

**TECHNICAL DATA SHEET
BIOPAD®**

DESCRIPTION

BIOPAD® is a wound dressing for topical use to control minor bleedings and for the management of any kind of ulcer and skin lesion to help wound closure.

BIOPAD® is a sponge shaped device, constituted exclusively by lyophilized type 1 native heterologous collagen extracted from horse flexor tendon.

When applied to a wound, BIOPAD® constitutes a barrier for wound against exogenous infective agents.

BIOPAD® is the ideal first-aid mean to control minor bleedings.

The device may be used by doctors, nurses, home care providers, unlicensed care providers.

The product is supplied sterile and for one-time-use only.

INDICATIONS FOR USE

BIOPAD® is a collagen wound dressing intended for the control of minor bleeding, and for the local management of moderately to heavy exuding wounds including:

- pressure sores,
- donor sites and other bleeding surfaces,
- dehisced surgical incisions,
- draining wounds,
- lacerations,
- venous stasis ulcers,
- diabetic ulcers,
- partial and full thickness wounds,
- post-laser surgery,
- podiatric,
- surgical and traumatic wounds.

The product is supplied sterile and for one-time-use only.

CONTRAINDICATIONS

DO NOT USE ON GROSSLY OR CLINICALLY DIAGNOSED INFECTED WOUNDS.

There are no contraindication in the use of BIOPAD®, unless known hypersensitivity to the collagen itself.

Do not use in 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.

USE DURING PREGNANCY OR NURSING

The product is not systemically absorbed, therefore it can be used even during pregnancy or nursing.

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MEDICAMENTOUS INTERACTIONS

No medicamentous interactions are known or have ever been reported.

DIRECTIONS FOR USE

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

The product – being sterile - is intended for one-time-use only.

Before the application of BIOPAD® an accurate cleansing of the lesion is needed: this is fundamental to allow the device to exert its best action.

Cleansing of the wound

It is defined as “cleansing” the action of removal of the necrotic material and exudates before proceeding with application of the product.

The cleansing action can be performed with surgical or not surgical methodologies: the non-surgical method consists in using wet gauzes while the surgical method consists on using lancets or scissors.

Application of BIOPAD®

After cleansing of the lesion, the treatment with BIOPAD® can start.

Before application, it is possible to wet the BIOPAD® pad with physiological solution, in order to have it more adaptable to the bed of the lesion.

Apply on the bed of the lesion one or more pads of BIOPAD® - depending on exudates - to completely cover the whole surface of the lesion.

After application, cover the pad or pads with an appropriate secondary dressing; there are no contraindications to the use of elastic bandages in case of ulcers caused by primitive varix or post-thrombophlebitic syndrome.

A first control is performed after 48 hours.

During the control a particular attention has to be given to the status of the pads applied.

The new medication foresees the repositioning of the device only in the areas where the pad is melted out.

The controls, which will be more frequent in the first phase of the treatment, can become less frequent the more the healing process develops.

There are no contra-indications on the simultaneous use of other topical products improving the cleansing of the lesion, unless these products make a barrier between BIOPAD® pad and the bed of the lesion.

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WARNINGS

The product is non-toxic; it does not expand nor form bolus if it absorbs humidity therefore it does not cause risk of suffocation, however it is recommended to KEEP OUT OF CHILDREN'S REACH

The product is supplied sterile and for one-time-use only.

PRECAUTIONS

It is important to apply correctly BIOPAD® previously cleansing the wound, eventually removing the necrotic tissues.

BIOPAD® is not intended to replace ligation or compression procedures in case of heavy bleeding.

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.

ADVERSE EVENTS

No side effects or undesirable effects have ever been revealed or reported.

SUMMARY OF CLINICAL STUDIES

In clinical practice, the use of BIOPAD® proved to be of particular efficacy in the wound management fastening the tissue repair process.

BIOPAD® has been used in general surgery, in the therapy of venous stasis ulcers and of skin's continuity solution to control minor bleedings and as stimulator of wound closure.

In the therapy of venous stasis ulcers and of skin's continuity solution, the sponge of BIOPAD® is simply compressed over the wound and never removed until healing is complete and new tissue is formed.

BIOPAD® efficacy in treating venous stasis ulcers is documented by controlled studies against traditional therapeutic methods (elasto-compression) and against control preparations (hydrocolloids) on historical groups of patients having the same pathology and treated in the past in the same hospital with other therapeutic methods.

The theoretical limit in comparing different groups was overtaken performing experiments, where possible, on symmetrical ulcers or multiple ulcers on the same patient or treating half ulcer with BIOPAD® and the other half with the control preparation.

The use of BIOPAD® on pressure sores compared with use of polyurethane showed its ability in accelerating the repair process.

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Similar good results were obtained in treating different etiology ulcers:

Healing time evaluation of diabetic ulcers in patients treated with BIOPAD or Hyaluronic Acid	BIOPAD 32 days	Hyaluronic acid 49 days
Healing time evaluation of pressure ulcers in patients treated with BIOPAD or with Polymerized dextran (Xerogel)	BIOPAD 23 days	Polymerized dextran 47 days
Healing speed evaluation of venous stasis ulcers in patients treated with BIOPAD or with hydrocolloid	BIOPAD 77.5 mm total / week	HYDROCOLLOID 55 mm total / week

The cost-benefit comparison results in all cases completely positive thanks to the sensible reduction of healing time, easiness of use, painless application, spaced applications (each 3 or 4 days) as well as possibility of outpatient treatment (in acute phase) and home-treatment (subsequently the acute phase).

STORAGE

No special or specific conditions or restrictions are needed.

It is however suggested, alike for all devices, to keep the product in a dry place, far from heat sources.

PRESENTATION

BIOPAD® is individually packed in a sterile blister, for one-single-use only.

MANUFACTURER

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