Lastodur light

General Product Description/Intended Purpose
The long-stretch compression bandages are narrow woven. They are provided with an end fixation. The bandages are made from 83% viscose, 12% polyamide, 4.5% polyurethane, 0.5% cotton. Lastodur light is non-active, non-sterile and is a white colored, permanently elastic long-stretch bandage with a yellow line in the center to guide through the application process. Lastodur light are long-stretch compression bandages which can be for used for long-term compression therapy for varicose symptoms; as prophylaxis for thrombosis on immobile patients; as a support and relief bandage in musculoskeletal injuries. They can be used by health professionals in clinical and home environment in combination with padding bandages and inner lining material.

Application/Indication
Lastodur light is designed to be used by healthcare professionals who have received appropriate training. The devices can be used for the treatment of:

- Varicose veins:
  Varicose veins | varicose veins in pregnancy | supportive in the invasive treatment of varicosis
- Thrombosis / thrombophlebitis:
  Thrombophlebitis as well as condition after healed thrombophlebitis | deep leg and arm vein thrombosis | condition after deep vein thrombosis | post-thrombotic syndrome | thromboprophylaxis
- Chronic venous insufficiency (CVI):
  CVI according to CEAP classification C3-C6 | primary and secondary prevention of leg ulcer venosum | venous insufficiency | angiodysplasia
- Other edema:
  lymphedema | edema in pregnancy | post-traumatic edema | hormonal edema | lipedema | stasis conditions due to immobility (arthrogenic congestion syndrome, paresis and paresis of the extremity) | medically induced edema (e.g., calcium antagonists, isosorbide dinitrate, lithium ointment, sex hormones, etc.)

The devices can also be used as a support and relief bandage in musculoskeletal injuries. They are suitable for use as a support and relief bandage in the management of limbs following amputation. There is an additional usage as support bandage for distorsions, contusions, tendon injuries, thoracic injuries and dislocations (bone).

Reference Numbers

REF	Name	Dimensions	Bandages per folding box	IfU per folding box
931652	Lastodur light	10 cm x 8,7 m	1	1

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Contraindications
Lastodur light must not be used in cases of:

- advanced peripheral arterial occlusive disease (PAOD) (if one of these parameters is applicable: ABPI <0.5, ankle artery pressure <60 mmHg, toe pressure <30 mmHg or TcPO2 <20 mmHg instep).
- decompensated cardiac insufficiency (NYHA III + IV)
- phlegmasia cerulea dolens
- in case of ankle-brachial pressure index (ABPI) > 1.3 and ≤ 0.5
- septic phlebitis

Precautions
Special precautionary measures are required in the event of:

- pronounced sensibility disorders of the extremity (e.g. in the case of advanced diabetic peripheral polyneuropathy)
- compensated peripheral arterial occlusive disease (PAOD) with a reduced ankle-brachial pressure index (ABPI 0.6-0.8)
- chronic compensated cardiac insufficiency
- florid infectious disease

Due to high resting pressure the bandage is recommended to be removed at night. If the foot pulse is not palpable, a Doppler ultrasound should be carried out to determine the ABPI prior to starting therapy.

Remarks
If the bandage is applied in a figure of eight with 50% stretch and 50% overlap the pressure achieved will be higher than if it is applied in a spiral with 50% stretch and 50% overlap.
Do not use the bandage as a primary dressing or directly on open wounds. The bandage should be used in conjunction with an undercast padding bandage to protect the leg and pad out bony prominences.
The bandage is recommended to be removed overnight.
Do not let the bandage get wet during showering / bathing
Incorrect bandaging technique can lead to constrictions, undesired pressure points or other damage.
If the patient develops severe pain, numbness, tingling or noticeable discoloration of the toes at any time during treatment with the medical device, a medical professional must be contacted immediately and the bandage must be removed.
A slipping of the bandage indicates a loss of compression. In this case, a medically trained person has to reapply the bandage.

Single Use Device
Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal
To minimize the risk of potential infection hazards, or environmental pollution, disposable components of the medical device should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

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Product Performance Characteristics

Property	First layer
Elongation	170%
Length stretched	870 cm
Width	10 cm
Area weight (stretched)	approx. 108 g/m²

Labelling

Lot-No. with 9-digit code

e.g.:

LOT	9	001	01	17	1
explanation definition	[9 = 2019] year	[999-000] serial production order		for internal purposes only	

Manufacturing date

e.g.:	2019 year	04 month	01 day

Use-by-Date

e.g.:	2022 year	04 month	01 day

Shelf life: 5 years

Medical Device

MD

Unique Device Identifier (UDI)

UDI

Latest date of revision: 2020-05-25