

Medical Maggots™

Description and Natural History -

Each vial of **Medical Maggots** contains approximately 1,000 *Phaenicia*. (= *Lucilia sericata* (blow fly) eggs, from which 250 - 500 maggots will normally hatch within 12 hours of preparation. Each vial also contains 2"x2" gauze and sterile food (containing soy protein and brewer's yeast). Many of the **Medical Maggots** will be in the gauze pad and difficult to see; others will be crawling along the sides of the vial (especially when the vial is warmed), and can be removed easily by wiping them off the sides of the vial with a 2"x 2" gauze pad moistened with sterile saline or water.

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 liquifying 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 "sterile" cap seal is broken or missing. This is a "single use only" item. The vial is not designed for multiple dosing, and the maggots may not be applied more than once. "Used" maggots must be handled as contaminated medical waste; unused maggots must be destroyed [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 pain or discomfort, 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 larger. If systemic analgesics do not control the pain, then 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.
- 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** 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 daily until removed.
- See also *Contraindications and Dosage and Administration*.

Contraindications -

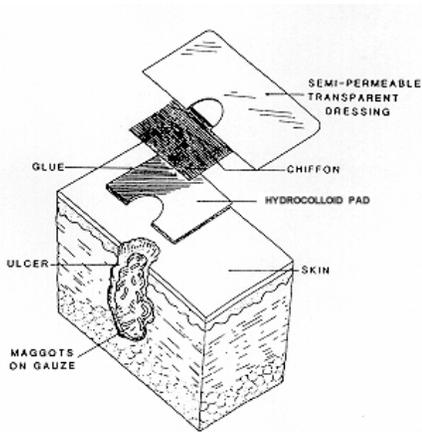
- Patients allergic to fly larvae, brewer's yeast, or soy bean protein may manifest allergic reactions to **Medical Maggots**, which are prepared in such media. Patients allergic to the other maggots dressing materials also may manifest contact dermatitis or more serious immunologic reactions. Patients 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 can 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-pseudomonas therapy may be needed during, or before, treatment with **Medical Maggots**.

Dosage & Administration -

The recommended dose of **Medical Maggots** is 5-8/cm² 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 immediately.



Dressing application. To apply **Medical Maggots** to a wound, gather the maggots on a sterile, moist (ie, normal saline or water) gauze pad, and place on the wound surface. Often the maggots will crawl up the sides of the vial when the vial is warmed to > 30°C (the heat increases their metabolism and activity). They can then be wiped from the sides of the vial with a moist sterile gauze. Alternatively, **Medical Maggots** in the gauze pad supplied with the vial can be applied directly to the wound, or the maggots may be rinsed out of the vial with sterile water or saline and poured over a sterile gauze pad. Then apply the gauze directly onto the wound. Note: there may be more maggots in the gauze than you can see. It is strongly recommended that the materials for the cage be assembled and the foundation be affixed to the patient prior to applying **Medical Maggots**, since the maggots will move quickly once they are applied, and they may rapidly emigrate out of the wound. Refrigeration for 30 minutes will slow the activity of **Medical Maggots**.

After the **Medical Maggots** have been applied, cover them with a little loose gauze, and cage them within the wound using a perforated material such as **Creature Comforts** (made from Dacron chiffon, 70 weaves per inch), Tegapore (3M), or nylon stockings. A multi-layered maggot dressing is shown in Figure 1; detailed description of dressing designs can be found in *Plast Reconstr Surg* 1997; 100: 451-6; and *Arch Dermatol* 1996;132: 254-256

Air must be able to enter through the dressings (so that the maggots do not suffocate) and the liquefied necrotic tissue must be able to drain out through the dressings. Place a light gauze top dressing over the cage layer, to absorb the drainage; and change this gauze every 4 - 8 hours. Leave the maggot dressings on for approximately 48 hours. Beware: maggots may try to escape from the wound.

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. Double-bag the sealed bag within another sealed bag for added security).

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 explanation must be considered in patients whose wounds are expanding during treatment.

How supplied -

Each vial contains approximately 1,000 *P. sericata* eggs, from which at least 250 **Medical Maggots** should have hatched. Each vial also contains 2" x 2" gauze and sterile food. Many of the larvae will be in the gauze pad and difficult to see; others will be crawling along the sides of the vial. Date of preparation is recorded on the vial as the "batch number" (YY/MM/DD). Every batch is tested for sterility.

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.

Complications and adverse events -

Report problems or complications immediately to the manufacturer (949-679-3000), supplier, or FDA. Incident report forms can be found on the internet at: www.MonarchLabs.com/forms/ae-report.pdf

Inquiries and Orders -

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

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