

myownskin™

INSTRUCTIONS FOR USE

Product Description

MyOwnSkin™ is an ambient temperature (15-25°C, 59-77°F) autologous skin-cell graft used for advanced wound coverage. The graft may be used independently or in combination with other wound care products.

Donor Screening

After legal authorization or consent is obtained, acquisition of the donor tissue is performed in an aseptic manner. Processing is performed in a controlled cleanroom environment to prevent contamination. No testing, medical or physical evaluations are performed to qualify donors for transplant as MyOwnSkin™ is an autologous graft.

Precautions

To reduce the risk of complications, the tissue should not be transplanted in the presence of neurotic tissue, exposed bone or ligaments or infected tissue. Although the tissue has been rinsed multiple times during processing, the presence of antibiotics (gentamicin) may remain in the tissue.

Adverse Reactions

Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to BioLab Sciences at QA@biolabsciences.net or by calling 480-656-5746, ext. 200.

Warnings

- ⚠ Each graft is intended for single patient use, on a single occasion only.
- ⚠ Use is limited to specific qualified health professionals.
- ⚠ This graft was not terminally sterilized.
- ⚠ Do not sterilize. Discard all open and unused portions of the product in a biohazard bin.
- ⚠ Do not use if the integrity has been violated, is opened or damaged, or if mishandling has caused possible damage or contamination.

MyOwnSkin™ is only for wound coverage and for single external and autologous use. It must be used on the patient from which the skin biopsy and blood were taken.

Please read these entire instructions prior to beginning the application process.

Following are the application instructions for MyOwnSkin™.

Ancillary products provided for sample application (Please note that the clinic can use its own instruments and these have been provided to you as a courtesy):

1. Each pouch contains a Petri dish with one autologous skin-cells sheet grown for the identified patient.
2. (1) Porous Silicone Bandage.
3. (1) Sterile Gauze
4. (1) Sterile Tweezers
5. Instructions for Use

- The integrity of the external packaging must be verified, as well as confirmation the patient's identity on the packaging correlates to the medical record
- All contents included in this delivery box must be opened using aseptic technique.

The following steps must be considered DURING the placement the MyOwnSkin™ membrane:

1. Debride the wound, if necessary.
2. Open the packaging in a horizontal position ensuring to maintain the lid of the petri dish right side up.
3. Aseptically lift two corners of the graft simultaneously.
4. Apply on the area to be treated. NO sweeping should be done on the membrane, and it must be completely adhered to the wound bed (without bubbles).
5. The excess of MyOwnSkin™ can now be folded onto itself or be trimmed.
6. Cover the MyOwnSkin™ membrane with the porous silicone cover.
7. Cover the treated area with a bandage as appropriate.

Remember that after the application of the membrane

- The attending qualified personnel should check the treated area every 5-7 days, at least until day 21.
- During each checkup, secondary healing dressings should be removed with care to not damage the MyOwnSkin™ membrane. It is also important to clean the area with sterile saline and ensure the area remains free of infection and do not remove the porous silicone cover during these checks.
- Excess secretion from the wound should be cleaned with a dry dressing.
- No other substance should be applied over the treated area.
- Only after day 21, can the porous silicone cover be removed.

**Autologous Tissue Processed By: BioLab
Sciences, Inc.
7662 E. Gray Road, Suite #107
Scottsdale, AZ 85260
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