Instructions for Use

NovoSorb® BTM

Device Description

NovoSorb® BTM is a biodegradable polyurethane porous matrix adhered to a transparent sealing membrane. The sealing membrane is designed to physiologically close the wound limiting evaporative moisture loss during integration of the matrix.

NovoSorb® BTM is supplied in various sizes, ranging from 4cm^2 to 800cm^2. NovoSorb® BTM is a fenestrated single use, terminally sterilized device, individually packed in a transparent polymer pouch enclosed in an aluminized pouch contained in a cardboard envelope.

Indications for Use

NovoSorb® BTM is indicated for use in the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

Contraindications

NovoSorb® BTM application is contraindicated in wounds where necrotic/devitalized tissue is present, such wounds must be surgically debrided to viable tissue pre-application. NovoSorb® BTM should not be applied into overtly infected wounds, such wounds should be debrided of non-vital tissue and be topically treated with antimicrobial dressings and/or systemic antibiotics before application is considered. NovoSorb® BTM should only be applied into surgically debrided chronic wounds where underlying pathology capable of potentiating the wound has been addressed (e.g. meticulous blood sugar control in diabetic ulceration, compression hosiery/dressings in venous ulceration to combat sustained venous hypertension, etc.). NovoSorb® BTM should be applied into wounds only after effective hemostasis has been afforded.

Warnings

1. Caution: Federal (USA) Law restricts this device to sale by or on the order of a licensed healthcare practitioner.
2. If any of the following conditions occur, NovoSorb® BTM should be removed: chronic inflammation, allergic reaction, excessive redness, pain or swelling.

Precautions

1. NovoSorb® BTM is sterile if the package is unopened and undamaged. Do not use if the aluminized pouch has been perforated or the seal is broken or any other contamination is suspected.
2. Opened and unused NovoSorb® BTM cannot be resterilized and must be discarded.
3. NovoSorb® BTM should not be applied until excessive exudate, bleeding, acute swelling and infection are controlled.
4. Debridement or excision must be meticulous and remove any remaining necrotic tissue that may cause infection.
5. NovoSorb® BTM has not been assessed in pregnant or nursing women nor infants. Caution should be exercised before treating pregnant or nursing women and infants.
6. Prior understanding of the application, monitoring and removal of dermal substitutes is recommended for effective use of this device.
7. Use caution when using products that may weaken the sealing membrane (e.g., high concentrations of sodium hypochlorite solutions such as Dakin's).
8. Use caution in the application of solutions, gels and creams as they may obstruct cellular migration into the matrix.
9. Use caution with medication and treatments that limit blood support as it may delay cellular infiltration and tissue integration.

Preclinical and Clinical Studies

In clinical studies requiring free-flap surgery, adverse events that were deemed "possibly related" to NovoSorb®

BTM by the investigators were reported at similar frequencies (14%) as in studies reported in the literature. Adverse events included graft failure and hematoma.

In patients undergoing NovoSorb® BTM application at donor harvest sites, recipient site complications were reported. These complications occurred at a similar frequency to those reported in the literature for patients undergoing similar free tissue transfer procedures.

In some patients treated with NovoSorb® BTM, elevations in liver function tests (LFTs) were reported at frequencies as in a control cohort of patients undergoing similar procedures requiring long duration anesthesia. The elevations proved to be transient in patients for which longer follow-up occurred, while levels remained elevated in patients with shorter follow-up durations. The investigators reported that the elevated LFTs were unlikely related to NovoSorb® BTM and were likely a side effect of long-duration anesthesia. However, the exact cause of the elevated LFT and their resolution in the patients with only short-term follow-up has not been established. In all cases, the patients had otherwise normal liver function and required no treatment for this event.

Patient biopsy data indicates that NovoSorb® BTM degrades by approximately 12 months, however, this may vary in some patients depending on a number of factors including but not limited to anatomical location, age and health status. The device is fully resorbed in the body within 18 months.

Instructions for Use

NovoSorb® BTM is designed to be placed onto a newly created wound bed and affixed to the wound bed (e.g. stapled). When the matrix appears integrated, the sealing membrane which is the outer superficial part of the device when placed in the wound is peeled off (delaminated) and discarded per institutional guidelines for medical waste.

Note: The packaging should not be opened until wound preparation is complete.

Wound Preparation

Shave any hair from around the wound, prepare the skin with antiseptic and use sterile drapes to isolate the surgical field. As with any device, the wound bed must be clean, with NO devitalized tissue present. Clinically demonstrable infection in a wound should be resolved prior to application of the NovoSorb® BTM. Deep structures (such as tendons etc.) should have their covering vascular layer (peritenon, perineurium, etc.) intact, if possible. Active bleeding must be controlled.

Opening the Packaging

The outer cardboard envelope should be removed and discarded. The aluminized peel-able pouch should be opened completely at the **chevron** end. Remove the transparent pouch from the aluminized pouch. Open the transparent pouch, also at the **chevron** end, and aseptically remove the NovoSorb® BTM.

Placement

Taking care to have the smooth **sealing membrane side** outermost, the **matrix side** can be pressed into the wound to create a 'blood picture' of the wound on the deep surface of the NovoSorb® BTM, which can then be cut to fit the wound. If desired, the wound can be rewashed with antiseptic. The material is laid onto the wound, **sealing membrane side** out, and affixed in place. It is important that the NovoSorb® BTM sits against the wound bed with its edges flush against the wound sides. If the wound bed is expected to be heavily exudative, the device may be further fenestrated with a scalpel to provide drainage holes.

Dressing

While dressing protocols may be decided by the operating surgeon, it is recommended to cover NovoSorb® BTM with a low-adherent antimicrobial dressing. Where appropriate, compression may then be afforded with crepe bandages, where edema is likely. Splinting may be desirable if placement has been into a wound over a highly mobile area. This dressing should be changed according to standard of care for the chosen dressing, or when

exudative strike-through is noted. NovoSorb® BTM is a synthetic and has no intrinsic antimicrobial properties. Splints can be discontinued at Day 7 post-placement.

Progress

The appearance of NovoSorb® BTM will change by each dressing change initially. By Day 3, the material appears bright red due to the ingress of fresh blood. By Day 6, the redness darkens. Depending on the original wound bed, the appearance evolves with time resulting in a paler, salmon/pink, opaque appearance which blanches and exhibits capillary refill on transient localized pressure. When integrated, the NovoSorb® BTM matrix which was previously visible through the transparent sealing membrane become obscured. It takes between one and two weeks for NovoSorb® BTM to adhere to the underlying bed. Tendons may remain visible for two or three weeks before the NovoSorb® BTM fully integrates over them.

Delamination (Sealing Membrane Removal)

On a wound bed of fat or muscular fascia, NovoSorb® BTM may be ready for delamination after three weeks of integration. Over tendons, it may be prudent to leave the NovoSorb® BTM for 4 - 5 weeks before delamination. The device should be left until the underlying matrix is firmly attached to the wound bed.

In surgery, under aseptic conditions, the skin should be prepared with antiseptic. Sterile drapes are applied to isolate the surgical field. Using forceps, grasp one corner of the sealing membrane and gently peel towards the center of the wound. The sealing membrane detaches with a 'Velcro-like' action, leaving matrix remnants attached to its underside. The sealing membrane is designed to detach in one piece, but if fragmentation occurs, ensure that all sealing membrane remnants are removed.

Storage Conditions

Store at ≤ 25°C, Keep Dry

Symbols Used on Labeling

	Manufacturer		Expiration Date (YYYY-MM-DD)
REF	Catalogue number	LOT	Batch number
RxOnly	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner	STERILE R	Sterile using irradiation
25° C	Upper limit temperature: 25°C		Keep Dry
	Caution: Consult instructions for use for cautionary information		Consult instructions for use
	Do Not Reuse		Do Not Resterilize
	Do not use if package is damaged		

Manufacturer
PolyNovo Biomaterials Pty Ltd
Unit 2 / 320 Lorimer Street
Port Melbourne, VIC 3207
Australia
Phone: +61 3 8681 4050
Phone (US): +1-760-448-5515
E: info@polynovo.com