

MOMOSAN®CLIMA mesh patches (green)**CAUTION**

Please read this information carefully.

Improper use and care, as well as misuse may cause premature wear or risks for patients and users.

PROPER USE

MOMOSAN®CLIMA mesh patches are suitable for positioning and the prevention of pressure sores. MOMOSAN®CLIMA should be used without direct skin contact. It is recommended to use it together with MOMOSAN®WHITE.

DESCRIPTION

MOMOSAN®CLIMA mesh patches prevent the accumulation of heat and moisture, as fluid and air can pass through it almost unhindered, and is therefore used as thick padding. MOMOSAN®CLIMA mesh patches regulate heat very well and are permanently elastic.

MOMOSAN®CLIMA mesh patches are always delivered unsterilised and may be sterilised prior to use.

APPLICATION AND SAFETY INSTRUCTIONS

The form of application needs to be decided individually by a doctor or a medically trained person / nurse (certified wound manager). MOMOSAN®CLIMA may be sterilised prior to use. Sterilisation should only be performed by trained staff. Sterilisation should be performed with vapour (5 minutes at 134°C) according to a validated procedure pursuant to ISO 17665 and EN 285. After sterilisation the packaging (sterile barrier system) must not be damaged during transport and/or positioning. Detailed information regarding reprocessing can be found in the manufacturer information pursuant to ISO 17664 below.

MOMOSAN®CLIMA must not be used together with oxidants like hypochlorite solution or hydrogen peroxide, as these substances may break down MOMOSAN®CLIMA.

Do not use if there are any clinical signs of a severe infection (e.g. swellings or pain) and consult a doctor immediately.

We have not tested application in contact, connection or combination with additional substances and medications. Sterility can only be guaranteed for undamaged packaging. MOMOSAN®CLIMA is a single-use product.

Reprocessing after use and renewed sterilisation is not permitted.

There are no known contraindications.

Please let us know immediately should you notice any side effects, risks or possible risks not described in this package leaflet.

APPLICATION

MOMOSAN®CLIMA is not suitable for direct skin contact and must therefore only be used in combination with MOMOSAN®WHITE or other pads such as linen patches etc. MOMOSAN®CLIMA mesh patches are cut to size and can be piled as needed in order to achieve the necessary supportive effect at the right places. MOMOSAN®CLIMA can be cut to size with scissors to be perfectly suitable for all purposes.

MOMOSAN®CLIMA is a single-use product and must not be reprocessed after use.

**REPROCESSING and MANUFACTURER INFORMATION Sterilisation MOMOSAN®****REPROCESSING of MOMOSAN®WHITE - MOMOSAN®BLACK - MOMOSAN®CLIMA**

MOMOSAN® is a single-use product and must not be reprocessed or applied after use.

STORAGE of MOMOSAN®WHITE - MOMOSAN®BLACK - MOMOSAN®CLIMA

It may only be stored in its original packaging and must not be used after the best-by date. The admissible storage conditions for sterile products are:

+10°C to +30°C at 30-65 % RH; for non-sterile products: -20°C to + 60°C

HANDLING of MOMOSAN®WHITE - MOMOSAN®BLACK - MOMOSAN®CLIMA

MOMOSAN should be transported with utmost care. If the packaging of MOMOSAN® is damaged, the product is no longer safe to use and must be discarded immediately. A possible renewed sterilisation in case of damaged packaging is not permitted.

GUARANTEE

MOLTOPLAST GmbH – HEALTHCARE only delivers tested and impeccable products to its customers. All of our products are made to the highest quality standard.

We do not assume liability for products that have been modified from the original (except for the option of cutting to size mentioned in the patient information leaflet), alienated, misused or applied improperly.

MANUFACTURER INFORMATION pursuant to DIN EN ISO 17664**On the sterilisation of the non-sterile Momosan products MOMOSAN®WHITE - MOMOSAN®BLACK - MOMOSAN®CLIMA**

General remarks: Non-sterile products of the Momosan product range may all only be sterilised once prior to the single use. It is not permitted to clean and resterilise them. The user is responsible for the sterility of the wound pads; please make sure that only validated procedures are used for sterilisation. All sterilisers must be maintained regularly. The parameters of the sterilisation cycles need to be checked regularly. Please observe your country's applicable legal provisions. Packaging and sterilisation of the products needs to take place in controlled conditions in der ZSVA and/or reprocessing of instruments) by trained staff (eg. Specialists for the reprocessing of medicinal products).

Checking of function: Momosan products by Moltoplast should be compressed shortly prior to reprocessing to check their mechanical characteristics and guarantee their intact function

Cleaning and disinfection: Momosan products by Moltoplast are delivered in clean packaging and do not need to be cleaned or disinfected prior to first use.

Packaging & labelling: Momosan products need to be packaged in standardised packaging material pursuant to the EN 868 and ISO 11607 standards. The packaging must have an appropriate size which can be sealed without tension. The products must be labelled pursuant to the EN 980 standard.

Sterilisation: Sterilisation needs to be performed by means of vapour sterilisation according to a fractionated vacuum method at 134°C / 3.0 bars for at least 5 min. (holding temperature). The steriliser must be in line with the EN 285 and/or EN 13060 standard. The maximum loading capacity of the steriliser must not be exceeded and the packaged Momosan products need to be placed in a way that enables optimum permeability vapour of. The products should dry for at least 10 min. Moltoplast GmbH can provide more information on other sterilising procedures. Packaging staying moist for more than 30 minutes after sterilisation is deemed unable to be stored and needs to be sorted out and repackaged.

Storage: The products must be stored in a dry place to prevent condensation. The storage conditions need to be in line with the instructions of the patient information leaflet.

Instruction for use

MOMOSAN®

Supports reliable healing of

- chronic wounds
 - decubitus ulcers
 - venous ulcers
 - burns, abrasions
- post-operative wound dressing**

**Ideal as
bedsore prevention**

Manufacturer:
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MOMOSAN®WHITE sterile/non-sterile**CAUTION**

Please read this information carefully.

Improper use and care, as well as misuse may cause premature wear or risks for patients and users. MOMOSAN®WHITE may have a yellowish colour.

This does not affect the product's quality.

PROPER USE

MOMOSAN®WHITE is suitable for wound treatment, debridement, prevention, for positioning and as therapeutic aid. It is made for contact with skin, mucosa, injured surfaces, body orifices, the oral cavity and throat, the auditory meatus as far as the eardrum and the nasal cavity. It may be applied for 24 hours up to a maximum of 30 days.

DESCRIPTION

MOMOSAN®WHITE is a therapeutically effective polyurethane foam with microtubule-like honeycomb structure. With its wide range of applications MOMOSAN®WHITE is perfectly suitable for wound treatment, mechanic debridement, prevention of pressure sores and intertrigo, positioning and fixation. MOMOSAN®WHITE is available in various forms (e.g. slabs, pads, compresses/ bandages, tamponades). MOMOSAN®WHITE-sterile is delivered sterilised and ready to use. Whether MOMOSAN®WHITE-non-sterile may need to be sterilised needs to be decided by a doctor or a medically trained person / nurse (certified wound manager).

INFORMATION ON APPLICATION AND SAFETY

The form of application of MOMOSAN®WHITE-non-sterile and whether it may need to be sterilised needs to be decided individually by a doctor or a medically trained person / nurse (certified wound manager). MOMOSAN®WHITE-non-sterile may be sterilised prior to use. After sterilisation the packaging (sterile barrier system) must not be damaged during transport and/or positioning. Sterilisation should only be performed by trained staff. Sterilisation should be performed with vapour (5 minutes at 134°C) according to a validated procedure pursuant to ISO 17665 and EN 285. Detailed information regarding reprocessing can be found in the manufacturer information pursuant to ISO 17664 below.

MOMOSAN®WHITE must not be used together with oxidants like hypochlorite solution or hydrogen peroxide, as these substances may break down MOMOSAN®WHITE.

Due to its mechanical stimulus, MOMOSAN®WHITE promotes blood circulation; this could have a negative effect on carcinomas.

Do not use if there are any clinical signs of a severe infection (e.g. swellings or pain) and consult a doctor immediately.

When cutting MOMOSAN®WHITE to size, make sure no snippets get into the wound.

We have not tested application in contact, connection or combination with additional substances and medications. Sterility can only be guaranteed for undamaged packaging. MOMOSAN®WHITE is a single-use product.

Reprocessing after use and renewed sterilisation is not permitted.

There are no known contraindications.

Please let us know immediately should you notice any side effects, risks or possible risks not described in this package leaflet.

APPLICATION**1. Wound treatment**

MOMOSAN®WHITE can be used to clean, cover or fill wounds. MOMOSAN®WHITE can also be applied in NPWT. Provided that the wound allows for outflow of secretion, it can be completely dressed directly with MOMOSAN®WHITE without prior treatment applying mild compression pressure. This also requires contact with the wound edges. If necessary, MOMOSAN®WHITE can be cut to size with scissors and covered with another piece of MOMOSAN®WHITE overlapping approx. 1-2 cm. In this case, an additional large slab of MOMOSAN®WHITE is used to treat the surroundings of the wound. The larger the area of the treated surroundings of a wound, the better the effect. The method of dressing needs to be adjusted individually for each case. The wound should be open for as short a time as possible to prevent it from cooling down. MOMOSAN®WHITE can be changed between once a day to once every three days. In case of strongly oozing wounds, MOMOSAN®WHITE should be changed multiple times a day.

1.1. Possible combinations

Under certain circumstances, for example if massive amounts of exudate need to be controlled, it may be combined with MOMOSAN®BLACK (see instructions for MOMOSAN®BLACK). MOMOSAN®BLACK is applied directly onto the wound in order to guarantee a quicker absorption and transmission of exudate. An additional layer of MOMOSAN®WHITE is applied on top, as it has a better absorbing capacity.

1.2. Mechanic debridement as wound dressing

The wound is filled with MOMOSAN®BLACK. The wound can still be washed. The cut edges of the cell struts of MOMOSAN®BLACK cause an increased mechanic stimulation in the wound, which makes the wound dressing work as mechanic debridement. As soon as exudate develops, another layer of MOMOSAN®WHITE is applied on top to absorb it.

1.3. Mechanic debridement through wound cleaning

The wound is first cleaned with MOMOSAN®BLACK. Based on the cut edges of the cell struts this is the preliminary cleaning. Then the wound is cleaned with MOMOSAN®WHITE. This is the fine cleaning.

2. Pressure relief and prevention**2.1. Positioning and prevention of pressure sores**

Correct positioning is not only a preventive measure for the treatment of pressure sores, it also prevents pressure sores from developing in the first place and supports treatment of an existing pressure sore. With its contact to the skin, MOMOSAN®WHITE causes microstimulation (promoting peripheral blood flow), as padding of the regulation of fluid (absorbing excessive sweat) and, with adequate thickness (no folds) guarantees distribution and reduction of pressure.

2.2. Prevention of mycotic infections, inflammations caused by skin-to-skin contact

The warm and wet, low-oxygen climate in the skin-to-skin contact between toes, fingers, abdominal folds, under the breasts, in the armpits etc. may promote the development of mycotic infections and dermatitis. An intermediate layer of MOMOSAN®WHITE may be used as preventive measure and for treatment.

2.3. Disturbed blood flow in the legs

An arterial blood flow disorder can be treated very well by tension-free (without compression) wrapping of a MOMOSAN®WHITE bandage (with half and/or three quarters overlapping in the region of joints). The mechanic stimulation of MOMOSAN®WHITE promotes blood flow.

MOMOSAN®BLACK sterile/non-sterile**CAUTION**

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PROPER USE

MOMOSAN®BLACK is suitable for wound treatment and debridement. It is made for contact with skin, mucosa, injured surfaces, body orifices, the oral cavity and throat, auditory meatus as far as the eardrum and the nasal cavity. It may be applied for 24 hours up to a maximum of 30 days.

DESCRIPTION

MOMOSAN®BLACK is a therapeutically effective polyurethane foam with microtubule-like honeycomb structure. With its wide range of applications MOMOSAN®BLACK is perfectly suitable for wound treatment. Furthermore, the cut edges of the cell struts are perfectly suitable for mechanic debridement due to their special structure. MOMOSAN®BLACK is available in various forms (e.g. slabs, pads, compresses/ bandages, tamponades). MOMOSAN®BLACK-sterile is delivered sterilised and ready to use. Whether MOMOSAN®BLACK-non-sterile may need to be sterilised needs to be decided by a doctor or a medically trained person / nurse (certified wound manager).

INFORMATION ON APPLICATION AND SAFETY

The form of application needs to be decided individually by a doctor or a medically trained person / nurse (certified wound manager). MOMOSAN®BLACK-non-sterile may be sterilised prior to use. Sterilisation should only be performed by trained staff. Sterilisation should be performed with vapour (5 minutes at 134°C) according to a validated procedure pursuant to ISO 17665 and EN 285. After sterilisation the packaging (sterile barrier system) must not be damaged during transport and/or positioning. Detailed information regarding reprocessing can be found in the manufacturer information pursuant to ISO 17664 below.

MOMOSAN®BLACK must not be used together with oxidants like hypochlorite solution or hydrogen peroxide, as these substances may break down MOMOSAN®BLACK.

Due to its mechanical stimulus, MOMOSAN®BLACK promotes blood circulation; this could have a negative effect on carcinomas.

Do not use if there are any clinical signs of a severe infection (e.g. swellings or pain) and consult a doctor immediately.

When cutting MOMOSAN®BLACK to size, make sure no snippets get into the wound.

We have not tested application in contact, connection or combination with additional substances and medications. Sterility can only be guaranteed for undamaged packaging. MOMOSAN®BLACK is a single-use product.

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There are no known contraindications.

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APPLICATION**1. Wound treatment**

MOMOSAN®BLACK can be used to clean, cover or fill wounds. MOMOSAN®BLACK can also be applied in NPWT.

Provided that the wound allows for outflow of secretion, it can be completely dressed directly with MOMOSAN®BLACK without prior treatment applying mild compression pressure. This also requires contact with the wound edges. If necessary, MOMOSAN®BLACK can be cut to size with scissors and covered with another piece of MOMOSAN®BLACK overlapping approx. 1-2 cm. In this case, an additional large slab of MOMOSAN®BLACK is used to treat the surroundings of the wound. The larger the area of the treated surroundings of a wound, the better the effect.

The method of dressing needs to be adjusted individually for each case. The wound should be open for as short a time as possible to prevent it from cooling down. MOMOSAN®BLACK can be changed between once a day to once every three days. In case of strongly oozing wounds, MOMOSAN®BLACK should be changed multiple times a day.

1.1. Possible combinations

Under certain circumstances, for example if massive amounts of exudate need to be controlled, it may be combined with MOMOSAN®WHITE (see instructions for MOMOSAN®WHITE). MOMOSAN®BLACK is applied directly onto the wound in order to guarantee a quicker absorption and transmission of exudate. An additional layer of MOMOSAN®WHITE is applied on top, as it has a better absorbing capacity.

1.2. Mechanic debridement as wound dressing

The wound is filled with MOMOSAN®BLACK. The wound can still be washed. The cut edges of the cell struts of MOMOSAN®BLACK cause an increased mechanic stimulation in the wound, which makes the wound dressing work as mechanic debridement. As soon as exudate develops, another layer of MOMOSAN®WHITE is applied on top to absorb it.

1.3. Mechanic debridement through wound cleaning

The wound is first cleaned with MOMOSAN®BLACK. Based on the cut edges of the cell struts this is the preliminary cleaning. Then, the wound is cleaned with MOMOSAN®WHITE. This is the fine cleaning.