EPIGARD®

CONSEPT

WOUND + INFECTION CARE

Synthetic skin replacement for temporary wound dressing.

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Technical description and clinical application

1. Technical description

1.1. *Materials*

EpiGARD is a nontextile, micro-porous plastic material without medicinal impregnation. The material is double layered. The bottom side, which is placed on the wound surface, forms an open matrix made of elastic soft polyurethane (PUR) foam. The top side consists of a thin, micro-porous polytetrafluorethylene (PTFE) film.

1.2. *Product components and characteristics*

EpiGARD is a synthetic skin replacement for temporary wound covering, wound cleaning and conditioning of the wound bed. It is absorbent, permeable to air and water vapor, as well as it prevents the migration of bacteria and the passage of fluid and secretion. In general, within 48h renewal of EpiGARD is recommended.

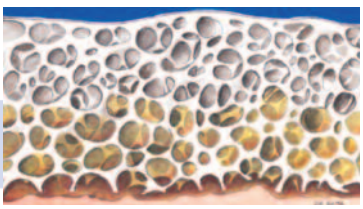
EpiGARD sticks to the wound surface rapidly and effectively through thrombogenic adhesion and coagulation of the exudate on the wound bed. This rids the wound of necrotic tissue and exudate when the bandage is changed for the first time. During this wound cleansing phase, fibroblasts and vessels start growing in the wound area and the open-pored PUR foam. After a few days a consistent, well vascularized wound bed is achieved, which can be covered with a secondary dressing.

The product is available in five sizes. Each individual product is double-packed and sterilized by means of ethylene oxide.

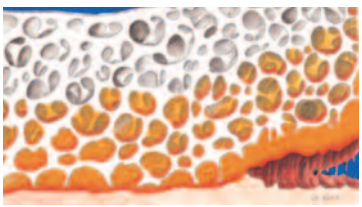
2. Intended use, indications, contraindications and clinical use

2.1. *Intended Use*

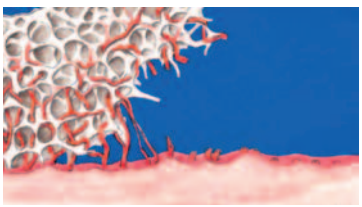
EpiGARD is a synthetic skin replacement for temporary wound covering, wound cleaning and conditioning of the wound bed.



The wound exudate adheres to the cavities in the polyurethane structure.



Necrotic tissue and wound exudate can be removed when the bandage is changed.



After the wound cleansing phase, fibroblasts and blood vessels begin to grow, which encourages a consistent and well vascularised granulation of the wound bed.

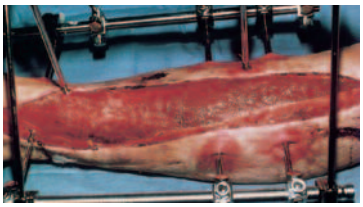
2.2. *Indications*

According to the instruction manual, EpiGARD is indicated for external wounds with open wound treatment and for preparation of a secondary wound closure, such as:

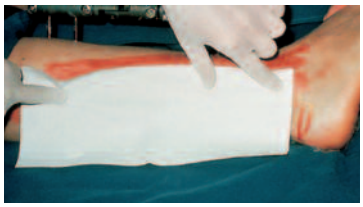
– Temporary infection protecting wound covering of defect wounds.
– Soft tissue injuries of open fractures and of open spongiosa grafts.
– Temporary infection protecting wound covering after surgical necrosis removal with severe burns to prevent microbial invasion and to contain the plasma loss.
– Interim covering of wound surfaces until final autologous transplantation.
– Temporary wound covering with provisional wound closure as well as for protection of exposed bones, tendons, ligaments and burn wounds.
– Wound cleaning of infected defect wounds and burn wounds.
– Wound cleaning with ulcera cruris, decubital ulcers, surface skin lesions and surgery wounds.
– Conditioning of the wound bed especially before transplants.

EpiGARD is also indicated for the exclusive treatment of all defect wounds with flat wound bed without subsequent skin transplantation, such as:

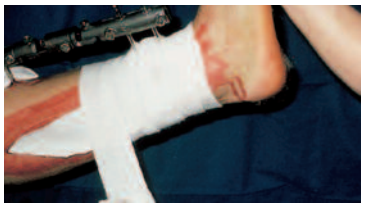
– Surface wounds to promote the granulation and epithelization.
– Skin defects at all locations, especially skin defects on the fingers.
– Defects that are caused trough surgical excisions.
– Defect covering with emergency compartment openings of the extremities.
– Wound covering to support the autologous enzymatic wound cleaning with defect wounds.



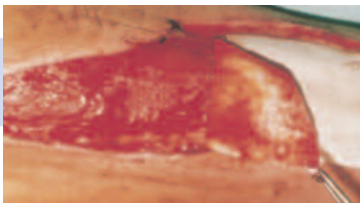
Thorough wound debridement to gain an overall impression of the condition of the wound.



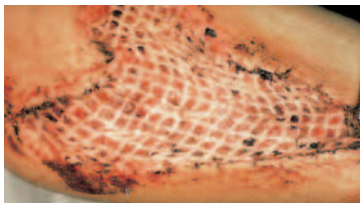
Precise adjustment of the skin replacement. Accurate cutting to size around the wound contour.



A lightly compressed dressing. Regular change of Epigard after 24 to 48 hours; examination of the wound, sterile dressing.



Repeated application of Epigard until a granulation bed that is ready for transplantation is achieved.



Definitive wound occlusion by means of a mesh graft or delayed primary suture after 3 to 7 days.

2.3. *Contraindications*

The following contraindications are listed in the instruction manual:

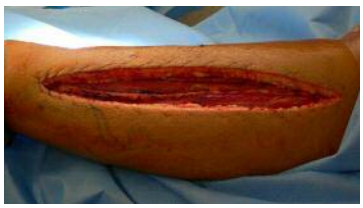
– Wounds with pocket formation.
– Massive infection with severe putrid secretion.
– Patients with restricted blood coagulation.
– Simultaneous application of creams or ointments.

2.4. *Clinical use*

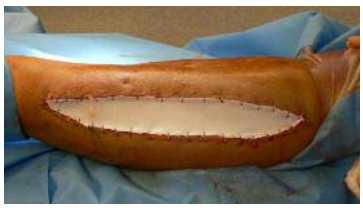
The following chapter describes how to use EpiGARD according to the instruction manual

– Before using EpiGARD the wound area must be carefully cleaned.
  Ointment residues and larger necroses are to be removed.
– Place EpiGARD with the open pore foam layer onto the wound!
– To ensure close contact with the wound surface EpiGARD must be trimmed according to the wound size and extend to the wound edges. It should be held in position e.g. with a light bandage. Due to frequent change of dressing saturation should be dispensed with.
– EpiGARD is to be regularly examined and with fluid accumulation or irritation of the wound edges it is to be replaced.
– In general daily renewal of EpiGARD is recommended.
– EpiGARD can be renewed any number of times and in this way serves as a secure infection protecting interim covering.
– With infected wounds such as e.g. with ulcerations, residual necroses and wound exudates can be removed from the wound area through frequent change of the dressing (1 to 2 times daily).

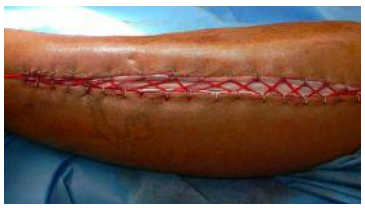
The removal of the infection is the requirement for the adhesiveness of EpiGARD on the wound and the granulation stimulation.



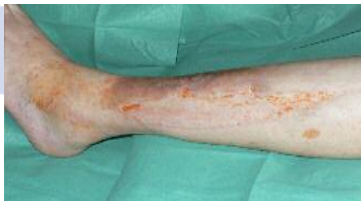
Laterale offene Dermatofasziotomie bei Unterschenkel Kompartment-syndrom.



Passagere Deckung der klaffenden Wunde mit Kunsthaut (Epigard).



Dynamisierung der Wundränder zum Erreichen eines direkten sekundären Wundverschlusses.



Folgezustand nach eingeheiltem Mesh-Graft nach Faszienspaltung wegen Kompartmentsyndrom.

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2.5. *Side effects and notes*

In the instruction manual the following possible negative effects, warnings and notes are listed.

2.5.1. Possible negative effects

During the renewal of the wound covering patient-dependent pain can occur. The specialist user should undertake individual measures for pain reduction. A renewal of the wound covering after a short interval can also significantly reduce the pain.

Your EpiGARD-Team

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