BIOPAD

CE 0373

Horse collagen

Medical device for use as haemostat and for the treatment of pressure ulcers, venous ulcers and diabetic ulcers.

INDICATIONS FOR USE

BIOPAD® is constituted by native heterologous type I horse collagen, lyophilized and sterile, under form of spongy pads, easily adaptable to the areas of application.

Local haemostat to be used in surgical procedures such as vascular reconstructive surgery, vascular surgery, carotid surgery, abdominal surgery and gynecological, orthopedic and traumatological surgery and odontology and for first aid to control capillary bleeding. Notwithstanding its excellent haemostatic properties, BIOPAD must not replace ligation or direct compression procedures in case of heavy bleedings. Anticoagulant therapies do not interfere with its activity.

Treatment of cutaneous lesions of different etiology such as sores for delayed healing, venous and diabetic ulcers, pressure ulcers, and as stimulus to the physiological process of wound healing.

DIRECTIONS FOR USE

Use the product immediately after opening of the primary package.
After opening of the blister if only part of the pad is used, do not re-use the remaining portions for subsequent applications.

Do not use if the bed of the lesion shows a local infection. In this case before using BIOPAD® perform a systemic or topical antibiotic treatment.
Treat previously the lesion with a disinfectant or a sterile physiological saline; cleanse the lesion with a dry gauze, removing if necessary the eventual purulent material and/or necrotic tissues from the bed and the edges of the lesion. Apply the pad on the lesion with a soft pressure; use one or more pads, in order to cover the whole lesion.
Fix the pad to the lesion and keep it in place by means of a sterile gauze or a non-occlusive bandage (even elastic) or using a plaster.

When used as haemostat and if the application is performed without being sure to have worked in aseptic conditions, after haemostasis the pad must be removed.

When used to treat ulcers, when the product is adhered to the bed of the lesion, do not remove nor detach it to control the lesion itself. The product is absorbed in the time. The lesion must be controlled every 2-3 days (every 24 hours in case of pressure sore) If, at the control, the product has been absorbed, place another pad on the bed of the lesion without removing eventual fragments still adherent to the lesion itself.

WARNING AND PRECAUTIONS

Do not administer the product to patients with known family history of auto-immune diseases, history of anaphylactoid reactions or known hypersensitivity to collagen, both topical and injectable, or in subjects undergoing desensitization therapy to meat products.
The product is non-toxic; it does not expand nor form bolus if it absorbs humidity therefore it does not cause risk of suffocation.
KEEP AWAY FROM THE REACH AND SIGHT OF CHILDREN

The device is intended for single use.
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.

STORAGE CONDITIONS

Keep the product in a dry place, far from heat sources.

PACKAGE

Box containing 3 sterile pads 5x5 cm in single blisters
Box containing 1 sterile pad 5x5 cm in single blister
Box containing 1 sterile pad 10x10 cm in single blister

MANUFACTURER

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DISTRIBUTOR

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