



DEPARTMENT OF VETERANS AFFAIRS  
Veterans Health Administration  
Washington DC 20420

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**UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER**

**MAGGOT DEBRIDEMENT THERAPY (MDT) AND LEECH THERAPY (LT)**

1. This Information Letter addresses the use of maggot debridement therapy (MDT) and leech therapy (LT) and is provided to assist staff at Veterans Health Administration (VHA) facilities in implementing these treatment modalities in accordance with current practice standards.

2. **Maggot Debridement Therapy (MDT)**

a. Reports of larvae present in infected wounds extend back to ancient times, but it was a French surgeon, Baron Dominique-Jean Larrey (1766-1842), who observed that the larvae of certain species of fly removed only dead tissue and appeared to promote healthy tissue. Dr. John Forney Zacharias (1837-1901), a surgeon during the American Civil War, is credited with the first intentional application of maggots for medical purposes. Development of antibiotics (sulphonamides and penicillin), as well as new antiseptics in the 1940's led to a rapid decline in use of larval therapy, but interest in MDT resumed in the 1980's and continues to today.

b. Reports 2004, the Food and Drug Administration (FDA) cleared the marketing of medicinal maggots (*Phaenicia [Lucilia] sericata*) 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.

c. Larvae are known to aid in wound healing by several mechanisms. Proteolytic enzymes secreted in larval saliva break down necrotic debris and the mouth hooks and rough surface of the maggot mechanically debrides the tissue. It has been noted that larvae applied at 5-10 maggots per square centimeter can consume up to 10-15 grams of tissue a day. It is also hypothesized that substances in maggot saliva stimulate new tissue growth.

d. Larval secretions have several additional properties that aid in preventing wound infections. The maggot saliva contains ammonia that alkalinizes the wound, which is presumed to inhibit bacterial growth. Also secretions from maggots appear to have a direct antimicrobial effect. Live maggots in vitro were found to kill or inhibit growth of *Staphylococcus aureus*, Groups A and B *Streptococcus* and, to some degree, *Pseudomonas* species.

3. **Leech Therapy**

a. Leeches have been used for "bloodletting" since antiquity to treat a myriad of maladies. Leech therapy reached a peak in the 18<sup>th</sup> and 19<sup>th</sup> centuries then began to decline in the 20<sup>th</sup>

century secondary to more modern scientific therapies and the lack of efficacy of leech therapy for multiple conditions. Over the past few decades the use of medicinal leeches has resumed in the area of cosmetic and plastic surgery to alleviate venous congestion. In 2004, the FDA cleared the marketing of leeches (*Hirudo medicinalis*) for use as an adjunct to graft tissue healing when venous congestion occurs.

(1) Venous congestion occurs in plastic surgery procedures such as limb reattachments and flaps where venous drainage is compromised in the presence of normal arterial flow. Leech therapy helps alleviate venous congestion until collateral vessels can be created by the patient's body. Collateral formation typically occurs in 3-7 days; therefore leech therapy is continued for that period of time.

(2) Leech saliva is excreted while feeding and has multiple components including hirudin, calin, hyaluronidase, a histamine-like substance, and acetylcholine that act to prevent coagulation and promote bleeding. The leech itself extracts blood, but more importantly, the bite wound continues to bleed after detachment. A leech can withdraw 5-15 milliliters (mls) of blood while attached with an additional 20-50 ml of blood lost from the site after detachment. Leech bites bleed for an average of 6 hours, but can ooze for up to 72 hours. The loss of blood releases the pressure on tissues due to venous congestion until collateral vessels can form for venous outflow.

b. The number of leech applications required is determined by the amount of blood to be removed. For example if one leech typically causes 50 ml of blood loss then two leeches can remove up to 100 ml of blood.

c. The bacterium *Aeromonas hydrophilia* is a commensal organism found in the gut of leeches and is associated with leech bite wound and/or blood stream infections in 7-20 percent of cases where *Hirudo medicinalis* is used. These infections can occur acutely or up to 26 days after starting leech therapy.

#### **4. Biotherapy Use**

##### **a. MDT**

(1) Indications. MDT is 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.

##### (2) Species

(a) Only germ free (disinfected) larvae are used medicinally because they dissolve and feed only on dead (necrotic) tissue. *Phaenicia (Lucilia) sericata* is the only FDA-cleared larvae for use in MDT.

(b) *Cochliomyia hominivorax* (screw worm) and other closely-related species are not used as they invade and destroy living as well as dead tissue. Larvae of Sarcophagidae (flesh fly) is not

used because they cannot be disinfected. *NOTE: It is not appropriate to leave maggots on wounds that are the result of natural infestation (myiasis) of wounds in hopes that they will debride the wounds.*

(3) Procedure. The Facility Directors need to designate the appropriate medical professionals with documented competency to administer MDT in order to ensure proper handling and application, and to prevent the possibility of fugitive larvae (see Att. A).

(4) Contraindications

(a) MDT is absolutely contraindicated in wounds with necrosis extending to and around major blood vessels for fear of hemorrhage.

(b) MDT is contraindicated in patients with known allergy to fly larvae or products used in maggot cultivation (e.g., brewer's yeast or soy proteins). The product labeling needs to be checked for specific ingredients and potential allergens.

(c) MDT is not recommended for use in:

1. Wounds in eyes, upper gastrointestinal tract, or respiratory tract;
2. Patients with an acute or progressive infection surrounding the wound;
3. The primary treatment of infected bone or tendon;
4. Wounds not exposed to the outside of the skin;
5. Patients who develop severe pain at the wound site, it may occur in patients with painful wounds, particularly as larvae grow; and
6. Patients with poor circulation and limited ability to heal as the maggots may cause significant enlargement of the wound.

(5) Relative Contraindications

- (a) Diabetes mellitus, which depends on the patient's degree of vascular compromise.
- (b) Coagulopathies, which need to be monitored closely for signs of bleeding.

**b. Leech Therapy**

(1) Indications. Leeches are used as an adjunct to the healing of graft tissue when problems of venous congestion may delay healing, or to overcome problems of venous congestion by creating prolonged localized bleeding.

(2) Species

(a) *Hirudo medicinalis* is the only species of leech cleared by the FDA for medicinal use.

(b) Other species including *H. orientalis*, *H. troctina*, *H. verbana*, *Hirudineria manillensis*, and *Macrobdella decora* have been used in medicine, but are not FDA cleared and are not to be used for biotherapy in the Department of Veterans Affairs (VA).

(3) Procedure. The Facility Directors need to designate the appropriate medical professionals with documented competency to administer leech therapy in order to ensure proper handling and application, and to prevent the escape of leeches (see Att. B).

(4) Contraindications. Leech therapy has known contraindications in the following conditions:

(a) Risk of gastrointestinal bleeding, e.g., known peptic ulcer disease or erosive gastritis;

(b) Active infection with sepsis, which can lead to impaired wound healing and potential bleeding diathesis;

(c) Severe patient allergic reactions to known proteins and, therefore, may have an increased possibility of reaction to foreign proteins in leech saliva;

(d) Previous allergic reactions to substances in leech saliva;

(e) Pregnancy;

(f) General or local wound healing disorders (e.g., diabetes mellitus, venous stasis ulceration, connective tissue disorder);

(g) Congenital or acquired hemophilia;

(h) Anemia or bone marrow suppression; and

(i) Marked immunosuppression (e.g., use of high-dose steroids [greater than 50 milligrams per day of prednisone], organ transplantation).

(5) Relative Contraindications

(a) Medications that prolong bleeding time or affect platelet aggregation (e.g., warfarin, aspirin, non-steroidal anti-inflammatory drugs) need to be stopped.

1. Clopidogrel needs to be held for 5 days prior to leech use, if possible.

2. Fish oil, ginkgo biloba, dong quai, garlic, ginseng and ginger may prolong bleeding time and need to be discontinued.

(b) Previous leech use may create a sensitization and lead to an allergic reaction, therefore, patients need to be monitored closely.

(c) Patients with chronic disease states such as cirrhosis, human immunodeficiency virus with cluster of differentiation four counts less than 200, immune defects, and end-stage renal disease on hemodialysis.

## 5. References

a. BioTherapeutics, Education and Research Foundation. Draft Policies and Procedures For Maggot Debridement Therapy (MDT). 2009. Retrieved January 13, 2011 from: [www.BTERFoundation.org](http://www.BTERFoundation.org).

b. Chepeha, D.B. *et al.* "Leech therapy for patients with surgically unsalvageable venous obstruction after revascularized free tissue transfer." Archive of Otolaryngology Head and Neck Surgery. 128: 960-965, August 2002.

c. Conforti, M.L. *et al.* "Evaluation of performance characteristics of the medicinal leech (*Hirudo medicinalis*) for the treatment of venous congestion." Plastic and Reconstructive Surgery. 109: 228, 2002.

d. FDA: K040187 Premarket database for medicinal leeches at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=14226>

e. FDA: K072438 Premarket database for medical maggots at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=25750>

f. Hunter, S. *et al.* "Maggot therapy for wound management." Advances in Skin and Wound Care. 22(1):25-27, January 2009.

g. Hyson, J.M. "Leech therapy:A history." Journal of the History of Dentistry. 53(1): 25 27, March 2005.

h. Medical Maggots™ package insert. [www.monarchlabs.com/maggotpi.pdf](http://www.monarchlabs.com/maggotpi.pdf)

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j. Weinfeld, A.B., *et al.* "Clinical and scientific considerations in leech therapy for the management of acute venous congestion: An updated review." Annals of Plastic Surgery. 45:207-212, 2000.

k. Whitaker, I.S. *et al.* "Larval therapy from antiquity to the present day: Mechanisms of action, clinical applications and future potential." Postgraduate Medicine. 83: 409-413, January 2007.

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**6. Inquiries.** Questions regarding this Information Letter may be addressed to the Infectious Diseases Program Office at (513) 475-6398.

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## ATTACHMENT A

### MAGGOT DEBRIDEMENT THERAPY -- SUGGESTED PROCEDURE

(Adapted from BioTherapeutics, Education and Research Foundation. Draft Policies and Procedures For Maggot Debridement Therapy (MDT). 2009. Retrieved January 13, 2011 from: [www.BTERFoundation.org](http://www.BTERFoundation.org).)

1. The Pharmacy-Prosthetics-Logistics workgroup in 2009 determined that individual facilities have different policies regarding the location of acceptance, storage, and distribution of biotherapy agents depending on the strengths of the individual departments (e.g., pharmacy, prosthetics, and logistics departments). Facility Directors need to develop a written procedure for accepting maggots from the supplier, as well as tracking and documenting the controlled movement of maggots within the facility to their eventual disposal, including designating a secure area within the facility to:
  - a. Ensure that maggots arrive from the manufacturer in good condition (e.g. ,alive, active) and the cap seal on the maggot vial is not broken or missing. If the cap seal is damaged or the vial emits a strong odor, the maggots should not be used.
  - b. Store larvae at room temperature (68-79°Fahrenheit) in the container in which they arrived from the manufacturer. This vial contains a 2x2 gauze pad and food for the maggots.
  - c. Secure the container of maggots to avoid larval escape. Each vial contains approximately 1000 *P. sericata* eggs from which at least 250 maggots should hatch.
2. All specific instructions from the manufacturer need to be followed.
3. Use larvae within 24 hours of receiving. Each vial of maggots is considered a one-time use item.
4. If the eggs have not hatched into maggots by arrival, this process may be hastened by gentle heating at 80-90°Fahrenheit. Conversely the activity of maggots can be slowed by gentle cooling at 45-55° Fahrenheit for 15-30 minutes.
5. Medicinal maggots should be applied by medical professionals with documented competency of the procedure and an understanding of chronic wound care.
6. Cut a hydrocolloid dressing (occlusive, adhesive dressing with gel-forming material) the size of the wound to protect the surrounding skin.
7. Collect the maggots from their vial on a sterile loose gauze moistened with sterile water or normal saline.
8. Place maggots on the wound surface with the loose gauze at a concentration of five to ten larvae per square centimeter. Dead maggots should not be placed on the wound.

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9. Place porous fabric such as a polyester net or nylon stocking over the wound to contain larvae and cover with a light absorbent gauze.
10. Change absorbent gauze as necessary.
11. Remove larvae from wound every 2-3 days.
12. Used maggots are considered contaminated medical waste. Double bag materials to avoid larval escape, and place in containers designated for autoclaving or incineration. Unused maggots are not considered a biohazard and may be discarded in regular trash after they are securely sealed to prevent escape. If the maggots are not destroyed, they could develop into flies within 10-14 days.
13. Never transfer used maggots from one patient to another.

## ATTACHMENT B

### LEECH THERAPY -- SUGGESTED PROCEDURE

(Adapted from Biotherapeutics, Education and Research Foundation Draft Template for Leech Therapy Policy and Procedure Accessed January 5, 2011 at:

[http://bterfoundation.org/indexfiles/Leech%20Therapy%20policy%20and%20procedure,%20edited,%206%2020%2008\\_for%20public%20comment.doc](http://bterfoundation.org/indexfiles/Leech%20Therapy%20policy%20and%20procedure,%20edited,%206%2020%2008_for%20public%20comment.doc) )

1. The Pharmacy-Prosthetics-Logistics workgroup in 2009 determined that individual facilities have different policies regarding the location of acceptance, storage, and distribution of biotherapy agents depending on the strengths of the individual departments (e.g., pharmacy, prosthetics, and logistics departments). Facility Directors need to develop a written procedure for accepting leeches from the supplier, as well as tracking and documenting the controlled movement of leeches within the facility to their eventual disposal, including designating a secure area within the facility to:

a. Store leeches at a temperature range of 40°F to 80°F in non-chlorinated water or specific storage fluids provided by the manufacturer of the leeches. Do not store leeches in distilled water. Up to 50 leeches can be stored per gallon (4 liters) of fluid.

b. Ensure the storage jar for leeches has a securely-tightened fabric cover to allow leeches to breathe, but to prevent escape.

c. Change the leech storage water every 3-6 days. Cover the storage jar with gauze and pour the water out. Replenish with 68-79°F non-chlorinated tap water or specific storage fluid provided by the manufacturer.

2. Leeches can live up to 1 year without food; therefore, no feeding is necessary.

3. Follow all specific instructions from the supplier.

4. Estimate the blood volume to be removed and therefore the number of leeches needed so as not to waste leeches. One leech typically causes 50 milliliters of blood loss.

5. Because of a risk of excessive bleeding if aspirin and heparin (or dextran) are used in addition to leech therapy for flap salvage, the patient needs to be monitored in the Intensive Care Unit (ICU) with frequent hematologic evaluations (at least every 4 hours), including complete blood count, complete metabolic profile, and partial thromboplastin time.

6. Transfuse blood products as needed (i.e., hemoglobin level less than (<) 7grams per decoliter).

7. Give antibiotic prophylaxis with activity against *Aeromonas hydrophilia*. Agents that typically have activity include: a cephalosporin (second, third or fourth generation); aminoglycosides; trimethoprim-sulfamethoxazol; or ciprofloxacin. Antibiotics need to start at

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least 1 hour before attachment, and may be appropriate to continue for 3-5 days after completion of leech therapy in patients with unhealed wounds.

8. Leeches need to be applied by medical professionals with documented competency of the procedure and an understanding of vascular flow in tissue grafts.
9. Clean the site of intended use with soap and water, rinse with distilled non-chlorinated water. Do not use saline.
10. Dampen a piece of gauze with normal saline and cut a 1 centimeter hole in the center. This helps keep the leech from wandering.
11. Place saline-moistened gauze on patient with the hole over the intended site of attachment.
12. Use forceps or tongs with light pressure to remove the leech from its container and place in a small plastic tube (i.e., the barrel of a 5-10 cubic centimeter syringe).
13. Direct the head of the leech to the hole in the gauze. If the leech does not rapidly attach, use a small needle to prick the skin and create a small droplet of blood to entice the leech to attach.
14. Leeches typically remain attached for 30-60 minutes and detach when satiated. If the blood supply to the area of attachment is poor, the leech may detach and search for a new area to feed.
15. Do not forcibly remove a leech from the skin. If detaching the leech is necessary, place a small amount of alcohol or normal saline on a cotton pad and swab the head of the leech until it detaches.
16. Used and any unused leeches dispensed for use are placed in a solution with 7 percent ethanol for 5 minutes, then discarded as contaminated medical waste.
17. Never reuse leeches and do not return leeches (used or unused) to the designated storage location.
18. Repeat the leech attachment procedure until venous congestion is resolved by the development of collateral circulation, but do not exceed 3-7 days.