EURORESEARCH
natural growing, natural healing

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BIOPAD.

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1. COMPOSITION

BIOPAD is a medical device, sterile, constituted by:

- 100%, native, equine, type I collagen.

This Technical Sheet is related to the following references:

Reference	Unit(s) in each box
5 x 5 x 0,6 cm	3
10 x 5 x 0,6 cm	1
10 x 10 x 0,6 cm	1
10 x 15 x 0,6 cm	1

Spongy pads of different sizes (standard 5x5 cm) ivory-white colour, tasteless, with characteristic smell, constituted by horse type I collagen.

The weight of each pad 5x5 cm is 0.25 g. Its composition consists in:

- 0,25 g of Collagen in 15 cm^3 (0,01666 g/cm^3);

The weight of each pad 10x10 cm is 1 g. Its composition consists in:

- 1 g of Collagen in 60 cm^3 (0,01666 g/cm^3);

2. PACKAGING

2.1 Primary packaging

Material of primary packaging of the device is composed of a PET or PVC blister in the form of a thermoformed basin, hot sealed in aluminium foil lacquered with thermosealing polyvalent paint on PET or PVC for pharmaceutical use suitable to sterilization by irradiation. Every blister contains one collagen pad (single use).

2.2 Secondary packaging

The secondary packaging is based on carton box, each containing:
n. 3 of 5x5 cm pads/case introducing one leaflet inside;
n. 1 of 10x5 cm pad/case introducing one leaflet inside;
n. 1 of 10x10 cm pad/case introducing one leaflet inside;
n. 1 of 10x15 cm pad/case introducing one leaflet inside.

2.3 External packaging

The last packaging step is to introduce cases into a carton box according to the following quantities (examples of standard packaging) :
n. 56 of 5x5 cm cases/carton box;
n. 34 of 10x 5 cm cases/carton box;
n. 34 of 10x10 cm cases/carton box;
n. 24 of 10x15 cm cases/carton box.

3. MANUFACTURING

BIOPAD is medical device manufactured in compliance with the EC Directive 93/42/EEC concerning medical device and its amendments.

The sterility of device has been guaranteed by irradiation process of sterilization.

The manufacturer has conducted all the tests of validation of biocompatibility, stability and sterility of device in compliance with ISO 13485 and its reference standards.

4. DESCRIPTION

Medical device constituted by native type I horse collagen, lyophilized and sterile, under form of spongy pads, easily adaptable to the areas of application.

The device is intended for single use.

5. INTENDED USE
Medical device for use as haemostat and adjuvant in the treatment of pressure ulcers, venous ulcers and diabetic foot ulcers, chronic and traumatic skin lesions and acute traumatic wounds.
Local haemostat to be used in general surgical procedures, such as vascular reconstructive surgery, vascular surgery, carotid surgery, abdominal and gynaecological surgery, orthopedics, traumatology, odontology and for first aid to control capillary bleeding.

6. EC DIRECTIVE 93/42/EEC
BIOPAD is a medical device constituted by "collagen pad, sterile" and classified as **Class III**, according to Rule 17, Annex IX of EC Directive 93/42/EEC.

The device has been manufactured according to the essential requirements.

7. BIOCOMPATIBILITY and RISK MANAGEMENT
The biological evaluation and biocompatibility assessment are in accordance with reference standard of EN ISO 10993 – "Biological evaluation of medical device".

According to clinical evaluation and the risk analysis assessment, the safety and the biocompatibility of BIOPAD are guaranteed if the device is used as intended.

The device is composed by equine type I collagen (non-medicinal substance), that is "BSE free". The device is "phthalate-free" and "latex-free", too.

The device is intended for single use. Do not re-use any remaining portions of pad. 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.

Collagen is not harmful nor toxic nor irritating.

There are no records of irritating effects caused by the use of collagen pads, even in case of prolonged use.
There are no known or reported cases of sensitization or any side effects.
The device has no effect on driving and use of machinery.
There are no known contraindications to the use of this device during pregnancy or lactation, but in the absence of specific data, use of the product is recommended only under the direct supervision of a doctor.

8. SHELF-LIFE
The sterile lyophilized collagen pad, packed in single intact blisters, when suitably stored is stable for 60 months (5 years) from the date of manufacture.
Keep the device in a dry place, far from heat sources.
Transportation temperature not exceeding 30°C, avoid direct exposure to sunlight.
It is advisable to keep the product in a dry cool place far from heat sources and at temperatures not exceeding 30°C.

9. DISPOSAL INFORMATION
No specific warning or cautions.
It is however recommended not to environmentally disperse the device but, in case of need, to follow local regulations on the disposal of medicinal products and of plastic containers (empty blister).

10. CND CODE
M04041001.

11. RDM CODE
102352/R.

12. **GMDN CODE**
45023 – Dressing, occlusive, collagen for wound healing.