PolyNovo®

Clinical Application Guide for Full Thickness Wounds

NovoSorb® BTM

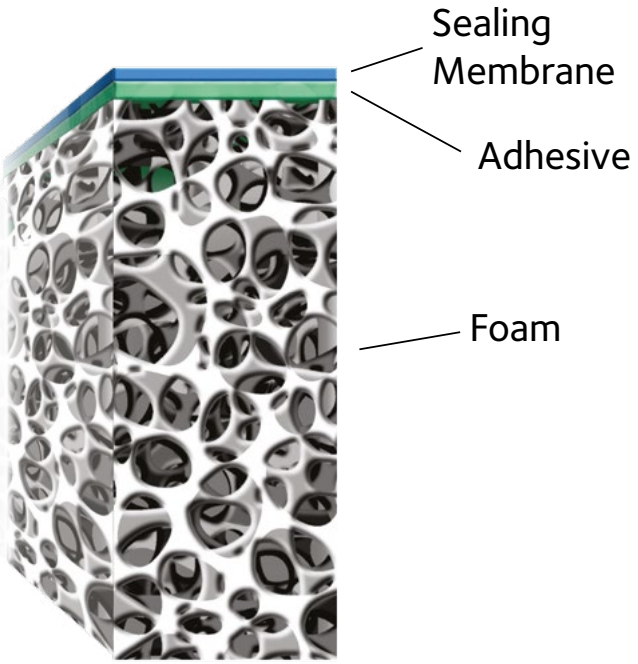
Biodegradable Temporising Matrix

Improving outcomes.
Changing lives.

NovoSorb® BTM
Description & Indications

Description

NovoSorb® BTM is a bioabsorbable dermal matrix developed for the treatment of full thickness wounds where the dermal structure has been lost due to trauma or surgical debridement. The NovoSorb® BTM Wound Dressing is composed of a polyurethane porous white foam adhered to a fenestrated transparent sealing membrane by a polyurethane adhesive.



Sealing Membrane
A temporary, transparent polyurethane membrane designed to physiologically close the wound and limit evaporative moisture loss.

Adhesive
A polyurethane adhesive which adheres the foam and sealing membrane together.

Foam
A wound-facing, 2mm thick, white, open cell foam. The foam is a bioabsorbable polyurethane material.

Indications

NovoSorb® BTM is indicated for full or deep partial thickness burns, surgical and reconstructive wounds and traumatic wounds.

Intended Use

The NovoSorb® BTM is intended to temporise dermal injuries, where the dermis has been decimated or lost, and to facilitate dermal repair by providing temporary wound closure and a scaffold for the generation of a neodermis.

This device is intended for single use.

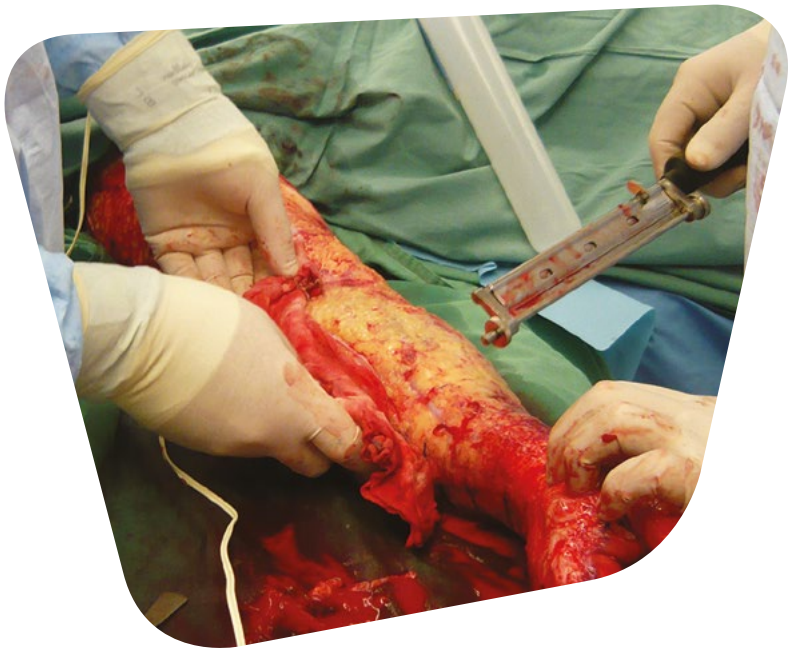
Step 1
Wound Preparation

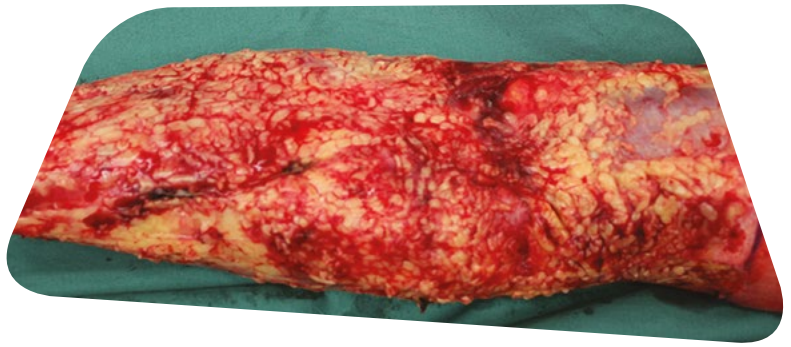
NovoSorb® BTM is designed to integrate to the wound bed if the margins and bed consist of viable tissue.

Preparing the Wound Bed

- Completely excise all non-viable tissue in the wound
- Hemostasis should be achieved in the wound bed
- The wound should be free of infection

These instructions are general guidelines, refer to IFU for full instructions. These guidelines are not designed to replace existing institutional protocols or professional clinical judgment regarding patient care.





Step 2
Prepare

Preparing the NovoSorb® BTM

- Open the package on the “chevron” side (the tip of the arrow-shaped seal)
- NovoSorb® BTM is supplied fenestrated. If the wound bed is expected to be heavily exudative, the sealing membrane may be further fenestrated with a scalpel to provide drainage holes
- NovoSorb® BTM is ready for application straight from the packaging, no further preparation is required.

Note:
Do not mesh NovoSorb® BTM.

Step 3
Application

Applying NovoSorb® BTM to the Wound Bed

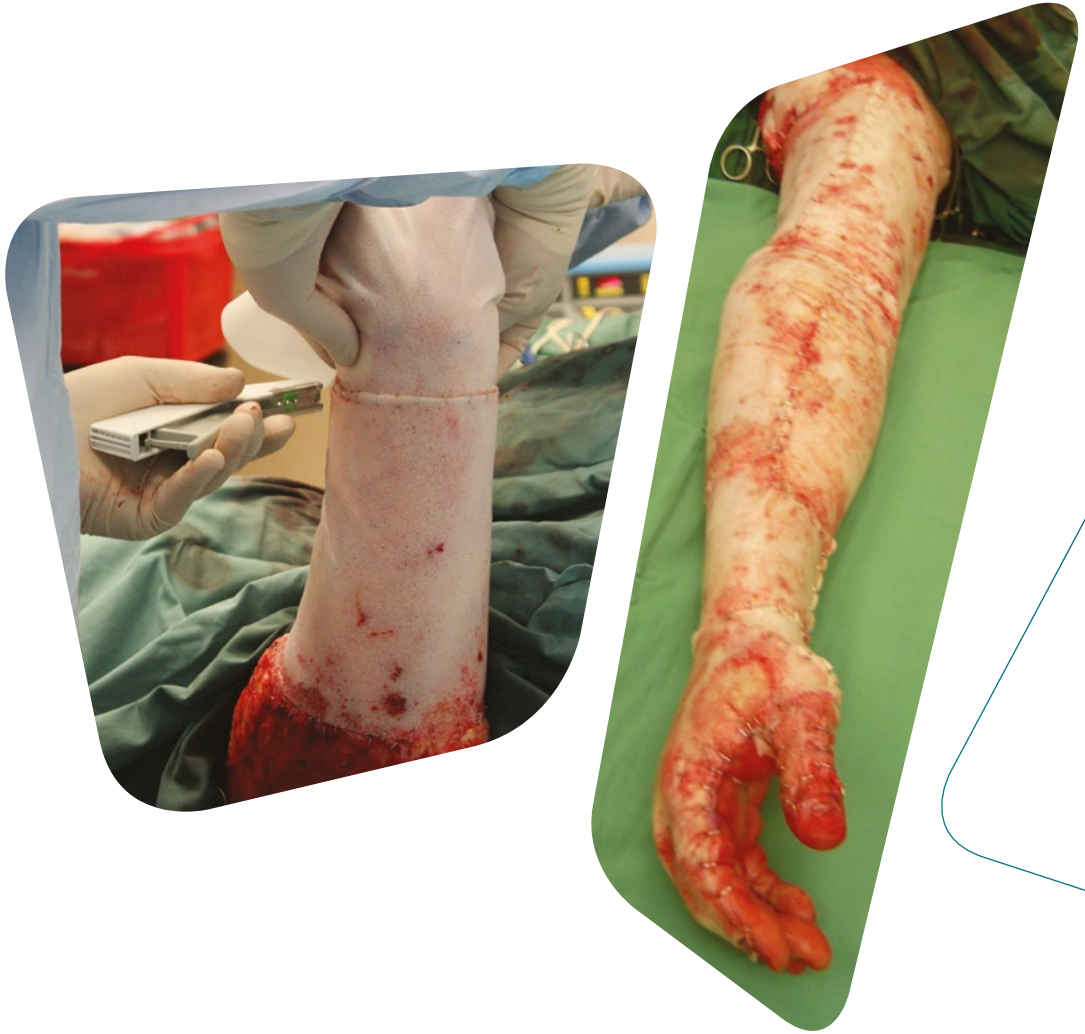
- Apply NovoSorb® BTM with foam side in contact with wound bed
- NovoSorb® BTM should lay flat in the wound bed with no creases
- Once flat against the wound bed, NovoSorb® BTM is secured with staples or sutures

Note:

– *For large areas of application, quilting staples can be used to secure the NovoSorb® BTM to the wound bed*

– *Adjacent pieces of NovoSorb® BTM can be stapled or sutured together as required*

– *Avoid overlapping adjacent pieces*



Step 4
Outer Dressings

Outer Dressings

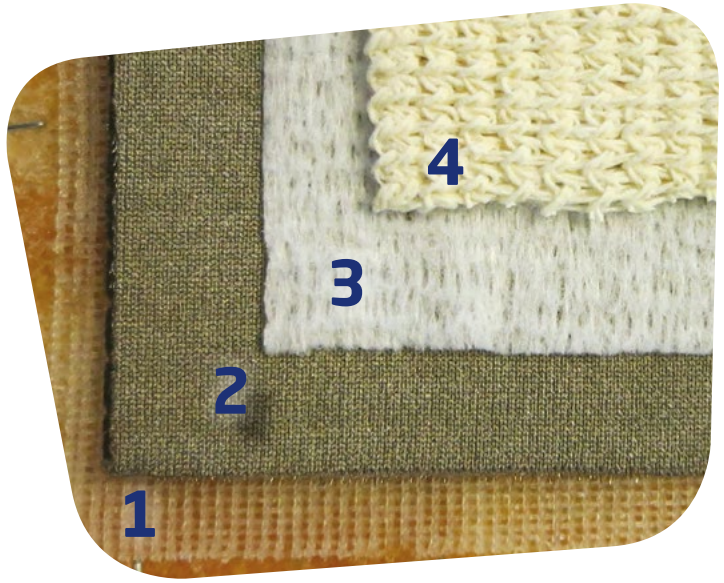
The choice of outer dressings should:

- Not adhere to NovoSorb® BTM
- Absorb mild exudate
- Possess an antimicrobial property
- Encourage continued contact of the NovoSorb® BTM to the wound bed without shear

Collections of turbid fluid or hematomas under the seal can be expressed via the fenestrations in the overlying seal. If necessary, the sealing membrane may be further fenestrated with a scalpel to provide drainage holes.

For example:

1. Apply a non-adherent contact layer directly over NovoSorb® BTM
2. Apply an antimicrobial dressing
3. Apply gauze or other absorbant dressing
4. Apply outer crepe dressing



Step 5
Perform Wound Care

Performing Wound Care

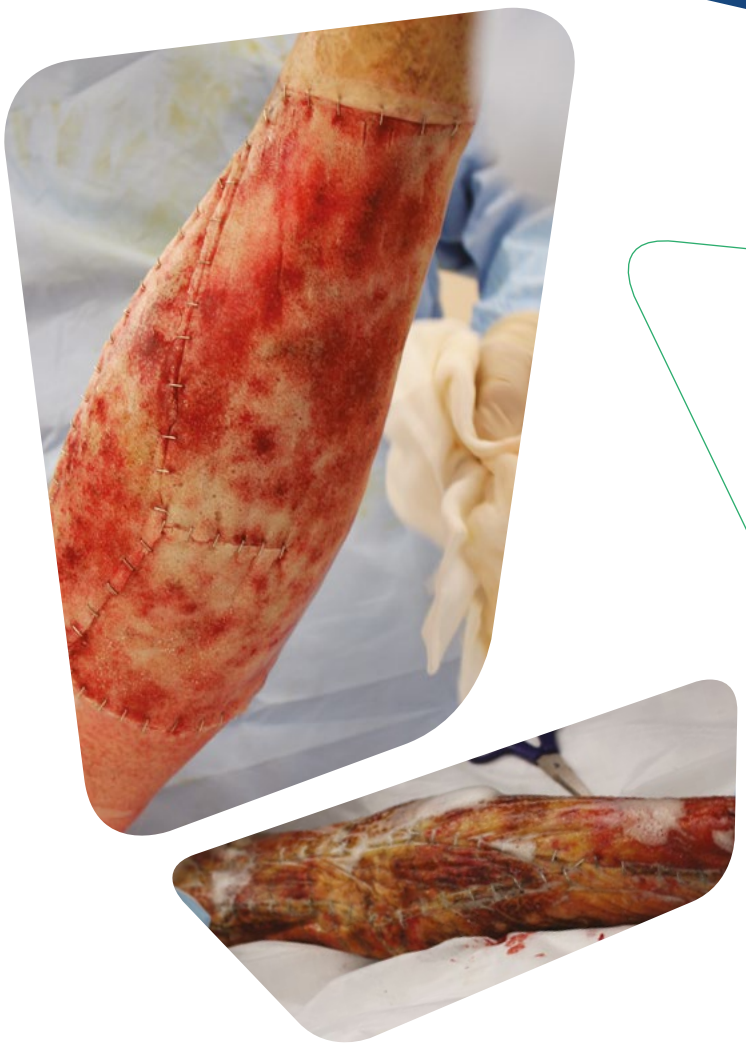
Under aseptic conditions:

- Remove all dressings, non-adherent contact layer may be retained or discarded at first dressing change per clinical judgment
- Do not remove NovoSorb® BTM and/or staples/sutures
- Gently wipe the NovoSorb® BTM surface with a saline gauze and/or antimicrobial preparation such as chlorhexidine solution or povidone-iodine solution
- Replace dressings following standard of care

The dressings should be removed and replaced as frequently as required for:

- Dressings with absorbed exudate to be discarded
- Replacement of antibacterial agents once their period of therapeutic effect has expired

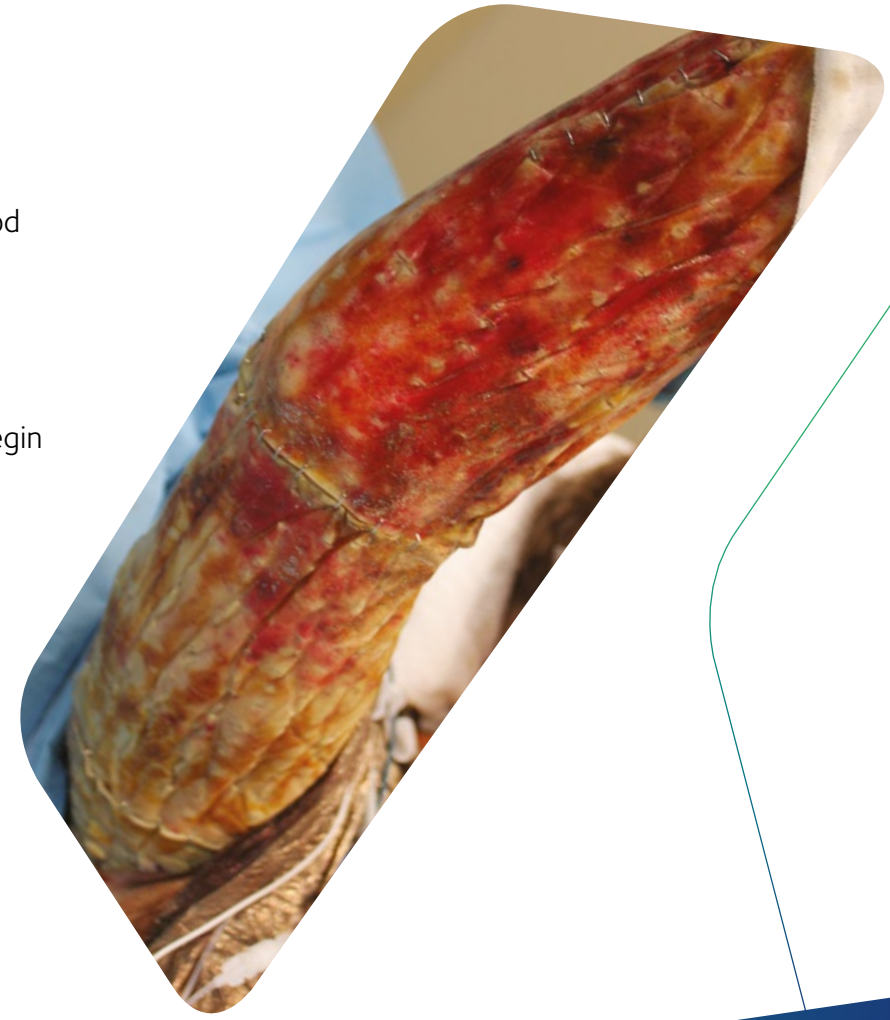
Staples or sutures remain in place until NovoSorb® BTM is fully integrated to the wound or until delamination.



Step 6
Assess Tissue Integration

Week 1-2 Tissue Integration

- NovoSorb® BTM foam is visible through the clear sealing membrane
- NovoSorb® BTM is dark red in color due to ingress of blood from the wound
- NovoSorb® BTM gradually changes to a lighter red color during this time period
- Collections of turbid fluid or hematomas under the seal can be expressed via the fenestrations in the overlying seal
- By the end of week 2, signs of integration should be visible
- Once NovoSorb® BTM has adhered to the wound bed, range of motion can begin



Note:

The color of the NovoSorb® BTM at various stages of integration may vary between patients.

Step 6
Assess Tissue Integration

Week 3-6 Tissue Integration

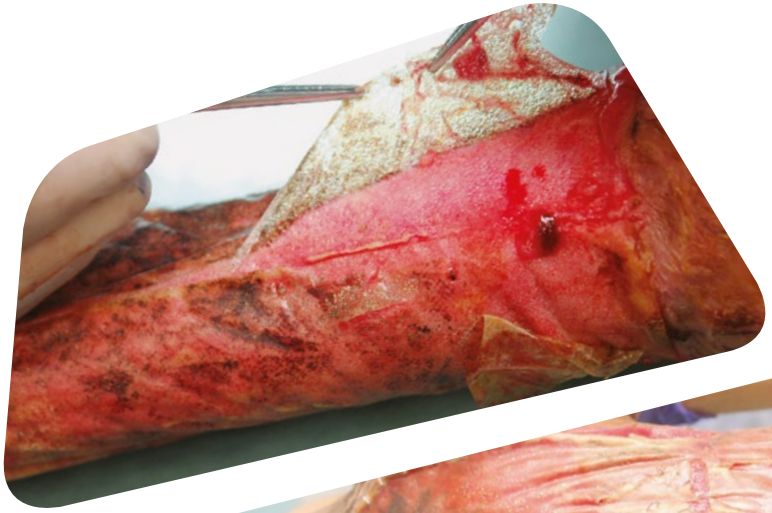
- The foam cell architecture and patterns seen initially through the seal are gradually obliterated as the NovoSorb® BTM further integrates
- Later during this time period capillary refill (blanching) may be observed by applying digital pressure to the sealing membrane
- When the foam cells are no longer visible, there is capillary refill and the matrix is a uniform pink colour, then the NovoSorb® BTM is ready for delamination

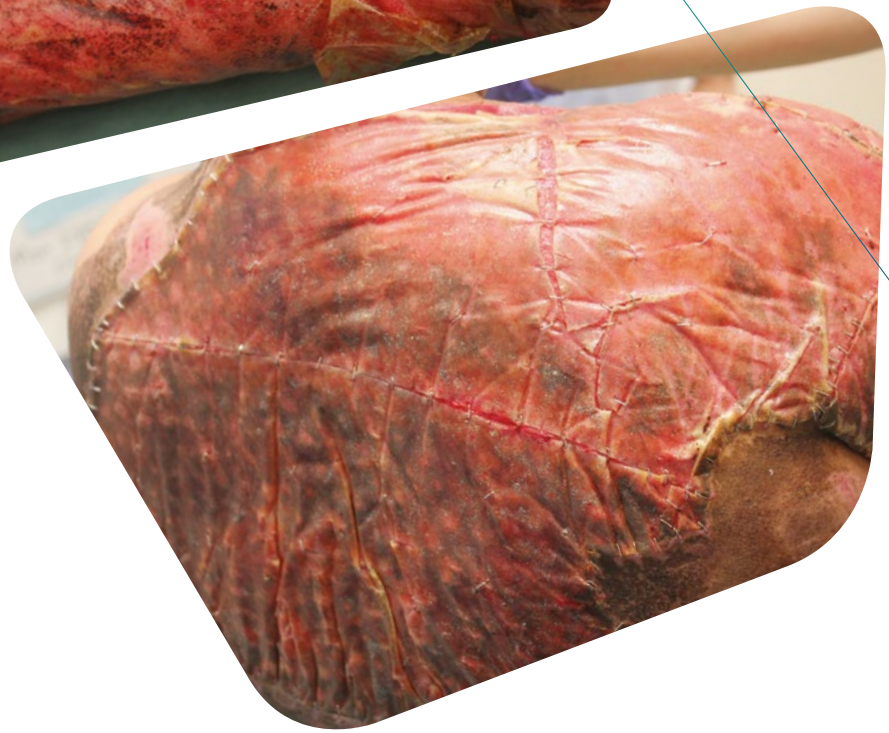
Note:
The use of certain silver dressings may leave a black tarnished appearance on the surface of the NovoSorb® BTM.

Step 7
Delaminate

Delaminating the NovoSorb® BTM

- Remove all staples and/or sutures
- Using forceps, raise a free edge of the sealing membrane
- Peel the membrane off the matrix using gentle, even traction





Note:

Any unintegrated matrix fragments will pull away with the seal. However, integrated NovoSorb® BTM will remain firmly adhered to the wound bed.

Step 8
Wound Closure Options

Methods of Wound Closure

Split Thickness Skin Graft

- Prepare skin graft for closure following standard protocol

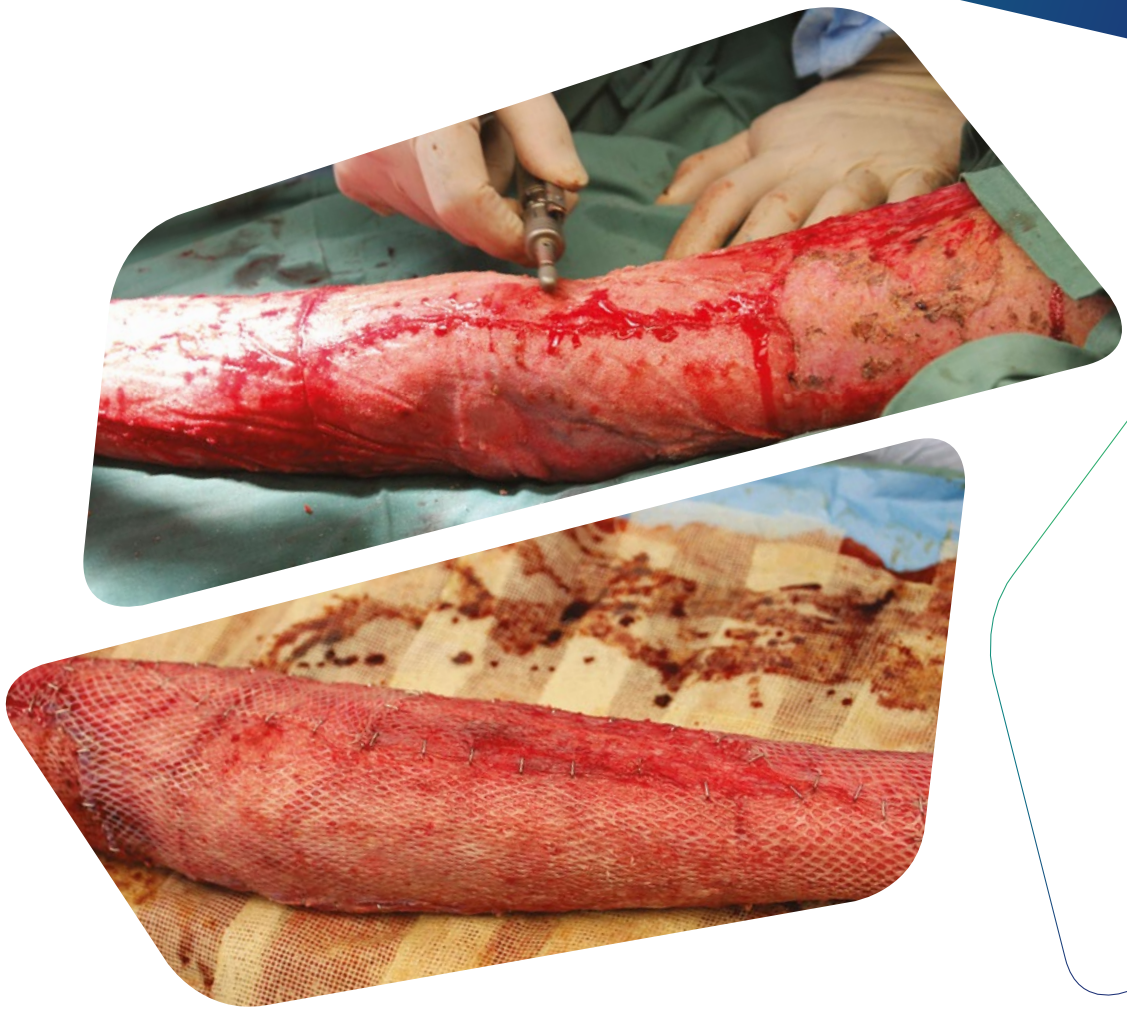
> **Note:**
> *A mild refresher to the newly delaminated surface may be considered.*[1,2]

- Skin grafts can be applied and dressed according to standard of care

Secondary Intention

- For wound closure by secondary intention healing, the integrated and delaminated NovoSorb® BTM can be dressed according to standard of care

> **Note:**
> *It is clinician's choice to determine best method of wound closure for their patient.*



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References
[1] Greenwood et al, Reconstruction of Extensive Calvarial Exposure After Major Burn Injury in 2 Stages Using a Biodegradable Polyurethane Matrix, Eplasty, Vol.16, ID e17, 2016.
[2] Wagstaff et al, Reconstruction of an Anterior Cervical Necrotizing Fasciitis Defect Using a Biodegradable Polyurethane Dermal Substitute, Eplasty, Vol. 17, ID e3, 2017.

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