NovoSorb®

BTM

Biodegradable
Temporising Matrix

Surgical Guide

PolyNovo®

Healing. Redefined.

NovoSorb®

BTM

Biodegradable
Temporising Matrix

Please refer to the Instructions for Use.

This document contains general guidelines and is not designed to replace existing institutional protocols or professional clinical judgment regarding patient care.

Indications for Use

Full or deep partial thickness burns and wounds, surgical and reconstructive wounds and traumatic wounds.

Intended Use

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.

Contraindications

Should not be applied into overtly infected wounds.

Preparation

Wound preparation:

- Clean and debride the wound
- Ensure the wound is free of infection
- Effective haemostasis should be achieved

NovoSorb BTM is ready for application straight from the packaging, no further preparation is required.

NovoSorb BTM is supplied fenestrated. If the wound bed is expected to be highly exudative, further fenestrations may be applied with a scalpel.

Note: Do not mesh.

Application

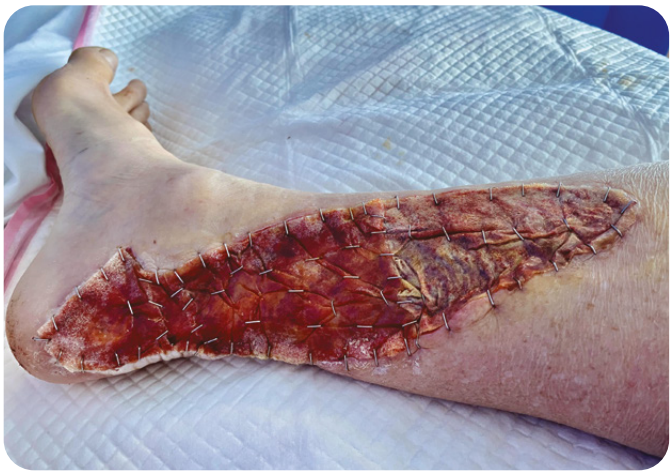
NovoSorb BTM is applied by cutting to shape and affixing to the wound with staples and/or sutures.

Do

- Create a template by pressing matrix against the freshly debrided wound
- The matrix should be in contact with the wound, with the sealing membrane facing externally
- Ensure good apposition with the wound edges and adjacent sheets
- Quilting staples over joints or large areas can help maintain contact with the wound bed
- Slight tension may be applied to conform over a convex surface and to allow for swelling to subside

Do not

- Overlap with intact skin or adjacent NovoSorb BTM sheets
- Affix with fibrin glue (not recommended as it may impact integration)



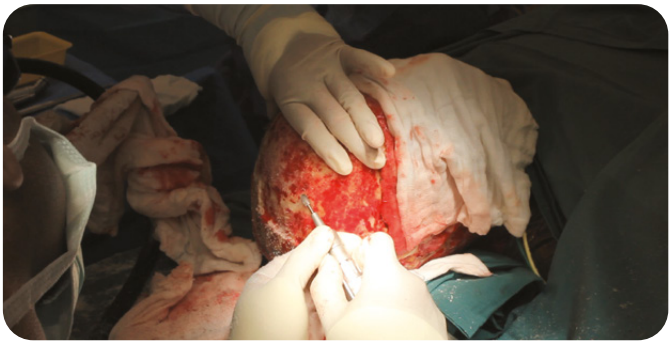
NovoSorb BTM cut to shape and affixed with staples, including quilting staples to help maintain contact with the wound bed.

Over avascular structures

NovoSorb BTM is designed to integrate if the margins and wound bed consist of viable tissue (i.e. dermis, subcutaneous fat, muscle, paratenon and/or periosteum).

Over bone:

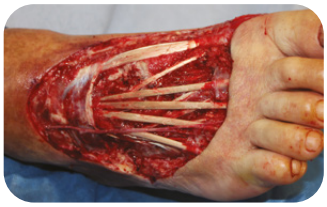
Exposed bone may need to be burred or drilled to induce punctate bleeding[1].



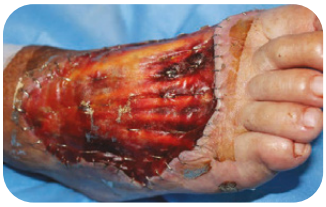
Outer skull table removed to expose underlying diploe.

Over tendon:

NovoSorb BTM may bridge avascular structures if it is in contact with adequate surrounding viable tissue[2].

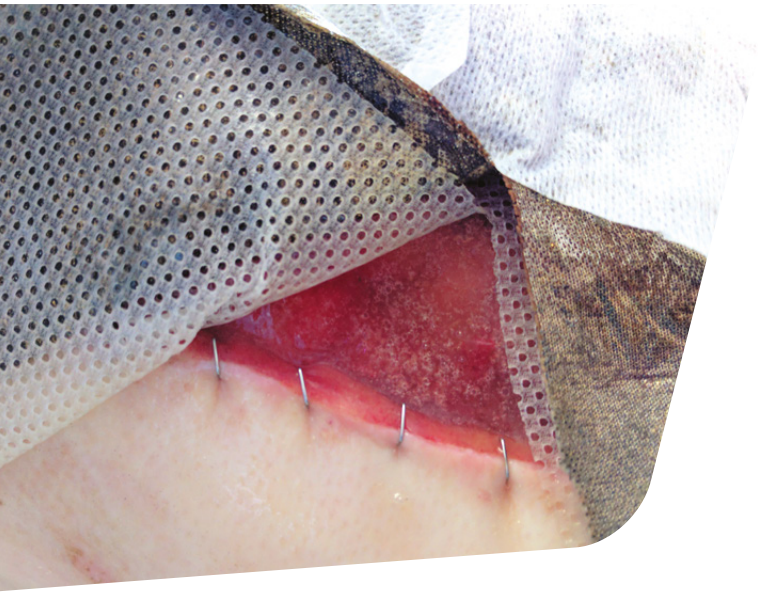


Following debridement, extensive exposed tendons denuded of paratenon.



Day 4 NovoSorb BTM affixed with staples. Note pallor over tendon, but integration has commenced over the rest of the wound.

Outer dressings



Apply dressings over NovoSorb BTM that:

- Are non-adherent against the sealing membrane
- Absorb mild exudate
- Maintain apposition with the wound bed
- Minimise shearing forces

As required

- Around limbs, compression may be applied with crepe bandages
- Dressings may contain antimicrobial properties (such as silver dressings)
- Splints over mobile areas may be used to reduce movement

Note: Silver dressings may leave a black appearance on the surface.

Negative Pressure Wound Therapy (NPWT)

Use of NPWT over NovoSorb BTM should be at the surgeon's discretion based on clinical indications.

- Use with NovoSorb BTM has been reported in publications and case reports[3,4,5]
- Publications reported usage on a continuous setting at 50-125mmHg
- Proper wound monitoring should be performed to ensure clinical events are appropriately managed

NPWT applied over NovoSorb BTM.

Performing wound care

Regular dressing changes are required to monitor integration and to ensure NovoSorb BTM stays clean. NovoSorb BTM is a surgical device and must not be removed as part of standard dressing changes.

Do

- Change dressings if strike through is evident
- Clean by gently wiping the surface with a saline gauze and/or antimicrobial solution
- Replace antimicrobial dressings as per your dressing protocol

Assess

- Degree of integration
- For excess exudate
- Presence of localised infections
- Presence of a haematoma

Avoid

- Shearing or lifting the matrix from the wound bed
- Removing staples/sutures unless necessary
- Solutions, creams or gels that may obstruct cellular migration into the matrix and impede integration

Note:

- If the sealing membrane has prematurely separated from the matrix, it may be trimmed.
- Granulation tissue is likely to form in this area over a few days.
- Neighbouring adhered sealing membrane may be secured with staples to prevent further separation.

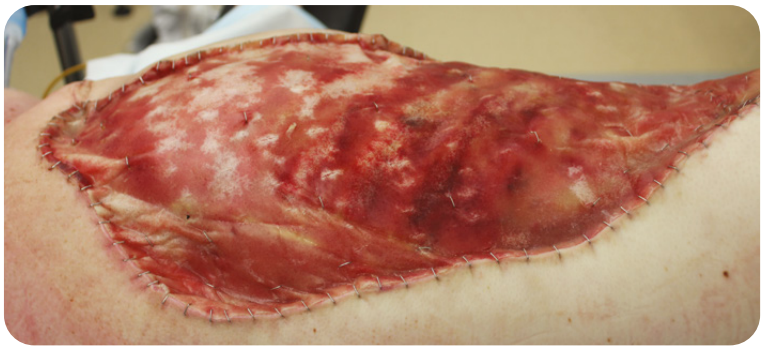
Monitoring integration

Cellular migration enables collagen production and neovascularisation throughout the matrix. As NovoSorb BTM integrates with the wound, its appearance will change over time.

Integration time depends on patient and wound factors.

Week 1

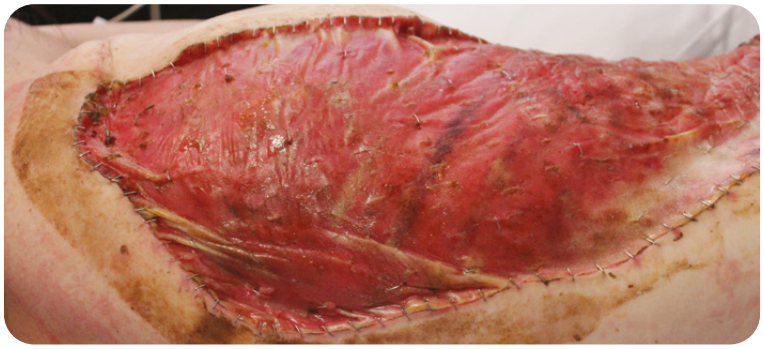
- May not yet be adhered to the wound bed
- Matrix is visible through the sealing membrane
- The haemoserous exudate and dark coagulated blood in the matrix may give it a dark red appearance



Day 5

Weeks 2-3

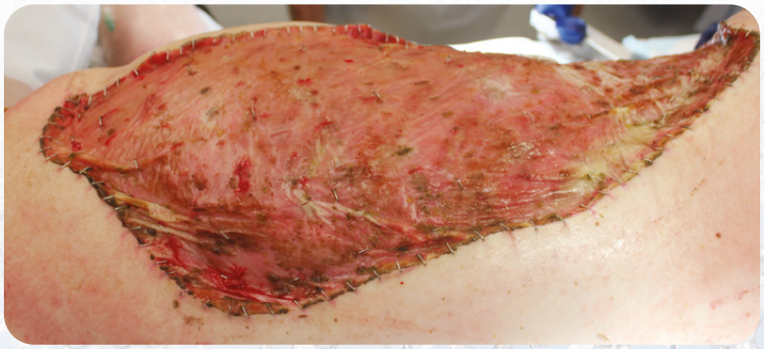
- Matrix adhered to wound bed
- Coagulated blood appears lighter
- Matrix may appear a range of colours including pink, yellow and orange
- Capillary refill may become evident



Day 15

Week 3 to full integration

- Capillary refill becomes more evident/rapid
- Matrix architecture becomes obliterated by infiltrating tissue
- Colour becomes more uniform and pink



Day 34

Integration over avascular structures may be slower, compared to other areas.

Physical therapy

Mobilisation and range of motion (ROM) should be performed without causing shear of the matrix against the wound bed.

It takes one to two weeks for the matrix to uniformly adhere to the underlying bed. Limited active ROM exercises may be possible earlier if they don't cause shear of the matrix against the wound bed. Therapy can build through to full active and passive range during the integration phase.

It may be beneficial to perform ROM exercises without outer dressings to allow monitoring of matrix adherence and to observe for areas of tension caused by NovoSorb BTM when progressing ROM[6].

Splints may be discontinued at day 7 post-placement.

For specific NovoSorb BTM Physiotherapy Guidelines from Royal Adelaide Hospital Physiotherapy Department, refer to appendix A of Schmitt B et al., 2020[6].

Managing clinical events

Haematoma

Early stage integration

A haematoma under the matrix, as opposed to blood within the matrix, presents as a bulge and can impact adherence with the underlying wound bed. The haematoma may be accessed and removed by creating and opening a slit or lifting the matrix. The impacted area of NovoSorb BTM may require removal and replacement.

Late stage integration

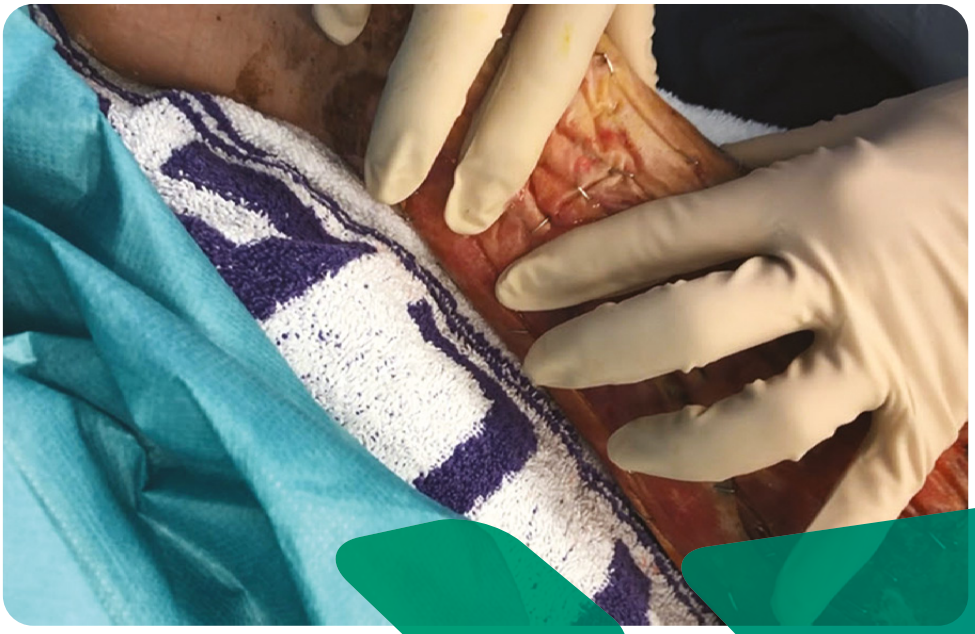
A haematoma that develops after NovoSorb BTM has adhered to the wound bed can separate the sealing membrane away from the integrating matrix. Removal of haematoma should be according to clinical judgment.

Heavily exudative wounds

Heavily exudative wounds should be drained to reduce the risk of infection, which may delay integration.

Excess exudate can be expressed:

- From the edges of NovoSorb BTM
- Through the fenestrations
- Through the holes from the quilting staples



Exudate milked out through the fenestrations and holes from quilting staples.

Additional fenestrations may be applied.

Localised infections with purulent collections

Purulent collections on the underlying wound bed rarely necessitate removal of NovoSorb BTM.[5,7,8]

Purulent collections are most likely to occur within the first two weeks after application. These may appear as grey/cream coloured plaques under the sealing membrane.

Management

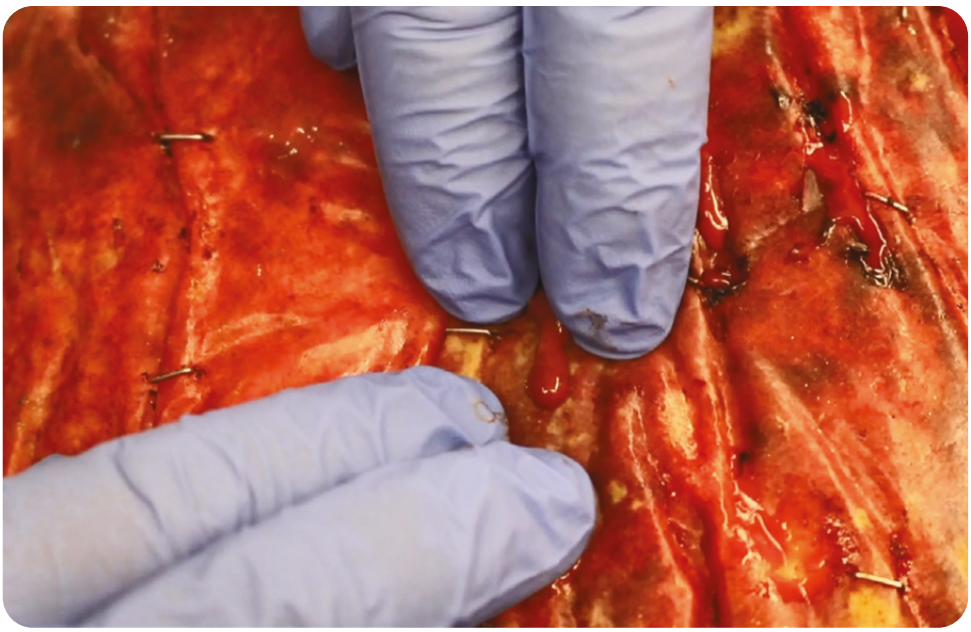
- Can be treated by expression at dressing change
- A slit with a scalpel may be required to allow expression
- Massage purulent collection to piercing or edge using rolled gauze
- Continue performing standard wound care

If purulent collection continues to enlarge or patient becomes systemically unwell, consider device removal to access the wound and manage the infection.

Monitoring

- Inspect at subsequent dressing changes to ensure resolution
- Consider increasing frequency of dressing changes to enable monitoring

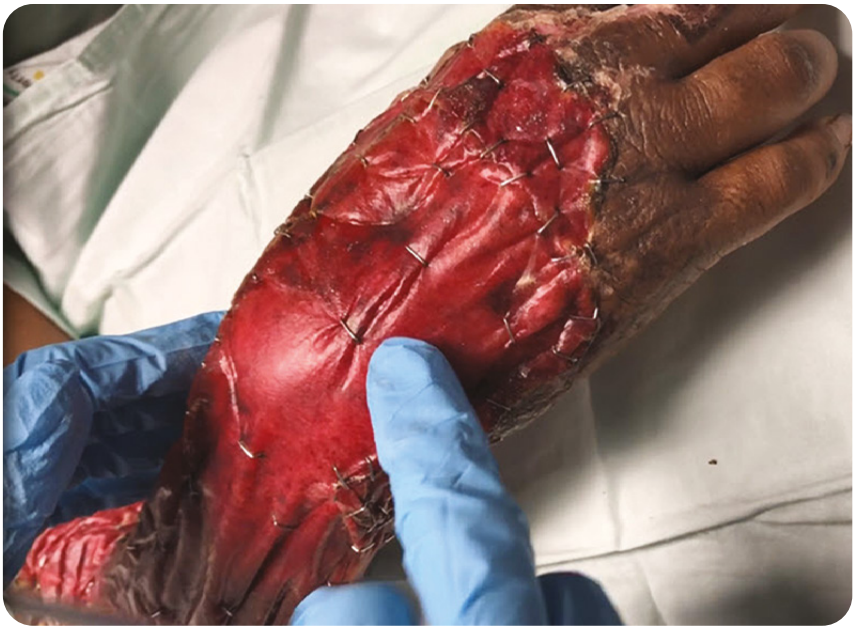
Infections should be treated according to hospital protocol.



Purulent collection drained from a slit in the sealing membrane.

Delamination

Delamination should be performed once the slowest area has integrated.



Blanch test assessing capillary refill.

For example:

- Over muscle or fascia, it may be ready after 3 weeks
- Over tendons and bone, it may be prudent to delaminate after 4–5 weeks

Readiness for delamination can be identified by[3]:

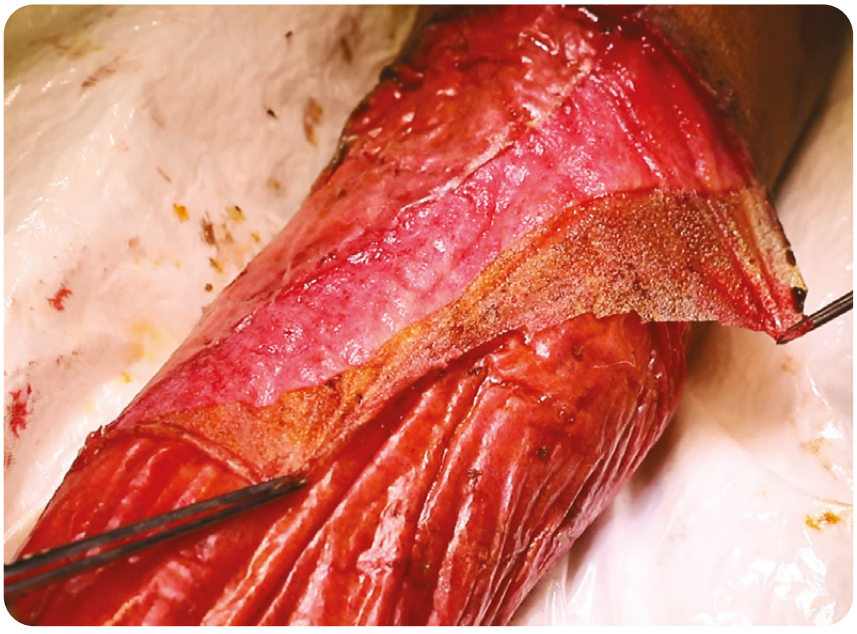
- Matrix architecture no longer being visible
- Rapid capillary refill on blanching from pressure*
- Uniformity of the salmon-pink colour*

* May be less apparent if the patient has a vascular deficiency.

When delaminating the sealing membrane:

- Gently peel from the corner towards the centre of the sheet, using a 'Velcro®-like' action. Note that matrix remnants remain attached to the underside.
- It is designed to detach in one piece, but if fragmentation occurs, ensure that all sealing membrane remnants are removed.

Re-epithelialisation and contraction resulting from secondary intention healing will commence if left without definitive closure.



Delamination of the sealing membrane.

Definitive closure

After delamination the neodermis may be refreshed before definitive closure.

A mild refresh of the neodermis may be considered if:

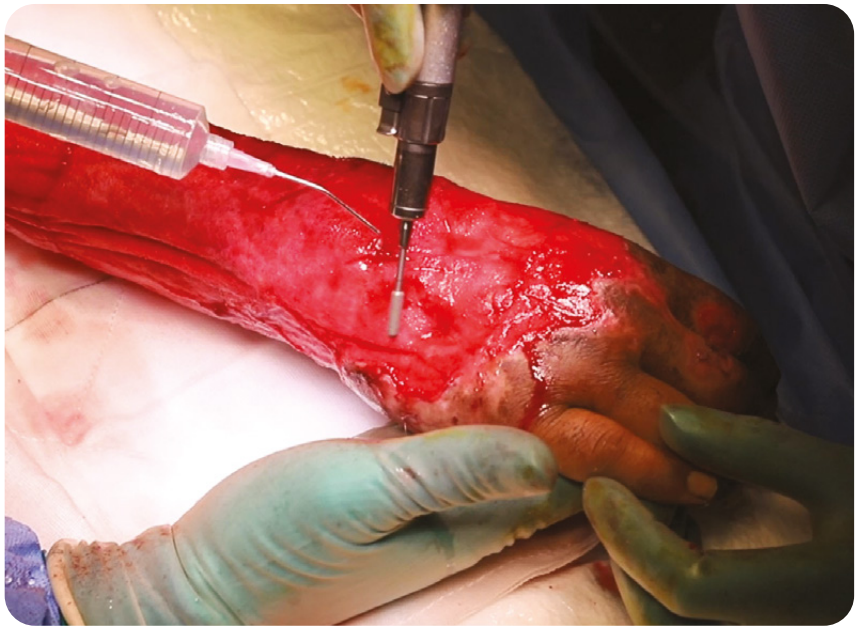
- There are any ridges, seams or raised edges
- Granulation tissue has formed across the surface (e.g. in areas of premature sealing membrane separation)
- Light bleeding is preferred before application of a skin graft

Using dermabrasion, hydrosurgery, curette, scratch pad etc.

Definitive closure is at the discretion of the surgeon, using methods such as:

- Split thickness skin graft
- Full thickness skin graft
- Cultured epithelial autograft
- Re-epithelialisation by secondary intention

Apply and dress according to standard of care.



Neodermis refreshed with dermabrasion prior to definitive closure.

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