Instructions for Use

VisioCompress® 1 Lite
2-in-1 compression bandage with reduced pressure

Product description

- VisioCompress® 1 Lite consists of a white inner padding side and a brown cohesive outer side with indicator print. This is a non-sterile medical device for single use only. VisioCompress® 1 Lite is indicated for long-term treatment in compression therapy that requires reduced compression (for patients with an ABPI – ankle brachial pressure index – of 0.6–0.8) or for patients unable to tolerate higher level of compression, or as part of a step up approach. The compression bandage can be worn for up to 7 days, depending on the condition of the wound and the wear time of the wound dressing used.
- The medical device must be used on intact (uninjured) skin only. Wounds must be treated beforehand with a suitable wound dressing.
- VisioCompress® 1 Lite can be used by healthcare professionals in both clinical and domestic settings.
- There is an indicator printed on the outside of the bandage to help with correct application. When the bandage is stretched, the shape of the indicator changes. When the indicator image turns into a square, this indicates that the bandage has the correct stretch to achieve the required compression pressure.

Composition

- The inner side of VisioCompress® 1 Lite is a white padding layer. The outer brown cohesive side (made without natural rubber) has an indicator symbol (rhombus) printed on it. The product contains approx. 64% polyester, 30% polypropylene, and 6% elastane.

Indications

Chronic venous diseases

- Therapy of mixed (arterial and venous etiology) leg ulcers
- 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, paresis and partial paresis of the extremities)
- Drug-induced oedema if not possible to switch

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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
- 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 (VisioCompress® 1 Lite) 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 while applying the compression dressing.
- Start with the base joint of the toe. After two securing turns, wrap the bandage over the top of the foot and include the heel in figure-eight turns. Be careful not to stretch the bandage when applying it to the foot and do not use the printed indicator as a guide.
- Wrap the bandage above the ankle in a spiral around the leg, overlapping by 50%. For optimum pressure, stretch the bandage until the printed indicator forms a regular square with sides of equal length (see illustration).
- About 2 cm below the fibula head, cut off any excess bandage material and carefully press the bandage firmly onto the entire leg. Please secure the bandage.



Illustration:
Final shape of the indicator

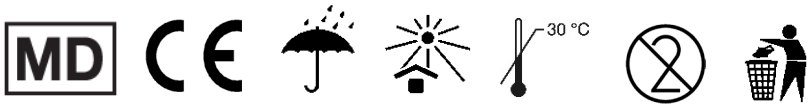
- It may be necessary to adjust the application technique to suit the anatomical or pathophysiological characteristics of the patient.
- The application technique may also need to be adjusted according to the medical prescription.

Additional information
- Before starting the therapy with VisioCompress® 1 Lite , a Doppler examination should be performed to determine the ABPI.

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- Before applying VisioCompress® 1 Lite , the wound must be cleaned and covered with a suitable wound dressing.
- When applying VisioCompress® 1 Lite , make sure that the bandage is evenly stretched and are kept parallel in order to achieve even distribution of pressure and to avoid constriction.
- After application, check that there is good circulation in the toes to ensure that the dressing pressure is not too high. If pain or complications, such as persistent discolouration (blue or white toes), occur during treatment with VisioCompress® 1 Lite , the bandage must be removed immediately and the treating doctor must be informed.
- Bandages may lead to skin dryness and itching.
- The bandage can be removed by unwinding the bandage or by cutting them with bandage scissors.
- It is hazardous to re-use a medical device that is intended for single use. Recycling medical devices 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.



KOB GmbH
Lauterstraße 50, 67752 Wolfstein, Germany
www.kob.de

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