application. Gently wash out of the wound any residual medications, secretions or debris. Clean the peri-wound skin with an appropriate skin cleaner, at least as large an area as this dressing will cover. Then protect the peri-wound skin from wound drainage during treatments with a polyurethane or similar skin protectant.

The original **Creature Comforts™** polyester netted dressing must be glued or taped to a hydrocolloid pad or to the patient. **LeFlap™**, Dual-layer maggot confinement dressing is already affixed to a hydrocolloid pad, on one hinged side. Remove it from the packaging, identify the hinged side, and fold backwards to access the hydrocolloid pad directly. Cut a hold in the hydrocolloid pad which perfectly matches the wound margins. When applied to the peri-wound skin, an accurately cut pad will completely cover the peri-wound skin and prevent maggots or their secretions from getting onto the skin, thereby minimizing the risk of itching, irritation, or dermatitis. The dashed circles on the hydrocolloid are intended to provide a sizing and cutting guide. Do not cut your hold beyond the outermost, solid circle, else there may not be enough surface to hold the mesh layer securely to the hydrocolloid.

Once the wound-sized hole is made, remove the adhesive backing on the hydrocolloid pad and carefully apply to the per-wound skin. Leaving the mesh layer folded open, place the medicinal maggots into the wound at a dose of 5-10 larvae per square cm of wound area, according to the manufacturer's instructions. Add a little loose gauze to add surface area for the maggots, but do not stuff.

Remove the adhesive liner from the mesh layer and carefully roll the mesh down over the hydrocolloid such that there are no folds or wrinkles through which the larvae might otherwise escape.

Cover loosely with a breathable absorbent pad (i.e., two ply of cotton gauze). For added security (especially in areas likely to perspire, become soiled, or loosen due to skin movement), frame the dressing with a transparent semi-permeable membrane dressing, with about 1 cm over the dressing and the remainder of the dressing over the skin. Remember: transparent "semi-permeable" dressings are not permeable enough to provide air to the maggots. Do Not cover the central wound area with transparent membrane dressings or any other dressing besides a breathable loose absorbent gauze-like dressing because the maggots may suffocate.

Change the top absorbent pad 4 - 8 hours and whenever it becomes soiled. If it is not wet after 8 hours, the wound and maggots may be too dry. Moisten the wound through the mesh with a little sterile irrigation fluid (water or saline). Leave the **LeFlap™** Dual-layer maggot confinement dressing in place for approximately 48 hours. If left longer than 48 hours, the risk of maggots escaping increases. Beware: Escaping maggots may upset the staff and/or hospital administrators.

Dressing removal. To remove the maggot confinement dressings with minimal effort, peel back the maggot dressing with one hand while wiping up the maggots with a wet 4" x 4" gauze pad held in the other hand, sandwiching the maggots between the two gloved hands. Discard the maggots as you do your other potentially infectious dressing waste (ie, discard in "red bag" securely sealed to prevent escape. Double-bag the sealed bag within another sealed bag for added security).

Duration of maggot therapy. The total number of treatment cycles will depend upon the size and character of the wound, clinical response, and goals of therapy). Most ulcers are completely debrided within 1 to 5 cycles. Do not re-use the **Creature Comforts™** or **LeFlap™** maggot confinement dressings because the seal will not be as strong with repeated use.

Disposal -

After use, handle and discard the maggots and maggot dressings as you do your other potentially infectious dressing waste (ie, discard in "red bag" securely sealed to prevent escape. Double-bag the sealed bag within another sealed bag for added security).

- See also **Disposal for Medical Maggots™** or whatever brand of medicinal maggots you are using.

Overdosage -

Guerrini (1988) demonstrated that blow fly strike in sheep resulted when very large maggot burdens (> 16,000 maggots per animal) infested the sheep. In these cases, serum ammonia levels were found to be elevated (presumably due to the large protein breakdown in the wound), and the animals became encephalopathic. Neither elevated serum ammonia levels nor hepatic encephalopathy have ever been reported in humans; but they should be sought in patients who develop fevers or altered mental states while receiving maggot therapy.

It has been suggested that too many maggots within a non-expanding dressing --- especially in an insensate wound --- could cause increased pressure on the wound as the maggots grow. This could lead to further ischemia and necrosis of the wound, leading to further debridement and growth of the maggots, leading to more pressure still (Sherman, 2002). This theoretical complication has never been documented to occur, but should be kept in mind.

How supplied -

LeFlap™ Dual-layer maggot confinement dressings are provided in a variety of sizes (i.e., 3"x 3", 6"x 6"), individually wrapped and sterilized. Check package wrapper for size and sterility validation markings. Batch numbers include the date of production (YY/MM/DD).

Restrictions and Disclaimers -

No warranty is made or implied regarding their therapeutic benefit of maggot therapy for any specific patient. **Creature Comforts™** and **LeFlap™** are not appropriate for all wounds nor all locations. Call Monarch Labs if you have any questions or concerns about the use or quality of this item.

Inquiries and Orders -

Medical Maggots™ are produced and distributed according to Ronald Sherman's specifications, by:

MONARCH LABS

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