NanoEx Regenerative Wound Dressing Matrix

CE 2975

Warnings and Primary Remarks:

⚠ Use of NanoEx by AKTISCHICHT dressing must be by, or on the order of a physician (or properly licensed practitioner). Our dressing is a sterile and single-use product and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Do not use the product if there is evidence of packaging damage or after the expiration date. This dressing should be held at room temperature. Keep the product away from sunlight or excessive moisture. If you experience any allergic reactions, discontinue use of the product, and immediately contact your healthcare professional. Please refer to the directions for use, and carefully and precisely follow them.

Indications (Intended Purposes):

Diabetic foot ulcer (DFU)
Decubitus / bedsores / pressure ulcer
Burn wounds
Traumatic wounds
Skin grafts/donor sites
Surgical wounds
Venous leg ulcer (VLU)
Cavity wounds
Infected and non-infected wounds
Exposed tendons and bones
Wounds with low to moderate exudation (wound discharge)

Contraindications:

- Malignancy in the wound
- Unexplored fistula
- Untreated osteomyelitis
- Necrotic tissue with eschar present
- Exposed blood vessels or organs (heavy bleeding)
- Allergic reaction
- Wounds with severe exudation (wound discharge)

Please report any serious incident related to this product by email to **regulatory@aktischicht.ch** and or **mp-vigilanz@bfarm.de**.

Disposal:

This product should be disposed based on the hospital or healthcare professional advice (According to local regulations and procedures).

Size:

10 x 10 cm

Directions for Use of Dressing Matrix:

1) Check the Indication. NanoEx by AKTISCHICHT dressing is indicated for wounds/ulcers with minimal to moderate exudate. Consider using a super absorbent secondary dressing if the wound exudate is high which has no Silicone or Calcium Alginate in it.
2) Wash your hands, use surgical gloves, and work in sterile setup and preparations.
3) Wash the wound/ulcer and the area around it (> 1 cm margin) and remove the contaminants using standard solutions (normal saline). Please do not use irritative or cytotoxic cleaning solutions.
4) If debridement of necrotic or hyperkeratotic tissue is required, let a physician (or properly licensed practitioner) do that.
5) Gently dry the skin around the wound. Take precautions not to cause any bleeding.
6) Measure the size of the wound/ulcer. Open the package. Cut the dressing and consider covering 1 cm around the wound as a safe margin for complete adhesion and protection.
7) Put the dressing on the wound/ulcer. If the wound is not wet enough itself, moisten it drop by drop with appropriate amount of normal saline or sterile distilled water, in such a way that no extra water is left.
8) If the dressing is not completely adhered to the wound/ulcer surface, gently press on those areas with sterile gauze pads or medical swabs until it is completely adhered to the wound surface ensuring no air is trapped between the wound surface and the dressing.
9) Cover the dressing with a simple non-adherent not Ag containing outer compress pad.

Side Effects:

In the case of allergic reaction or irritation, discontinue the use of product.

Intended Users (Target Users):

Properly licensed practitioner / health care professionals and technicians in the field of wound care and healing.

Intended Environment and Place of Use:

This product has no restriction or limitation for place of use.

Target Population:

Adults (excluding pregnant).

Target Location (Application Site in the Body):

In direct contact with patient's breached skin.

Catalog Nr. EX/01/01

⚠ Warnings

- This product is for single-use only and should not be re-used.
- Re-use may lead to increased risk of infection or cross contamination.
- In the case of redness of skin, discontinue use of product.
- Do not use if package is damaged.
- Store in a dry and cool place preferably at room temperature.
- Keep away from sunlight or excessive moisture.
- If you experience any allergic reactions, discontinue use of the product, immediately contact your healthcare professional.

Symbol:

	Manufacturer		Do not resterilize
EC REP	Authorized representative in the European Community		Do not re-use
	Date of manufacture		Consult instructions for use
	Use-by date		Do not use if package is damaged
LOT	Lot Code		Keep dry
REF	Catalogue number		Keep away from sunlight
STERILE R	Sterilized using irradiation		Latex free
STERILE R	Sterilized using irradiation		Upper limit of temperature

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AKTISCHICHT Nano F. N. Teb ACTA1 holding, No. 1462, Pharmaceutical Incubator Center of Tehran University of Medical Sciences, North Kargar Street, Tehran, Iran

EC REP

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