BioMonde®
LABORATORIES

BIOSURGERY MADE SIMPLE

PRODUCT DESCRIPTION

BioMonde biosurgery dressings are an unique debridement tool, developed for the management of chronic and complex wounds. VITA⬢PAD and BIOBAG contain aseptically produced stage II larvae of *Lucilia sericata*. Biosurgery with VITA⬢PAD or BIOBAG combines the following advantages:

- Fast effective debridement[i]
- Reduction in Bioburden (including MRSA)[ii]
- Simple to application and removal[iii]
- Cost effective wound management[vii]

INDICATIONS

I. VITA⬢PAD is indicated for the debridement of the following chronic or non-healing wounds:

- Diabetic ulcers[iv, v]
- Pressure ulcers[iv, vi]
- Dehisced or complex surgical wounds[i]
- Venous leg ulcers[vii, iv]

II. VITA⬢PAD is indicated for the reduction of wound infection including MRSA[ii].

CONTRAINDICATIONS

- VITA⬢PAD or BIOBAG should not be used on wounds with a predisposition to bleeding or wounds near to an exposed major blood vessel.
- VITA⬢PAD or BIOBAG should not be used on wounds where extensive surgical debridement is necessary.
- VITA⬢PAD or BIOBAG should not be used on wounds with an insufficient blood supply to support wound healing.

VITA⬢PAD

VITA⬢PAD is ideal for patients and caregivers who do not wish to see or feel the larvae. VITA⬢PAD is composed of a sterile outer PVA dressing and an inner nylon net containing the larvae and a polyester spacer. VITA⬢PAD offers the proven power of biosurgery in an user and patient friendly dressing, while the PVA outer dressing offers the advantages of moist wound healing[viii].

BIOBAG

BIOBAG is composed of a sealed polyester net containing larvae and a PVA spacer to protect the larvae.

Due to the wide range of available sizes and the flexible Polyester net, BIOBAG can conform to most wound shapes and sizes.

FAST EFFECTIVE DEBRIDEMENT

The larvae of *L. sericata* have a voracious appetite, able to consume up to 0.3 g[ix] of necrotic tissue per day each! This means for example that 10 larvae are able to consume up to 3 grams per day. No non-surgical method of debridement delivers faster wound cleansing[x].

L. sericata are necrophages consuming only dead tissue, while leaving healthy, viable tissue intact[vi]. Both BIOBAG and VITA⬢PAD allow the free exchange of larval secretions[xi] and wound debris, while ensuring the larvae cannot escape.

ANTIMICROBIAL ACTIVITY

Antibiotic resistant bacteria present a significant problem to healthcare professionals. The larvae of *L. sericata* have been shown to be effective at reducing infection, even by resistant bacteria.

The antibacterial activity of larvae has been observed for many years. All the contributing factors to the antibacterial activity have yet to be characterized however the following effects are known to occur:

- Larvae are able to ingest and destroy bacteria[xii, xiii]
- Larval secretions have been shown to have antibiotic properties against certain bacteria (including MRSA)[ii]

EASY TO USE

VITA⬢PAD and BIOBAG are designed to be used in any setting, while overcoming the objections many patients and medical staff have to "free range" larvae. VITA⬢PAD and BIOBAG can be quickly and easily removed and reapplied at any time to inspect the wound.

COST EFFECTIVE THERAPY

In today's cost conscious healthcare systems reducing hospital stays and nursing time is essential for effective wound care. Biosurgery can deliver significant cost savings by achieving effective debridement first time, without the need for expensive surgical procedures or extending hospital stay.[xi]

CLINICALLY PROVEN

Since the reemergence of biosurgery in the 1990s an increasing number of studies have shown the efficacy of Biosurgery in a variety of wounds. At the time of writing over 6,000 documented cases of biosurgery have been published as case studies or as a part of clinical trials.

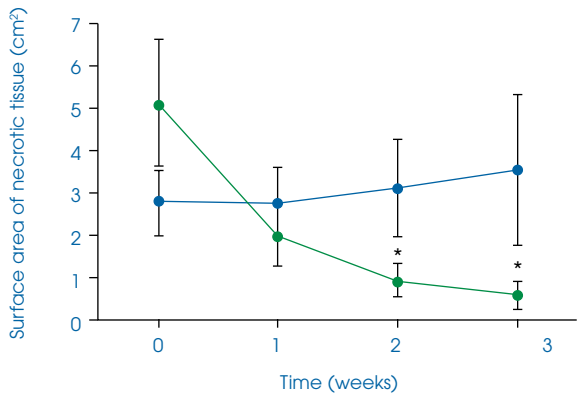
Biosurgery has been mentioned as a suitable debridement tool by several consensus groups including the:

- German Diabetic Association and the International Working group on Wound Healing and Treatments for People with Diabetic Foot Ulcers[xiv]
- International Working Group on Wound Healing and Treatments for People with Diabetic Foot Ulcers[xv]

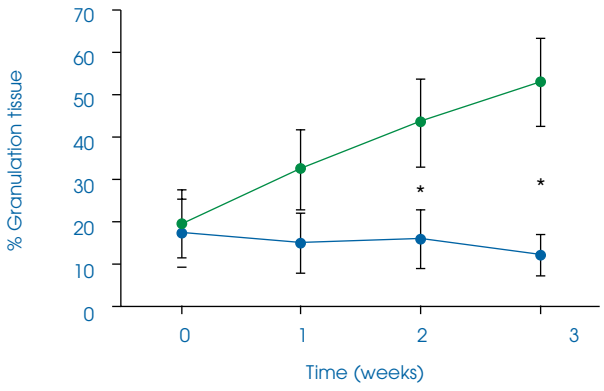
In a 12 patient trial in the UK, Wyman et al showed in 1997 that Biosurgery offered clinical efficacy and a significant cost saving when compared to hydrogels in the debridement of venous leg ulcers.

Biosurgery not only offers effective debridement but also in prepares the wound to heal, more effectively than conventional therapy as reported by Ron Sherman in 2003.

The below charts are reproduced with the kind permission of the author.



Surface area of necrotic tissue over time, during treatment with maggots (• ; n 14) or standard therapy (• ; n 14).



Percent of wound base covered by granulation tissue, over time, during treatment with maggots (• ; n 14) or standard therapy (• ; n 14).

CASE STUDIES

TREATMENT WITH BIOBAG

1: This patient was admitted to hospital with a non-healing wound on an amputation site. Despite repeated surgical debridement under anesthetic, the necrosis returned and the wound bed showed no evidence of granulation.

2: Following unsuccessful surgical and conventional interventions, the wound was treated with BIOBAG.

3: The wound after a single application of BIOBAG the wound bed is observably cleaner

4: After 13 days and three applications of BIOBAG, the wound is largely free of necrotic material, granulation tissue is well established and the wound is beginning to close.

TREATMENT WITH VITA⬢PAD

1: Following a lengthy period of immobility this patient developed an infected ulcer on his right elbow. A wound culture showed the presence of Staphelococcus aureus, on a yellow fibrinous film.

2: Following three VITA⬢PAD applications over 8 days the film was completely removed and the wound showed no visible signs of infection. The wound was then treated with conventional moist wound dressings.

BIOSURGERY – THE NURSING PERSPECTIVE

We have been using medicinal maggots in the treatment of acute, chronic and infected wounds since 1996, in the last few years we have been making up to 1,000 applications each year.

From my perspective as a nurse, the development of the VITA⬢PAD has revolutionised this therapy. Unlike free range larvae, dressing changes with VITA⬢PAD are simple, quick and can be done by anybody. This saves a significant amount of time and allows the wound to be easily inspected.

Through the secure retention of larvae by VITA⬢PAD, and that the larvae are no longer visable I have found much greater acceptance of biosurgery by patients and colleagues.

Birke Thöner
Bietigheim Hospital, Department of Accident and Reconstruction Surgery
21.06.04

GUIDELINES

VITA⬢PAD and BIOBAG are "made to order" and delivered on behalf of the physician in a sealed vial containing the dressing and a small foam designed to keep the dressing moist while in transit.

Biosurgery is indicated for the debridement (removal of dead or devitalised tissue) of wounds. The therapy should be discontinued once the wound bed is free of necrotic material or if after three or more applications no progress can be seen.

Should there be any "islands" of necrosis in an otherwise clean bed, VITA⬢PAD and BIOBAG can be applied in a targeted fashion to the necrotic areas. If for any reason the larvae should die during the therapy the dressing is no viable and must be exchanged, the vitality of the larvae can be examined at any time by removing the secondary dressing and (in the case of VITA⬢PAD) looking through the dressing "window".

BIOSURGERY

Many chronic wounds contain devitalised or necrotic tissue, which is an impediment to wound healing. In wounds where healing is impaired by the presence of dead tissue, it must be removed for healing to occur in a process known as debridement. Biosurgery is the established practice of using living organisms to achieve debridement, most typically the larvae of *Lucilia sericata*.

Prior to the availability of antibiotics, biosurgery was a well established therapy in the management of necrotic and infected wounds[xvi]. However since the 1940s larval therapy has been used only as the "salvage" treatment of last resort by a small number of specialists, but with the emergence of antibiotic resistant bacterial strains, human medicine is again "discovering" the benefits of biosurgery.

L. SERICATA

Lucilia sericata (also known as Phaenicia sericata) was first established as an ideal species for biological debridement by W.S. Baer shortly after the First World War[xvii]. The larvae of *L. sericata*, the blowfly, feed exclusively on devitalized tissue and are unable to digest living tissue.

The larvae of *L. sericata* must pupate before they transform into flies and become able to lay eggs, assuming an abundance of food, the larvae are able to pupate 140 hours (5–6 days) after hatching. The larvae are only able to pupate in a dry environment, therefore correctly used, larvae cannot pupate in VITA⬢PAD.

IMPORTANT GUIDELINES FOR THE USE OF VITA⬢PAD AND BIOBAG

VITA⬢PAD and BIOBAG dressings contain living organisms, there for care must be taken to maintain an ideal environment for the larvae:

DO

- Ensure the dressing is kept moist, but not wet
- Ensure the wound is rinsed irrigated to remove any residue or ointment
- Ensure adequate ventilation to the dressing
- Ensure the dressing cannot be crushed (e.g. by the patient walking on the dressing)
- Monitor larval activity

DO NOT

- Concurrently use products that may be harmful to living organisms (such as detergents or antiseptics)
- Use occlusive dressings over VITA⬢PAD or BIOBAG
- Wrap secondary bandages too tightly

APPLICATION GUIDE

1: The wound should first be irrigated with sterile saline in order to remove any loose non-viable tissue or ointment residue. Remove VITA⬢PAD* or BIOBAG from its transport container with sterile pincers. Moisten gently with sterile saline and apply to the desired areas of the wound. If two or more dressings are used they should not overlap.

2: VITA⬢PAD and BIOBAG can be folded to fit uneven wound surfaces or cavity wounds.

3: VITA⬢PAD and BIOBAG should be covered with sterile, saline moistened gauze and held in place with a permeable bandage or adhesive tape. Ensure secondary dressing does not deprive the wound bed of air.

4: Larval activity and vitality can be monitored at any time during the treatment, in the case of VITA⬢PAD through the dressing "window", in the BIOBAG the larvae can bee seen through the polyester net.

5: VITA⬢PAD and BIOBAG should be left in place for a maximum of five days, depending on the wound environment and treatment progress. The dressing can then be easily removed and disposed of in a sealed bag as per the facility's usual protocol for used dressings.

* SPECIAL CONSIDERATIONS FOR THE USE OF VITA⬢PAD AND BIOBAG

In order to ensure an ideal exchange of larval secretions, VITA⬢PAD and BIOBAG dressings must be kept moist (but not wet). VITA⬢PAD and BIOBAG dressings should be checked two times daily and remoistened if necessary with sterile saline.

PRESCRIBING INFORMATION

Description of the medicine
See Brochure Text

Prescription only medicine
VITA●PAD and BIOBAG are only available on prescription and are manufactured and shipped at the request and at the responsibility of the prescribing physician. VITA●PAD and BIOBAG are manufactured for the patient named on the prescription (named patient basis), and must be ordered individually for each patient. VITA●PAD and BIOBAG are single use only. The information contained within this brochure is based on available clinical publications and the advice of leading physicians.

Indications and Contraindications
See Brochure Text

Instructions for use
See Brochure Text

Duration of treatment
See Brochure Text

Dosage and Application
See Brochure Text

Special precautions for use
See Brochure Text

Warnings
None known

Interactions with other substances
Factors such as an inadequate supply of oxygen through inappropriate or too tight secondary dressings, radiation, disinfectants and cytostatic substances can have a negative effect on the vitality of the larvae, therefore the effectiveness of the treatment. Concurrent treatment with the above named substances should be avoided. Infection with pseudomonas, Proteus or E. coli should be treated and reduced prior to treatment with VITA●PAD or BIOBAG.

Side effects
On rare occasions bleeding has been reported during treatment, therefore it is recommended to check the dressings at least once a day. In the event of bleeding discontinue VITA●PAD or BIOBAG treatment and continue to monitor the wound. Usually treatment with VITA●PAD and BIOBAG reduces pain associated with the wound, in rare case an increase in pain had been reported, in this event either discontinue treatment or administer systemic analgesics.

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