

Instructions for Use

2-Component System Indicator

Product description:

- This 2-Component System with indicator consists of a white padded bandage and a brown cohesive compression bandage with an indicator print. This is a non-sterile product for single use only. The 2-Component System with indicator is indicated for long-term compression therapy for venous diseases and oedema caused by other factors (in patients with an ABPI* of 0.8–1.3). Positioning the two bandages in a layered combination forms a compression system, which can be worn for up to a week, depending on the condition of the wound and the time for which the wound dressing is worn.
- The product must be used on intact (uninjured) skin only. Wounds must be treated with a suitable wound dressing in advance.
- The 2-component system with indicator can be used by medical specialists in both clinical and domestic settings.
- Due to its short-stretch properties, the 2-Component System with indicator has a high working pressure and a low resting pressure (in mobile patients). As a result, oedema can be reduced.
- There is an indicator printed on the outside of the brown cohesive compression bandage to help with correct application. When the bandage is stretched, the shape of the indicator changes. When the indicator image forms a square, this indicates that the bandage has the correct stretch to achieve the required compression pressure.

Composition

- The first layer is a white padded bandage made from polyester and elastane with a cohesive coating on one side (manufactured without natural rubber).
- The second layer is a brown compression bandage made from polypropylene and elastane with a cohesive coating on both sides (manufactured without natural rubber). There is an indicator symbol printed on this bandage (diamond shape).

Indications

Chronic venous diseases

- Prevention and treatment of venous oedema
- Prevention and treatment of venous skin changes
- Eczema and pigmentation
- Lipodermatosclerosis and atrophie blanche
- Treatment of venous leg ulcers
- Prevention of recurrent venous leg ulcers
- Varicose veins
- Initial phase after treatment of varicose veins
- Functional venous insufficiency (associated with obesity, jobs that involve sitting or standing)
- Venous malformations

Thromboembolic venous diseases

- Superficial venous thrombosis
- Deep arm and leg venous thrombosis
- Post-thrombotic syndrome
- Thrombosis prophylaxis in mobile patients

Oedema

- Lymphoedema
- Oedema in pregnancy
- Post-traumatic oedema
- Post-operative oedema
- Post-operative reperfusion oedema
- Idiopathic cyclic oedema
- Lipoedema from stage II
- Congestive states as a result of immobility (arthrogenic congestive syndrome,

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- paresis and partial paresis of the extremities)
- Drug-induced oedema if not possible to switch

Other indications

- Obesity with functional venous insufficiency
- Inflammatory dermatosis of the legs
- Congestive conditions in pregnancy

Contraindications

- Advanced peripheral arterial occlusive disease (if one of the following parameters applies: ABPI < 0.5, ankle blood pressure < 60 mmHg, toe blood pressure < 30 mmHg or TcPO₂ < 20 mmHg instep).
- Decompensated heart failure (NYHA III + IV)
- Septic phlebitis
- Ankle brachial pressure index (ABPI) > 1.3 and < 0.5
- Phlegmasia coerulea dolens

Relative contraindications

- Severe exuding dermatosis
- Intolerance to compression material
- Severe sensory disturbances of the extremity
- Advanced peripheral neuropathy (e.g. associated with diabetes mellitus)
- Primary chronic polyarthritis

Method of application (recommended) or according to doctor's instructions

- Before use, please measure the circumference of the patient's ankle (this 2-Component System with indicator is indicated for an ankle circumference of 18–32 cm).
- Make sure that the patient's foot remains at a 90° angle to the lower leg throughout the application of the compression bandage..
- **White padding bandage:** Start by applying the white padded bandage to the metatarsophalangeal joint. After two fixing turns, guide the bandage over the back of the foot and include the heel in figure-of-eight turns. Do not stretch the padded bandage while applying it to the foot.
- Wrap the white padded bandage in a spiral around the leg above the ankle at full stretch with an overlap of 50%. Tear off excess bandage material around 2 cm below the head of the fibula. Additional fixation is not required, but plaster strips can be used if necessary.
- **Brown cohesive compression bandage:** Apply the brown cohesive compression bandage to the foot in the same way as the padded bandage. Do not stretch the brown compression bandage while applying it to the **foot** and do **not** use the printed indicator as a guide.
- Wrap the brown compression bandage in a spiral around the leg **above the ankle** with an overlap of the layers of 50%. For optimal pressure, stretch the bandage until the printed **indicator** shows a regular shaped **square** with all sides of equal length (see illustration).



- Tear off excess bandage material about 2 cm below the head of the fibula and carefully press the bandage down over the entire leg. This will ensure optimal adhesion. Additional fixing is not required, but plaster strips can be used if necessary.
- It may be necessary to adjust the application technique to suit the anatomical or pathophysiological characteristics of the patient.
- The application technique may also need to be adjusted according to the medical prescription.

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Additional information

- Before starting treatment with the 2-Component System with indicator, a Doppler examination should be performed to determine the ABPI.
- Before applying the 2-Component System with indicator, the wound must be cleaned and covered with a suitable wound dressing.
- When applying the 2-Component System with indicator, make sure that the bandages are evenly stretched and are kept parallel in order to achieve even distribution of pressure and to avoid constriction.
- After application, ensure that there is good circulation in the toes to ensure that the pressure of the bandage is not too high. If pain or complications, such as sustained discoloration (blue or white toes), occur during treatment with the 2-Component System with indicator, the bandage must be removed immediately and the treating doctor must be informed.
- Bandages may cause dryness and itching of the skin.
- During treatment with the 2-Component System with indicator, the patient should be encouraged to move in order to support the therapeutic effect.
- Both bandages can be torn by hand.
- The bandage can be removed by unwinding the two bandages or by cutting them with bandage scissors.
- It is hazardous to re-use a medical device that is intended for single use. Recycling products in order to re-use them can have a seriously negative impact on their properties and performance.

Please note: **If, during the use of this product, you have any reason to assume that a serious event has occurred, please report the event to the manufacturer and your national regulatory authority.**

Medical device



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