

# Medical Maggots™

## Description and Natural History -

Each vial of **Medical Maggots** contains 2" x 2" gauze, seeded with approximately 1,200 *Phaenicia* (= *Lucilia sericata* (blow fly) eggs, from which approximately 500-1,000 maggots will have hatched before the vial leaves our laboratory. Most of the **Medical Maggots** will be in the gauze pad and difficult to see; think of this dressing as "maggot-impregnated gauze." A few of the larvae will be crawling along the sides of the vial (especially when the vial is warmed). If you need only a few maggots, then you can easily wipe those from the walls of the vial, with a sterile water- or saline-moistened 2"x 2" gauze pad.

*P. sericata* eggs are yellow, rice-shaped, 2 mm long. After hatching, the egg shells will turn brown, soft, and ultimately dissolve. The newly hatched larvae are 2 mm long, and translucent white. Young *P. sericata* larvae feed upon necrotic tissue and wound fluids. The maggots release their digestive enzymes into the local environment, and ingest the liquefying and semi-solid tissue. As they grow, they molt twice. In nature, the maggots would leave their food source when satiated, and burry themselves in a suitably protected area. There they would pupate in relative safety. Adult flies emerge (eclose) approximately 10-20 days later. Developmental times are temperature-dependent.

## Mechanisms of Action -

Debridement results partly from the **Medical Maggots** proteolytic digestive enzymes liquefying the necrotic tissue and partly from the physical action of the mouth hooks on the tissue, which pierce and tear the necrotic tissue, allowing the digestive enzymes to reach the depths of the necrotic tissue.

## Clinical Indications:

**Medical Maggots** and maggot debridement therapy (MDT) are indicated for: debridement of non-healing necrotic skin and soft-tissue wounds such as pressure ulcers, neuropathic foot ulcers, chronic leg ulcers, or non-healing traumatic or post-operative wounds.

## Storage & Handling -

Upon arrival, **Medical Maggots** should be inspected for maggot activity; any problems must be reported to the manufacturer

immediately (contact information listed below). **Medical Maggots** should be used within 24 hours of receipt (preferably on the day of arrival) to ensure sterility and optimal viability. Do not use if the cap seal is broken or missing. This is a "single use only" item. The vial is not designed for multiple dosing, and the unused maggots should not be applied to the same or another patient, for they may become contaminated with each opening of the product. Unused larvae are germ-free, and may be discarded (after securing the lid) with routine non-infectious waste. "Used" or applied maggots become contaminated by the patient's wound, and must be handled as contaminated medical waste [see **Disposal** and **Restrictions and Disclaimers**, below].

## Warnings -

- Patients allergic to fly larvae, brewer's yeast, or soy proteins may manifest allergic reactions to **Medical Maggots** which are prepared in such media. Special preparation and media is available upon request.
- **Medical Maggots** can cause discomfort or pain particularly in patients already experiencing wound pain. Maggot-associated pain or discomfort usually manifests at about 24-36 hours into therapy, and increases as the larvae grow. If systemic analgesics do not control the pain, remove the maggot dressing to achieve immediate pain relief. Do not apply local anesthetics (i.e.: lidocaine) to the wound while **Medical Maggots** are in place.
- This product is for single-use only. Every batch of **Medical Maggots** is cultured during production to ensure sterility; but contamination through the delicate air-permeable vial can occur later during handling, shipping, storage, or any time the vial is opened **Medical Maggots** should not be used if the sterile seal is broken, if the filter is damaged, if the maggots have a strong offensive odor, or if they are known or suspected of being contaminated. The vial of **Medical Maggots** is not intended for multiple dosing.
- Wounds should never be allowed to close over the maggots.
- Patients with fever or changes in mental status should be evaluated for spread of infection (i.e., bacteremia, cellulitis) or elevated serum ammonia levels. Maggot dressings may need to be removed immediately to facilitate wound inspection.
- **Medical Maggots** should not be allowed to remain in the wound when they are dead; for

they may trigger an allergic response or may become the nidus for further infection.

- After use, handle **Medical Maggots** as you would other infectious dressing waste. Used maggot dressings should be double-bagged (contained within a sealed plastic bag, which is completely contained within a second sealed plastic bag) to ensure that the maggots do not escape.
  - Beware: **Medical Maggots** may try to escape from the dressing, especially when they have debrided all necrotic tissue or when they are satiated (finished eating). **Medical Maggots** may escape through stretchable weave fabrics, or pores larger than 200 microns. More likely, satiated larvae will squeeze between the skin and the dressing (i.e., hydrocolloid pad) to make their escape. This can usually be prevented by framing the dressing with a transparent membrane dressing, partially covering the edges of the polyester net and partly extending outwards, over the peripheral, peri-wound skin. This way, any larvae that manage to squeeze between the skin and hydrocolloid will likely be trapped by the transparent membrane dressing (see Figure 1). Escapes are most common after 48 hours, by which time some of the larvae are mature and ready to leave the host to pupate. Any dressings left on for more than 48 hours are at increased risk for escapes, and should be well secured.
  - **Medical Maggots** should not be used on more than one patient, nor allowed to wander away from their host patient. Once they have been applied to a patient, they must be considered as fomites. Escaping maggots have been known to upset the hospital staff and/or patients. If not properly disposed, escaped maggots could pupate and mature to adult flies approximately two weeks later.
  - During the first application, and whenever problems with infection, pain or dressing integrity are likely, the maggot dressings should be inspected at least once daily until removed.
  - See also **Contraindications** and **Dosage and Administration**.
- ## Contraindications -
- Patients allergic to fly larvae, brewer's yeast, or soy bean protein may manifest allergic reactions to **Medical Maggots**, which are prepared in such media. Patients allergic to the other maggots dressing materials also may manifest contact dermatitis or more serious immunologic reactions. Patients with serious

allergic reactions should not be treated with **Medical Maggots**, or should be treated in such a way as to avoid all contact with the offending antigens. If treatment is undertaken, then it should be done only with close attention and immediate access to care.

- Patients with acute, rapidly advancing, life- or limb-threatening infections should not be treated with maggot debridement dressings, because the dressings may interfere with the close and frequent observation that these patients require, and because MDT may delay definitive treatment (i.e., surgery).
- Maggot therapy is not indicated as the primary treatment for infected bone or tendons. These structures usually require surgical and/or antibiotic treatment as the primary therapy (with or without adjunctive maggot therapy).
- Maggot therapy should never be used to treat wounds which are not directly exposed to the outside (for example, abscesses not incised and drained). Wounds should never be allowed to close over the **Medical Maggots** either intentionally or unintentionally.
- Use of **Medical Maggots** is contraindicated in patients whose circulatory integrity is compromised to the extent that the wound ultimately has minimal chances of healing. In such circumstances, maggot therapy is likely to enlarge the wound as it is debrided, removing necrotic tissue and debris, but leaving the patient with a wound which will again succumb to advancing infection.
- Mild bleeding is common during maggot debridement, and it is common that the wound drainage is blood-tinged. Patients with natural or pharmacologically induced coagulopathies are at risk of significant bleeding during maggot therapy. Maggot therapy in such individuals, if done at all, should be done under close supervision.
- Maggot debridement of, or around, necrotic blood vessels may lead to rupture of those blood vessels, which could be life-threatening. Use of **Medical Maggots** in that situation is contraindicated. If maggot therapy is attempted, the patient must receive close, continuous, intensive observation for bleeding, vascular rupture, infection, or thrombosis.
- **Medical Maggots** should not be given unlimited access to deep organs and tissues when such access could disrupt important neurovascular structures or intact sterile cavities.

- **Medical Maggots** should never be introduced into sterile body cavities; they are contraindicated for use in eyes, upper gastrointestinal tract, or respiratory tract.
- *Pseudomonas aeruginosa* wound infections may not be controlled maggot therapy alone. Specific anti-pseudomonal therapy may be needed during, or before, treatment with **Medical Maggots**.

### Dosage & Administration -

The recommended dose of **Medical Maggots** is 5-8/cm<sup>2</sup> of wound surface; applied topically. If the eggs have not hatched by the time they arrive, hatching will be hastened by warming the vial in an incubator (i.e., 37°C). If the eggs are brown and no maggots are seen, the maggots may have died within their shells during shipping. Do not use. Call supplier immediately for refund or replacement instructions.

**Dressing application.** Gently wash the wound of any residual medications, secretions or debris. Clean the peri-wound skin with a gentle skin cleaner, and protect the skin from wound drainage during treatments with a polyurethane or similar skin protectant. **Do not use povidone iodine or other potential skin irritants.**

You will want to contain the maggots with a mesh dressing that permits air to reach the larvae, and facilitates drainage of maggot secretions and patient exudates out from the wound (that is, a pore size of 100-160u). Examples include *Creature Comforts*<sup>™</sup>, *LeFlap*<sup>™</sup> or *LeSoc*<sup>™</sup> (for non-planar surfaces like heels, toes, and amputation stumps), by **Monarch Labs**. Alternatively, some people find nylon stockings to be a reasonable alternative

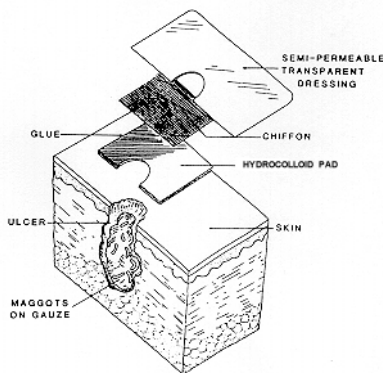


Figure 1. Multi-layered dressing sample.

(although they have a larger pore size and stretchable weave, allowing the smallest maggots to escape before they start growing). In order to minimize skin trauma with strong tapes or glues or other tacky materials, the mesh can be affixed to a hydrocolloid pad with a central hole cut out to match the wound margins. This multi-layered maggot dressing is shown in Figure 1, and a detailed description of dressing designs can be found in *Plast Reconstr Surg* 1997; 100: 451-6; and *Arch Dermatol* 1996;132: 254-256

**Placement of the Maggots.** **Medical Maggots** should be applied to the wound on or with a sterile, moist (ie, normal saline or water) gauze pad. Think of the gauze at the bottom of the vial as "maggot-impregnated gauze." If you need half of the maggots in the vial (the dose is 5-8 larvae per cm<sup>2</sup> of wound surface area), then take half the gauze; if you need one quarter of the maggots, then take one quarter of the gauze, and place it on the wound surface. If you need only a few maggots, you can moisten a 2"x2" pad and gently wipe up the maggots on the walls of the vial. Warming the vial to >30°C will make more maggots leave the gauze pad and crawl up the sides of the vial. Refrigeration for 15-30 minutes will slow down the maggots, and cause most to return to the gauze pad. Place the medicinal maggots into the wound at a dose of 5-8 larvae per square cm of wound area. A little *loose* gauze will provide the larvae with more surface area for the maggots to crawl on, but **do not tightly pack the wound.**

After the **Medical Maggots** have been applied, cage them on the wound, using a mesh fabric (i.e., *Creature Comforts*<sup>™</sup> or *LeSoc*<sup>™</sup> by Monarch Labs). Then cover the mesh and dressing 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 membrane over the skin. Remember: transparent "semi-permeable" dressings are not permeable enough to provide air to the maggots. Do **not** cover the central mesh 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 every 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 maggot containment dressings 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, patients, and/or hospital administrators.

**Dressing removal.** To remove the maggot cage dressings with minimal effort, loosen the maggot cage dressing from the patient's skin, and then peel back the 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 hands. Discard the maggots as you do your other potentially infectious dressing waste (ie, discard in "red bag"), securely sealed to prevent escape. Seal the bag within another bag, and seal the second bag.

**Duration of maggot therapy.** The total number of 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 6 cycles.

### Disposal -

After use, handle and discard **Medical Maggots** and the maggot dressings as you do your other infectious dressing waste (ie, discard in "red bags" destined for autoclaving or incineration). To prevent escape, seal the bag securely, and seal that bag within a second, sealed waste bag [see also *Dosage and Administration - Dressing removal*]. Unused larvae must be destroyed in a similar fashion; they may not be allowed to mature. The recipient is **not** authorized nor licensed to breed, re-sell, or redistribute **Medical Maggots** without specific permission [see *Restrictions and Disclaimers*].

### Overdosage -

Large maggot burdens in blow fly infested sheep (>60,000 maggots per animal) are associated with serious complications ("blow fly strike" including elevated serum ammonia levels (presumably due to the large protein breakdown in the wound), and encephalopathy. Neither elevated serum ammonia levels nor hepatic encephalopathy have been reported in humans; but they should be sought in patients who develop fevers or altered mental states while receiving maggot therapy. Furthermore, patients should not be treated with more than 3,000 larvae at a time.

It has been suggested that too many maggots within a rigid 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. Although never reported, this scenario must be considered when building cage-dressings.

### How supplied -

Each vial contains 2" x 2" gauze and sterile media, sprinkled with approximately 1,200 germ-free *P. sericata* eggs, from which at least 500 **Medical Maggots** will hatch. Most of the larvae will remain in the "maggot-impregnated gauze," but a few larvae will be crawling along the sides of the vial. Date of preparation is recorded on the vial as the "batch number" (YY/MM/DD), and the calculated number of hatched larvae will be labeled on the vial.

### Restrictions and Disclaimers -

**Medical Maggots** are provided for the sole purpose of patient care, as prescribed by the ordering physician. The recipient is **not** authorized nor licensed to rear, breed, re-sell, or redistribute these larvae or their progeny without specific permission. Unused larvae must be destroyed and not allowed to mature.

Practitioners outside the Continental United States require valid import permits by their local Departments of Agriculture before ordering or accepting **Medical Maggots**. Practitioners in Europe should contact one of the European commercial suppliers, listed on our internet site.

**Medical Maggots** will be replaced or refunded if contaminated or if not viable upon arrival. No warranty is made or implied regarding their long-term viability, therapeutic efficacy or safety for any specific patient.



**Report problems or adverse events** to the manufacturer (949-679-3000), supplier, or FDA, immediately. Report forms can be found at: [www.MonarchLabs.com/ae-report.pdf](http://www.MonarchLabs.com/ae-report.pdf)

### Inquiries and Orders -

**Medical Maggots** are produced and distributed per specifications of Ronald Sherman, by:

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### Revision History:

Date Change Initiated	DCO #	Initiated by	Summary of Changes	Rev #	Date Implemented	Approved by
New	N/A	RAS	New	A	7/1/09	
5/20/09	09-002	RAS	Addition of warnings concerning use of povidone iodine and skin irritants.	B	7/25/09	
1/02/12	12-001	RAS	Addition of LeSoc dressing, and more ways to prevent maggot escapes.	C	1/21/112	