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HYALO4 Regen CE 0373

Bioactive dressing consisting of heterologous type I horse collagen and hyaluronic acid, in the form of lyophilized sterile spongy pads, easily adaptable to the areas of application; adjuvant in the physiological processes of wound healing. Collagen and hyaluronic acid are two of the most important structural and biologic components of the organism and play a vital role in rebuilding tissue architecture after injury. Collagen is the support structure of the dermis and performs a mechanical action favouring the anchoring and orientation of fibroblasts and the formation of new tissue. Hyaluronic acid, due to its hygroscopic properties, controls tissue hydration and maintains a environment moist, favouring also the ideal conditions for orderly arrangement of collagen.

Indications for use
Acute and chronic lesions, from moderately to highly exuding wounds. Treatment of pressure ulcers, vascular ulcers, diabetic foot ulcers, chronic skin ulcers with delayed healing, surgical lesions, acute and traumatic wounds, general and specialized surgery, traumatology, gynaecology and orthopedics, dentistry, first- and second-degree burns. Local haemostat to be used in general surgical procedures, such as vascular reconstructive surgery, vascular surgery, carotid surgery, abdominal and gynaecological surgery, orthopaedic and trauma surgery, dentistry and in first aid to control capillary bleeding. Notwithstanding its excellent haemostatic properties, the dressing must not replace ligation or direct compression procedures in case of heavy bleeding. Anticoagulant therapies do not interfere with its activity.

Directions for use
Use the product immediately after opening of the primary package.

After opening the blister if only part of the pad is used, do not re-use the remaining portion(s) for subsequent applications.

Do not use on infected wounds. In such cases, before using the product perform a systemic antibiotic and/or topical antimicrobial treatment for several days.

Pre-treat the wound bed and cleanse the lesion with a humid gauze soaked in saline solution, dabbing it repeatedly. After the process of debridement to remove any purulent material and/or necrotic debris, apply the pad on the wound. In case of low exudate moisturize the pad with saline solution. The product has a smoother and a rougher surface: for better performance it is suggested to apply the smooth surface in contact with the wound.

Use one or more pads, placed contiguously or overlapped if necessary, in order to cover the entire lesion, ensuring that the pad has full contact with the entire area to be treated. Fix the pad to the lesion by means of a sterile gauze or a non-adherent dressing. Then apply elastic compression bandage. It is recommended to apply the dressing every 3-4 days or at smaller intervals, according to the wound exudate.

The product in contact with the exudate gelifies adapting perfectly to the lesion; it is absorbed and dissolves over time. The wound should be monitored every 2-3 days.

To maintain a humid microclimate cover ideally with more or less absorbent secondary dressing depending on the level of exudate and apply a bandage. The product not yet reabsorbed upon the new application must be left in situ. In the treatment of ulcers, when the product is still adherent to the wound bed, do not remove it or tear it away to check the status of the lesion.

When used as haemostat, and if unsure whether the application occurred under aseptic conditions, after haemostasis device must be removed.

Warning and precautions
Do not administer the product to patients with known family history of anaphylactic reactions or individual hypersensitivity to the components.

The product is non-toxic; it does not form bolus, if it absorbs humidity it does not cause swelling and therefore causes no risk of suffocation.

KEEP AWAY FROM THE REACH AND SIGHT OF CHILDREN.

The device is intended for single use. Do not re-use the leftovers of the pad.

The device is sterile. Do not use if the package is damaged.

Do not use after the expiry date. The expiry date refers to an integral package, suitably stored.

Contraindications and side effects
The device is biocompatible and bioresorbable. There are no known or reported cases of sensitization or any unwanted or side effects. The device does not impair the ability to drive or to operate machinery. There are no known contraindications for use during pregnancy or breastfeeding; but in the absence of specific data, the use of the device is recommended under the direct supervision of a doctor.

Storage and transport conditions
Keep the product in a dry place, away from heat sources.

Package
Box containing 5 sterile pads 5x5 cm in single blisters
Box containing 5 sterile pad 10x10 cm in single blisters

Manufacturer
EURORESEARCH s.r.l.-Via Larga, 15-20122 Milano-Tel.+39 02 8055660

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