



CLINICAL GUIDELINE

Prescribing Larvae, Unlicensed Medicine Protocol

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The Intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

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Introduction

Larval Debridement Therapy

Larval Therapy is a natural form of wound debridement using living Larvae of the greenbottle fly species *Lucillia Sericata*. Larval therapy is indicated for the debridement of necrotic, sloughy wounds such as pressure ulcers, diabetic foot ulcers, surgical and traumatic wounds such as haematomas.

The larvae produce enzymes which contain a variety of proteolytic enzymes which break down the devitalised tissue and bacteria into a liquid form which they then remove and digest reducing the bioburden within the wound. They need to be able to penetrate their 'mandibles' to achieve mechanical debridement, the physical action assists in liquidisation of the devitalised tissue and physical removal of the slough.

Prescription for larvae

All patients with a wound requiring debridement must have holistic assessment, diagnosis and treatment plan initiated to optimise positive patient outcomes.

Larvae are classified as an Unlicensed Medicine (ULM). For this reason clinical staff should be aware of and follow the advice in the ULM policy and Medicines and Healthcare products Regulatory Agency (MHRA) guidance. At present, the following healthcare professionals can prescribe an unlicensed medicine: doctors, independent prescribers and supplementary prescribers (on completion of a Clinical Management Plan). This protocol is to support the appropriate use of larvae across NHS GGC healthcare services.

"All healthcare professionals who can prescribe are subject to: their individual clinical competence; the professional codes and ethics of their statutory bodies; and the prescribing policies of their employers." (MHRA, 2009)

Prior to initiating the prescription of larvae, the clinician prescribing the therapy should be satisfied that an alternative, licensed medicine would not provide a similar clinical outcome. (Appendix 1). The clinician will take responsibility for prescribing larvae and provision of a plan of care. If other clinicians are involved in the patient care this should be communicated by the prescribing clinician prior to administration to those involved.

If at any time in the process one of the multi-disciplinary team decide that the larvae prescription should not be processed, in favour of a licensed product, it is considered best practice to discuss the rationale for this, with the patient and the originating prescribing clinician or multidisciplinary team.

Patient consent

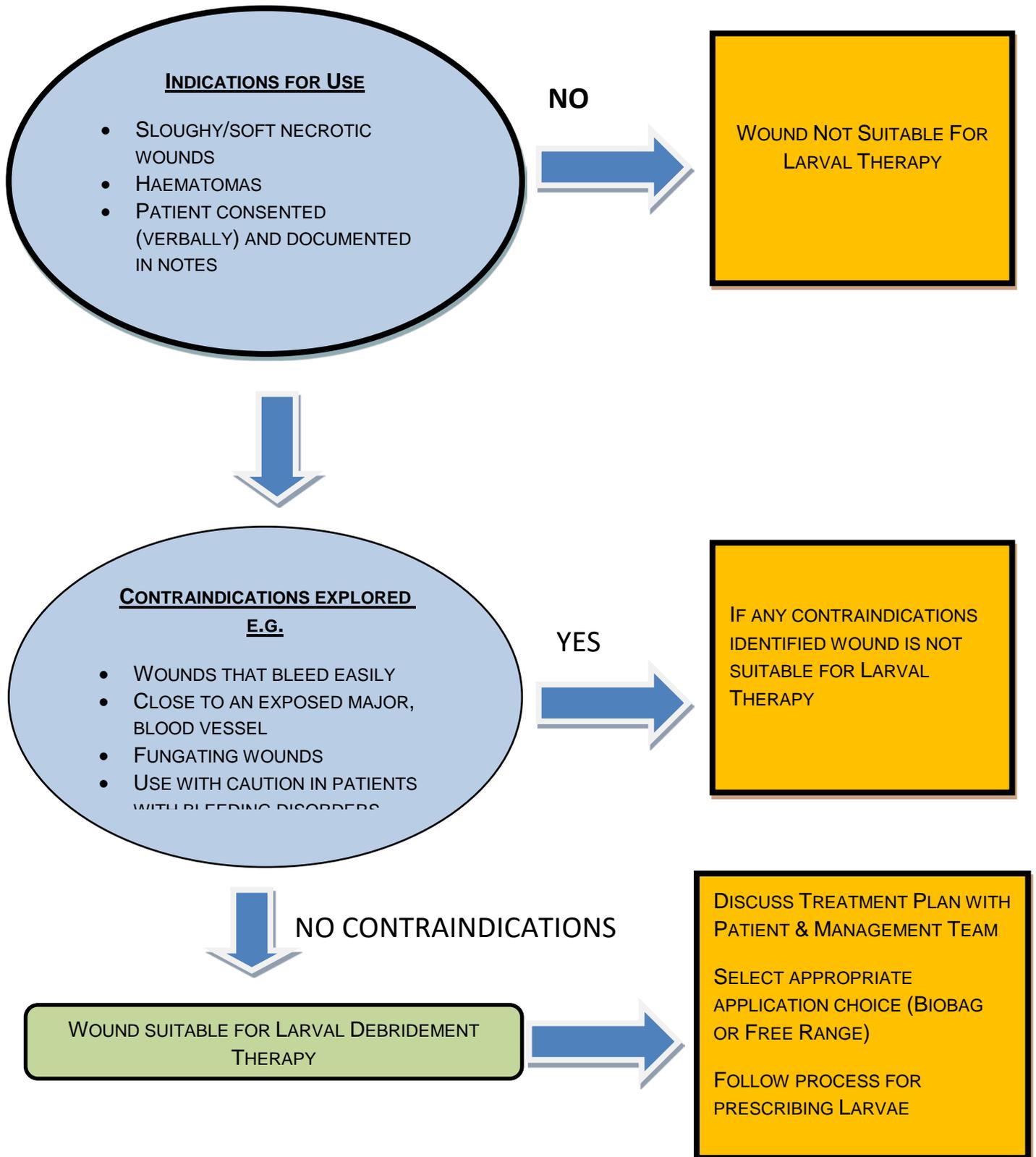
"It is good practice to give as much information as patients or carers require or may see as relevant. (MHRA, 2009). This includes any known serious or common adverse reactions, to enable them to make an informed decision"

Application of Sterile Larvae

Healthcare professionals are accountable for their practice and when they consider larvae therapy to be optimum clinically effective choice must be competent in the application and ongoing management.

Clinicians, who are involved in the clinical management team and require further support, should contact the relevant service involved e.g. Vascular Liaison Nurse, Podiatrist or Tissue Viability Nurse. Information on correct clinical management can also be accessed on www.biomonde.com.

Larval Therapy Flowchart



Larvae Presentation

Two methods:

Larvae are available either enclosed in a heat-sealed mesh pouch or BioBag™ and Free Range. Both products are effective in wound debridement, however the choice of product is a clinical decision taken on a patient by patient basis. The BioBag™ is a sealed mesh bag containing the larvae; it provides ease of application and allows examination of the wound. It is placed directly onto the wound and can be used on almost all wound types. The Free Range Larvae are particularly suitable for cavities, undermining, deep wounds and circumferential or awkwardly shaped wounds.

Both products are delivered in a polystyrene temperature-controlled box and should be stored at room temperature until use. Delivery is available Monday to Saturday and can be delivered to Acute Care, Pharmacy and Care Homes.

1. BioBags are enclosed in a sealed container. Sudocrem™ is supplied to protect the peri-wound margins from enzymes produced by the Larvae. Wound should be cleaned with water/saline and Sudocrem applied to wound margins.

The BioBag is placed directly onto the wound (see below for details on retention).

2. Free Range Larvae are enclosed in a sealed container and applied directly onto the wound. The kit contains:
 - A Hydrocolloid dressing, Granuflex™ to frame the wound top protect peri wound margins.
 - Retention net/boot net, to contain larvae at wound bed.
 - Sleek™ adhesive tape to attach net to hydrocolloid border. This should not cover active larvae area.
 - Normal Saline pod to flush larvae from container, are supplied.

Application and daily care guides are supplied with each delivery. A moist gauze swab should be placed over the Biobag or Free Range Larvae retention net and held in place with a simple secondary non-occlusive dressing applied on top e.g. Zetuvit™. Refer to Wound Formulary for further information on product choices.

[http://www.ggcprescribing.org.uk/media/uploads/other_formularies/2018_wound_formulary_\(amended_december\)_1\).pdf](http://www.ggcprescribing.org.uk/media/uploads/other_formularies/2018_wound_formulary_(amended_december)_1).pdf)

NEVER apply foams, or coated dressings on either Biobags or Free Range Larvae. These will suffocate the Larvae.

Dosage and duration of treatment:

For guidance on volume or larvae required refer to Biobag and Loose larvae size guide (Appendix 2)

- One or more Bio Bags can be applied to cover the entire area of devitalised tissue, taking care not to overlap the dressings.
- Bio Bags can be left in place for a maximum of four days, depending on the wound environment and the progress of the treatment.
- Free range larvae can be left in place for three days.
- If the wound is not completely clean within four days; consider repeating treatment or using an alternative method of debridement.
- Treatment should be discontinued once the wound is suitably debrided, or if no progress can be observed after two applications.

Nb if wound slough continues to reappear between wound management interventions, patient may require vascular referral to assess perfusion and consider if vascular intervention is required.

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Additional information on application:

Clinical management and patient information leaflets can be obtained from BioMonde at <http://biomonde.com/en/>. Clinicians are advised to access this site prior to use of larvae and seek additional support if required, to ensure that they are working to their level of competency.

To support Continuous Professional Development and evidence for revalidation/eportfolio on accredited on line learning for larval debridement therapy access www.larvalacademy.com.

Acute Care Process for prescribing Larvae

Do not prescribe/order larvae direct from Biomonde.

This will be processed by your Pharmacy Distribution Centre

Process steps: Ward or clinical department

1. Larvae must be prescribed on patient prescription chart (as with any medication).
2. Complete Larvae Proforma to be delivered to local pharmacy for Pharmacy Distribution Centre (PDC) (Appendix 3)

In order to ensure timely delivery and accurate order ensure all details are complete prior to sending Proforma.

Information required by Biomonde:

Delivery date, place of delivery including full address and postcode, Ward/Clinic Ascribe Code, Patient Initials and what is needed (i.e. presentation Biobag or Free Range with size required). (Appendix 2)

The remaining information on form is necessary for GGC internal use.

3. Deliver Proforma and a copy of the prescription form to your LOCAL Hospital Pharmacy Department (local numbers provided on following page)

Process steps: once proforma sent to PDC

4. Ensure contact telephone number for your area is included in case you need to be contacted to prevent any unnecessary delays.
5. Once this is complete your pharmacy department will email the Proforma to the Pharmacy Distribution Centre (PDC) during working hours, 9am – 5pm, Monday to Friday

Note: it is imperative that orders for larvae are placed with your LOCAL Pharmacy Department no later than 9.30am to ensure delivery the next day

Action required on receipt of larvae:

1. Receiving areas must confirm receipt of larvae by emailing a copy of the delivery note (which will accompany the larvae) to PDC Customer Service Department at the following e-mail address: support@ggcpdc.zendesk.com
2. Queries should be directed to PDC Customer Services at 0141 347 8974.

Contact Numbers for LOCAL Pharmacy Departments (Acute Care)

Delivery of Larvae order proforma delivery and contact number for Local Pharmacy Departments.

Hospital Site	Larvae Order Proforma Delivery	Telephone Number
Beatson Gartnavel General	<ul style="list-style-type: none">• Internal Mail• Hand Deliver	0141 211 (5) 3315
Inverclyde	<ul style="list-style-type: none">• Fax 01475 504930• Internal Mail• Hand Deliver	01475 504620
Stobhill Hospital Glasgow Royal Infirmary	<ul style="list-style-type: none">• Internal Mail• Hand Deliver	Stobhill (satellite) 0141 211 (1) 1653 Royal 0141 (2) 211 5004
Royal Alexandra Hospital	<ul style="list-style-type: none">• Pod System• Internal Mail• Hand Deliver	0141 314 (0) 7070
Queen Elizabeth University Hospital	<ul style="list-style-type: none">• Pod System• Internal Mail• Hand Deliver	0141 452 (8) 2957
Vale of Leven	<ul style="list-style-type: none">• Internal Mail• Hand Deliver	01389 817540 87540

Primary Care Process for Prescribing Larvae via Community Pharmacy

Do not prescribe larvae direct from Biomonde

1. Medical or independent prescriber may prescribe with completion of prescription form as per procedure for prescribing medication, with prescription submitted to community pharmacist.
2. Supplementary prescribers must have a completed Clinical Management Plan (CMP) and follow above steps. The CMP is retained in the patient's notes.
3. In order to ensure timely delivery and accurate order Biomonde must have information on the required delivery date, place of delivery, an order number and what is needed (i.e. presentation Biobag or Free Range with code and size required).(Appendix 2)
4. Community pharmacist will order the product from Biomonde and submit the prescription and invoice for payment in the usual way.
5. Delivery of larvae to be arranged between the Community Pharmacist and the Prescriber detailing name and address with postcode of the health centre and named nurse delivery to the relevant health centre.

It is essential that completed prescription details the delivery address as the Health Centre/Clinic/Care Home with post code and NOT patient home to ensure documentation is received and completed by health care professional.

Further reading and references:

1. All Wales Guidance for use of: larval debridement (2013): http://www.welshwoundnetwork.org/files/6513/8632/3119/AWTVNFlarval_finalforweb_opt.pdf
2. Biomonde: Information on Use of Larvae: <http://biomonde.com/en/>
3. Biomonde: Larval Academy at: www.larvalacademy.com
4. Biomonde: Patient Home Care Guide: https://biomonde.com/images/US_Linked_Docs/BM018_US_01_0316.pdf
5. Gov.Uk (2009) Off-label or unlicensed use of medicines: prescribers' responsibilities: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>
6. Gov.UK (2015) Report a problem with a medicine or medical device ("Yellow Card"): <https://www.gov.uk/report-problem-medicine-medical-device>
7. Griffin J (2014) Wound Care: What nurses need to know about the application of larval therapy. Journal Community Nursing. Vol. 28, No 2, 58-62: <https://www.jcn.co.uk/files/downloads/articles/04-2014-what-nurses-need-to-know-about-the-application-of-larval-therapy.pdf>
8. Health Care Professions Council (HCPC) Standards of conduct, performance and ethics (2016): <http://www.hcpc-uk.org/aboutregistration/standards/standardsofconductperformanceandethics/>
9. MHRA (2019) Yellow Card System and Datix: <https://yellowcard.mhra.gov.uk/>
10. Nursing & Midwifery Council. The Code: Professional standards of practice and behaviour for nurses and midwives (Updated 10th October 2018): <https://www.nmc.org.uk/standards/code/>
11. Wounds UK (2013): Effective debridement in changing NHS: a UK consensus: https://lohmann-rauscher.co.uk/downloads/clinical-evidence/Effective_debridemen.pdf
12. Wounds UK (2013) Maximising the secondary beneficial effects of Larvae: <https://www.wounds-uk.com/download/resource/957>

Appendix 1: Debridement selection Tool – two pages

This tool can aid you in your choice of appropriate debridement method, reducing risk to the patient, ensuring a positive patient experience, promoting continuity of care, and reducing variations in practice - thereby delivering cost effectiveness. The method of debridement chosen must deliver a patient centred approach taking into account patient issues such as pain, comorbidity and lifestyle choices

More than one method of debridement may be required for a wound dependent on a number of wound bed factors, including perfusion to wound bed; stage of hydration and viscosity of slough or necrotic tissue. Removing barriers to healing through debridement will also reduce bacterial burden, reveal underlying wound bed and support ongoing management plan. Choice of debridement method does *not* therefore follow a hierarchy from gel to surgical debridement.

For information on NHS GGC wound formulary products noted below refer to <http://www.ggcprescribing.org.uk/nonmedicines/formularies/>

Key and definitions

L: Larval Debridement Therapy	Bagged or Free Range Larvae debrides and reduces bacterial burden over a period of 3 – 5 days, revealing underlying wound bed. There is no need for additional dressing changes or products.
A: Autolytic: e.g. hydrogel, hydrocolloid and hydrofibre dressings*	The destruction of non-viable tissue by hydration/donation action. Products vary in duration taken to hydrate slough and sequester into dressing. Dressing changes will be dependent on method chosen and level/viscosity of exudate
M: Mechanical Debridement- Debrisoft™ monofilament pad (Primary care) and UCS cloth™ (Acute).	Enables debridement and cleansing of wounds by removing moist slough. Efficacy of debridement is apparent at time of use. Requires wound dressings between changes e.g. hydrofibre dressings to facilitate further debridement and manage exudate.
↑ GENERALIST USE	↓ SPECIALIST USE
H: Hydrosurgical: Versajet™	Excises and evacuates necrotic tissue, bacteria and contaminants from wounds, using a razor-thin saline jet that spares viable tissue. Procedure can remove all slough/necrosis at one intervention and can be carried out in outpatient department or theatre. Specialist use only.
S: Sharp/surgical:	Use of scalpel to remove slough/necrosis and infected tissue. Specialist use only. May not always achieve full debridement at one intervention. Risk of disrupting viable tissue. Surgery may be required with general anaesthetic to carry out extensive debridement, due to proximity to vital organs/blood supply, pain.
<p>Nb if wound slough continues to reappear between wound management interventions patient may require vascular referral to assess perfusion.</p>	

2. Assessment of the Wound – selected debridement therapy guidance

L = Larvae;

A= Autolytic;

M = Mechanical;

H = Hydrosurgery;

S = Sharp

SU = Surgical

Suitability of selected treatment choices:

Sloughy wound bed

Thin, watery, white mobile slough			M		S	SU
Stringy, yellow, patchy slough	L	A	M	H	S	SU
Yellow, thick tenacious slough	L	A		H	S	SU
Thick tenacious gum-like slough	L	A		H	S	SU

Necrotic wound bed

Soft islands of necrosis	L	A	M		S	
Soft soggy necrosis	L	A	M		S	
Black/brown eschar with loose edges	L	A		H	S	
Hard, brown/black eschar firmly fixed		A		H	S	SU
Haematoma	L	A	M			

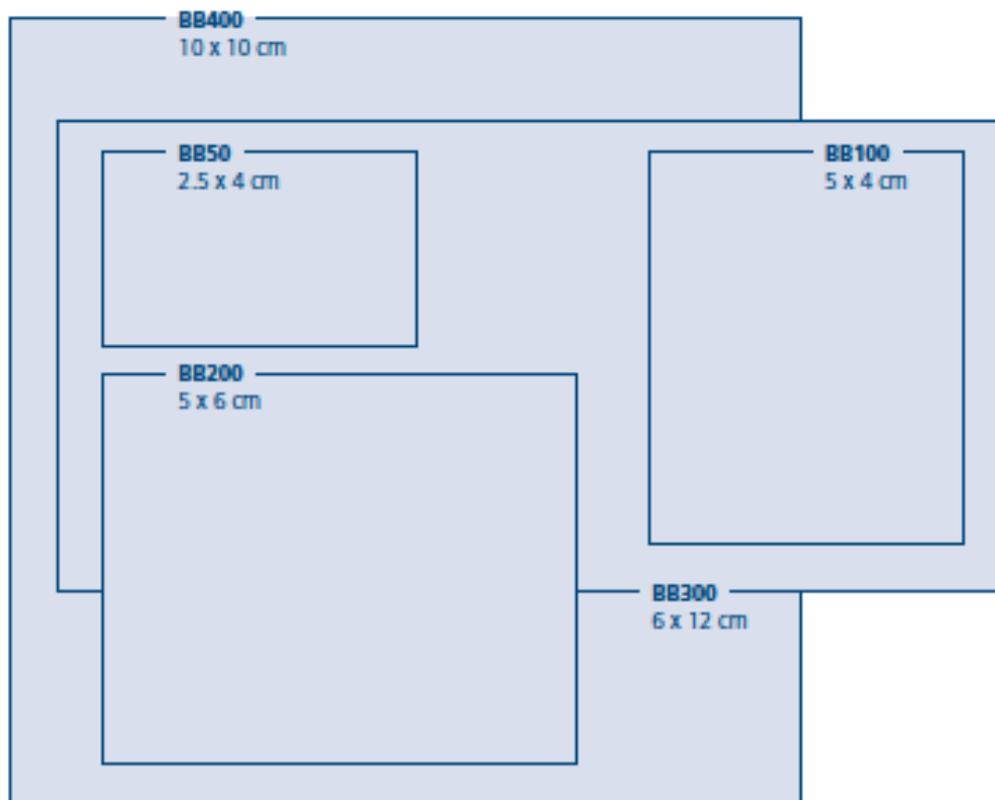
Key Points

- Remember debridement may remove surface contaminants as well as barriers to healing such as bacteria and dressing residue to reveal wound bed
- Choose appropriate debridement method from above, based on your clinical Judgement
- If wound continues to produce slough or is resulting in unwanted side effects e.g. peri-wound maceration, odour, review method of debridement
- Apply **SIMPLE** acronym to double check correct treatment choice. This should include consideration to cost of debridement choice, number of expected interventions and clinician time.

SIMPLE: Safe, I ndicated, M easurable, P atient advantage, L ongevity, E nd point



BloBag® Size Guide



Loose Larvae Calculator

1. Measure the dimensions of the wound in centimetres
2. Pick the nearest size from the measurements on the left of the chart
3. Move sideways to the appropriate percentage of wound coverage
4. The recommended number of larvae required is indicated.

Key

- 1 x Larvae100®
- 1 x Larvae200®
- 1 x Larvae100® + 1 x Larvae200®
- 2 x Larvae200®
- Use combination of Larvae100® + Larvae200® as required

Maximum wound size (cm)	Percentage of wound covered with slough/necrotic tissue				
	20%	40%	60%	80%	100%
up to 2 x 2	100	100	100	100	100
5 x 5	100	100	100	100	200
5 x 10	100	100	200	200	300
10 x 10	100	200	300	400	500
10 x 15	200	300	500	600	800
15 x 15	300	500	700	900	1200
15 x 20	300	600	900	1200	1500
20 x 20	400	800	1200	1600	2000

Note that the calculator only measures the surface of the wound. If the wound has significant depth, more larvae may be required.

BM48_EN_09_0618

To: CUSTOMER SERVICE

PHARMACY DISTRIBUTION CENTRE

Tel: 0141 347 8974

WARD/CLINIC ASCRIBE CODE:

PATIENT INITIALS:

DELIVERY DATE REQUIRED:

AUTHORISATION SIGNATURE:

REGISTRATION NUMBER:

(GMC/NMC/HCPC/GPhC)

YOUR NAME

YOUR SIGNATURE

TEL NO:

ZOOBIOTIC PRODUCT CODE	ASCRIBE NSV CODE	QTY	DESCRIPTION
BB50	PDC793M		BioBag 2.5cm x 4cm
BB100	PDC794N		Biobag 5cm x 4cm
BB200	PDC795O		Biobag 5cm x 6cm
BB300	PDC796P		Biobag 12cm x 6cm
BB400	PDC797Q		Biobag 10cm x 10cm
STVIAL100	PDC409A		Larvae 100 with Retention Net
STVIAL200	PDC410B		Larvae 200 with Retention Net
BTVIAL100	PDC411C		Larvae 100 with Boot Net
BTVIAL200	PDC412D		Larvae 200 with Boot Net