

## **NovoSorb™ BTM Wound Dressing Instructions for Use**

### **Device Description**

The NovoSorb™ BTM Wound Dressing is a 2mm thick, biodegradable polyurethane porous white foam bonded with a polyurethane adhesive layer to a fenestrated one-sided transparent sealing membrane. The sealing membrane is designed to physiologically close the wound limiting evaporative moisture loss during integration of the foam.

NovoSorb™ BTM Wound Dressing is supplied in various sizes, ranging from 4cm<sup>2</sup> to 800cm<sup>2</sup>. The NovoSorb™ BTM Wound Dressing is a single use, terminally sterilized device, individually packed in a transparent polymer pouch enclosed in a white aluminized pouch contained in a cardboard envelope.

### **Indications for Use**

The NovoSorb™ BTM Wound Dressing 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. The device is for single use only.

### **Contraindications**

The NovoSorb™ BTM Wound Dressing application is contraindicated in wounds where necrotic/devitalized tissue is present, such wounds must be surgically debrided to viable tissue pre-application. The NovoSorb™ BTM Wound Dressing should not be applied into overtly infected wounds, such wounds should be debrided of non-vital tissue and be topically treated with antimicrobial dressings +/- 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). The NovoSorb™ BTM Wound Dressing 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, the NovoSorb™ BTM Wound Dressing should be removed: chronic inflammation, allergic reaction, excessive redness, pain or swelling.

### **Precautions**

1. NovoSorb™ BTM Wound Dressing is sterile if the package is unopened and undamaged. Do not use if the package has been perforated or the seal is broken or any other contamination is suspected.
2. Opened and unused BTM cannot be resterilized and must be discarded.
3. NovoSorb™ BTM Wound Dressing 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.

## Preclinical and Clinical Studies

In clinical studies requiring free-flap surgery, adverse events were reported at similar frequency as in studies reported in the literature. Adverse events included graft failure and hematoma.

In patients undergoing NovoSorb™ BTM Wound Dressing 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 Wound Dressing after major reconstructive surgery, incidental and asymptomatic elevations in liver function tests (LFTs) were detected. Similar elevations and frequencies were reported in a control cohort of patients undergoing similar procedures requiring long duration anesthesia. None of the patients were treated for abnormal liver function during the study.

Patient biopsy data has shown that NovoSorb™ BTM Wound Dressing degrades by 18 months. In vitro degradation data indicates that the NovoSorb™ BTM Wound Dressing disintegrates by approximately 10 months. However, actual degradation time in patients may vary depending on a number of factors including but not limited to anatomical location, age, and health status.

## Instructions for Use

The NovoSorb™ BTM Wound Dressing is designed to be placed onto a newly created wound bed and stapled/sutured to the edge of the wound. The NovoSorb™ BTM Wound Dressing is a sterile, 2mm thick white foam, with one smooth side which is bonded to a transparent film, sealing membrane. This is important, since the film side is the outer, superficial part of the dressing when placed in the wound. When the foam appears integrated, the film sealing membrane is peeled off (delaminated) and discarded.

**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 dressing, 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 Wound Dressing. 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 white peelable pouch should be opened completely at the "chevron" end. A pair of surgical forceps are used to remove the transparent pouch from the white pouch. Open the transparent pouch (also at the chevron end) and grab the NovoSorb™ BTM Wound Dressing with non-toothed forceps.

### 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' of the wound on the deep surface of the NovoSorb™ BTM Wound Dressing. This can be cut around with scissors to create a dressing that fits the wound. If desired, the wound can be rewashed with antiseptic. The material is laid into the wound, **sealing membrane Side** out, and held in place with surgical staples. It is important that the NovoSorb™ BTM Wound Dressing sits against the wound bed with its edges flush against the wound sides. If the wound bed is expected to be heavily exudative, the Sealing Membrane 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 the NovoSorb™ BTM Wound Dressing with a low-adherent antibacterial dressing. 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. The NovoSorb™ BTM Wound Dressing is a synthetic dressing and has no intrinsic antibacterial properties. Splints can be discontinued at Day 7 post-placement.

### Progress

The appearance of the NovoSorb™ BTM Wound Dressing will change by each dressing change initially. Starting as a white foam, 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, this picture evolves with time resulting in a paler, salmon/pink, opaque appearance which blanches and refills on transient localized pressure. Staples may be removed from Day 14 onwards. Tendons may remain visible for two or three weeks before the NovoSorb™ BTM Wound Dressing fully integrates over them.

### Delamination (Sealing Membrane Removal)











On a wound bed of fat or muscular fascia, the NovoSorb™ BTM Wound Dressing may be ready for delamination after three weeks of integration. Over tendons, it may be prudent to leave the NovoSorb™ BTM Wound Dressing for 4 - 5 weeks before delamination. The dressing should be left 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 fine-toothed forceps, one corner of the sealing membrane is grasped and gently peeled towards the center 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 Labeling

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

**Manufacturer **

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