NovoSorb® BTM
Instructions for use

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Device Description

The NovoSorb® Biodegradable Temporising Matrix (BTM) is a biodegradable polyurethane porous foam adhered to a transparent sealing membrane. The sealing membrane is designed to physiologically close the wound limiting evaporative moisture loss during integration of the foam.

The NovoSorb® BTM is a fenestrated, single use, terminally sterilised device, individually packed in a transparent polymer pouch enclosed in an aluminised pouch contained in a cardboard envelope.

Indications for Use

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

Contraindications

The NovoSorb® BTM should not be applied into overtly infected wounds.

Warnings

1. In wounds where necrotic/devitalized tissue is present, such wounds must be surgically debrided to viable tissue pre-application.
2. 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/dressing in venous ulceration to combat sustained venous hypertension, etc).
3. NovoSorb® BTM should not be applied onto clinically infected tissue.
4. NovoSorb® BTM should be applied into wounds only after effective haemostasis has been afforded.
5. NovoSorb® BTM integration requires an interface with a viable wound bed. Post-operative wound complications such as haematomas, wound bed necrosis secondary to peripheral hypoperfusion and excessive movement or device shear can subsequently affect this interface and preclude integration. This may indicate partial or total removal of the NovoSorb® BTM and further preparation of the wound bed prior to re-application of fresh NovoSorb® BTM.
6. If any of the following conditions occur, the NovoSorb® BTM should be removed: 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 aluminised pouch has been perforated or the seal is broken or any other contamination is suspected.
2. Opened and unused NovoSorb® BTM cannot be resterilised and must be discarded.
3. NovoSorb® BTM should not be applied until bleeding and infection are controlled.
4. Debridement or excision must be meticulous and remove any remaining necrotic tissue that may cause infection.
5. Split-thickness skin graft take post NovoSorb® BTM integration remains subject to the recognised complications associated with standard application onto viable tissue. These include shear, blistering, haematomas and infection. Prevention and management of these events should be according to standard of care.
6. The 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.
7. Prior understanding of the application, monitoring and removal of dermal substitutes is recommended for effective use of this device.
8. Use caution when using products that may weaken the sealing membrane (e.g., high concentrations of sodium hypochlorite solutions such as Dakin's).
9. Use caution in the application of solutions, gels and creams as they may obstruct cellular migration into the matrix.
10. Use caution with medication and treatments that limit blood support as it may delay cellular infiltration and tissue integration.

Instructions for Use

The NovoSorb® BTM is designed to be implanted into the newly debrided wound bed and stapled/sutured to the wound. The NovoSorb® BTM is a sterile foam adhered to a transparent sealing membrane which is the smooth side. This is important, since the sealing membrane side is the outer, superficial part of the device when placed in the wound. When the foam appears integrated, the sealing membrane is peeled off (delaminated) and discarded per institutional guidelines for medical waste.

One or more NovoSorb® BTM devices of one or more sizes may be necessary for patient treatment depending on the specific needs of each patient and the wound size to be managed, at the discretion of the physician.

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 wound, the wound bed must be clean, with NO devitalized tissue present. Clinically demonstrable infection in a wound should be eradicated prior to application of the NovoSorb® BTM. Deep structures (such as tendons, nerves, etc.) should have their covering vascular layer (paratenon, perineurium, etc.) intact, if possible. Active bleeding must be controlled.

Opening the Packaging

The outer cardboard envelope should be removed and discarded. The aluminised peel-able pouch should be opened completely at the **chevron** end. Remove the transparent pouch from the aluminised 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 foam side can be pressed into the wound to create a 'blood picture' template of the wound area on the deep surface of the NovoSorb® BTM which can then be cut with scissors to fit the wound. If desired, the wound can be rewashed with antiseptic. The NovoSorb® BTM is laid into the wound, **sealing membrane side** out, and held in place with surgical staples or sutures. NovoSorb® BTM can be placed under slight tension to conform over a convex surface and allow for swelling to subside. It is important that the NovoSorb® BTM sits against the wound bed with its edges flush against the wound margins. In addition to fixation at the wound margins, NovoSorb® BTM can be 'quilted', or affixed to the wound bed using surgical staples to further appose the matrix to the underlying tissue. If the wound bed is expected to be heavily exudative, the sealing membrane may be further fenestrated with a scalpel to provide drainage holes. Any unused materials of the NovoSorb® BTM should be discarded in accordance with institutional guidelines for medical waste.

Dressing

While dressing protocols may be decided by the operating surgeon, it is recommended to cover the NovoSorb® BTM with a low-adherent antimicrobial dressing, capable of absorbing exudate expressed through the fenestrations in the sealing membrane. Where appropriate, for example around limbs, compression may then be afforded with crepe bandages, to reduce oedema. Splinting may be desired 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. The NovoSorb® BTM is a synthetic dermal matrix device and has no intrinsic antimicrobial properties. Splints can be discontinued at Day 7 post-placement.

Progress

There will be a progressive change in appearance of the NovoSorb® BTM with each dressing change. By Day 3, the foam appears bright red due to the ingress of fresh blood. By Day 6, the redness darkens. Depending on the original wound bed, this appearance evolves with time resulting in a paler, salmon/pink, opaque appearance which blanches and exhibits capillary refill on transient localised pressure. When integrated, the NovoSorb® BTM foam cells, which were previously visible through the transparent seal, have become obscured with tissue. Staples may be removed from Day 14 onwards or left in place until delamination. It takes between one and two weeks for NovoSorb® BTM to uniformly adhere to the underlying bed. Tendons may remain visible for two or three weeks before the NovoSorb® BTM fully integrates over them.

Note: Patient Biopsy data indicates that the 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.

Delamination (sealing membrane removal)

On a wound bed of fat or muscular fascia, the 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 not be delaminated until the underlying foam 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 centre of the wound. The sealing membrane detaches with a 'Velcro-like' action, leaving foam 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 Labelling


Manufacturer

Catalogue number

Upper limit temperature: 25°C

Consult instructions for use


Caution: consult instructions for use for cautionary information


Do not reuse

Do not resterilise


Expiration date (YYYY-MM-DD)

Batch number

Sterile using irradiation


Keep dry


Do not use if package is damaged

Authorised representative in the European Community


Product complies with requirements of directive 93/42/EEC