



BIO-THERAPEUTICS EDUCATION & RESEARCH FOUNDATION

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Advancing Healthcare through Education & Research in BioTherapy

Template for

Maggot Debridement Therapy (MDT) Consent Form

DISCLAIMERS AND LEGAL NOTICES

This template for Informed Consent to maggot debridement therapy is provided by the BioTherapeutics, Education and Research Foundation, without warranties concerning the applicability of this draft at any specific facility. Please modify the document as needed to fit the specific policy, procedure, formulary, or logistic demands of your institution. Be sure to read and follow all warnings and labeling information associated with products used in the application and removal of maggot therapy dressings, and inform your patients of the true risks, benefits and options, as this is only a sample of the document that you should use.

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The BioTherapeutics, Education and Research (BTER) Foundation is a public charity whose mission is to support patient care, education, and research in maggot therapy, leech therapy, and the other diagnostic and treatment modalities that use live animals. More information about our services can be found at the address below, or on the internet at: www.BTERFoundaiton.org

Draft / Template for Executing and Documenting
Maggot Debridement Therapy (MDT) Informed Consent

I, _____, hereby acknowledge that I have been informed about the procedure of maggot therapy, the reasons for its use, reasonable goals of therapy, likely risks, and appropriate alternatives, as outlined below. Furthermore, I acknowledge that I have had the opportunity to ask questions and have had those questions answered to my satisfaction.

Description of the maggot therapy procedure (check those that apply):

- Placement of live, germ-free ("medical-grade") fly larvae ("maggots") on the wound, within special dressings to confine them to the wound. The dressings and maggots will be removed within 24-72 hours
- Photographs may be taken for the purposes of (delete all those not applicable) monitoring efficacy of the treatment, documentation in the medical record, teaching or publication.
- Other aspects of treatment: _____

Persons who will be involved in the procedure

- _____
- _____
- _____

Indications (reasons) for using maggot therapy (check those that apply):

- Debridement (removal) of dead tissue
- Debridement (removal) of dead, infected tissue
- Other: _____

Risks, Warnings Possible Complications

The following risks occur in over 10% of patients:

Pain or discomfort, particularly in patients already experiencing wound pain. Maggot-associated pain or discomfort usually manifests at about 24 hours into therapy, and increases as the larvae grow larger. If pain medication does not control the pain, then the maggots can be removed early to achieve immediate relief of maggot-associated pain.

The following risks occur in approximately 1-2% of patients:

Because medicinal maggots are highly perishable, they should not be stored for more than 24 hours. Therefore, they are prepared and shipped overnight, immediately before their intended use. Rarely, they are delayed during transport (especially by bad weather conditions).

The instinctive behavior of maggots is to leave the wound (host) once they are finished working (satiated). Therefore, they are "self-extracting." But some are finished earlier than others. Depending on a variety of conditions, most maggots will be satiated by 48 hours; a few will not be satiated until nearly 72 hours. If the dressings are left on for the full 72 hours, then those that are already satiated will attempt to escape. If the dressing comes loose, they may be successful. If the dressing is removed at 48 hours or earlier, before all of the larvae are satiated, then some may hide in crevices if there is still necrotic tissue to be found. These will leave once they, too, are satiated, most likely within the following 24 hours, by entering the covering dressings and hiding therein. Those dressings should be removed and discarded as wound dressing (infectious) waste in a sealed container to prevent their escape from the waste container. If not properly disposed, escaped maggots or those not properly disposed of could pupate and mature to adult flies approximately two weeks later.

The following risks occur in less than 1% of patients:

Patients allergic to fly larvae, brewer's yeast, soy proteins or other ingredients may manifest allergic reactions

Although medicinal maggots are disinfected, they could become contaminated during processing, shipping, or handling by the user. This could lead to infection of the wound.

Fever or changes in mental status could occur, and may or may not be due to the therapy. Sometimes they are due to the wound itself; sometimes to other medical problems in the body. Regardless of the cause, if such symptoms do occur it may be necessary to remove the maggot dressings in order to examine the wound and determine the cause of the fever or mental changes.

Additionally, medicinal maggots are not guaranteed to be effective for every wound. The amount of necrotic tissue may be too extensive to be debrided within one or two treatments, and may require additional treatments with maggots or other methods. If the blood flow is inadequate to support the growth of new, healthy tissue, then the cleaner, bigger wound may not heal; it may even become infected or necrotic, again, before it has had a chance to heal, requiring additional debridement or more aggressive removal (resection or amputation).

Mild bleeding is common during maggot debridement, and it is common for the wound drainage during maggot therapy to be blood-tinged. Patients with coagulopathy ("bleeding tendency") or delicate or damaged blood vessels ("friable tissue" and vascular grafts) are at increased risk of significant bleeding during maggot therapy. Close supervision of the wound and dressing may be necessary in such situations, and you will need to inform your therapist immediately should you observe more than a small amount of blood-tinged drainage from the wound or maggot dressings.

Pseudomonas aeruginosa wound infections are particularly difficult to treat by any means, and they may be more resistant to maggot therapy as well. If your wound is suspected of having *Pseudomonas* infection, you may be asked to use special treatments before maggot

therapy in order to reduce or eliminate the *Pseudomonas*. Your therapist may use "extra" maggots in order to better combat the *Pseudomonas*. Nevertheless, cases have been reported in which *Pseudomonas* infections persist, or even grow bigger, during maggot therapy. Like your therapist, you will need to be vigilant about monitoring and reporting any signs of growing infection, before, during, and after maggot therapy.

Alternative treatment options (check those that apply):

- Surgical debridement or resection.
- Amputation
- Enzymatic debriding agents
- Autolytic debriding agents
- Mechanical debriding agents/devices

Pre-procedure requirements (check those that apply):

- Answer all questions completely and honestly, including all underlying medical and surgical problems, medications, allergies, etc.
- Study all of the information given: reading materials, videos, etc.
- Stop any medication or wound treatments so recommended by your health care provider, such as: _____
- Begin any medication or wound treatments so recommended by your health care provider, such as: _____

Requirements during therapy (check those that apply):

- Ensure that dressings are changed as frequently as recommended, and even more so if they become wet or soiled.
- If the dressings being removed (or the wounds themselves) are dry, apply moist gauze, not dry gauze (i.e., irrigation water or saline).
- Inform your therapist immediately if you find that the maggot dressing has become soiled or loose.
- Inform your therapist immediately if you are having pain that is not adequately controlled.
- Inform your therapist immediately if you or your wound develops symptoms that are unusual or problematic (bleeding, fever, confusion, etc).
- Keep all required appointments.
- _____

Post-therapy requirements (check those that apply):

- Keep all required appointments.
- Inform your therapist immediately if you or your wound develops symptoms that are unusual or problematic (fever, confusion, etc).
- _____

Additional requirements (check those that apply):

- _____
- _____
- _____

Of my own free will and without coercion, I agree to undergo maggot therapy and promise to adhere to the treatment and post-treatment activities, as stipulated above, as they are intended to make the treatment most successful.

Patient:

Printed Name

Signature

Date

Consent administered by:

Printed Name

Signature

Date

Witness:

Printed Name

Signature

Date