

Varolast® Plus

General Product Description/Intended Purpose

Varolast® Plus is a ready-to-use zinc paste bandage which is lengthwise elastic. The bandage has a carriage material made of viscose and polyamide, and an impregnation mass made of zinc oxide and glycerin (zinc paste). The bandage is white in color. Varolast® Plus is a single use, non-sterile zinc paste bandage that is used for semi-rigid support and as compression dressings. It can be applied for long-term treatment in compression therapy of chronic venous diseases, thromboembolic venous diseases, oedemas and other indications. This zinc paste bandage is indicated with an ABPI of 0.8-1.3 only. Moreover, it can be used as a support and relief bandage following injuries of the postural and locomotor system and as follow-up treatment when plaster casts are removed. The product is to be applied on intact skin only. This zinc paste bandage is indicated for humans (not for children under 3 years of age) and can be applied by healthcare professionals in clinical and home environment.

Application/Indication

Varolast® Plus is designed to be used by healthcare professionals who have received appropriate training. It can be used for the treatment of:

- Chronic venous diseases (prevention and treatment of venous oedemas, 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)
- Oedemas (lymphoedema, oedema in pregnancy, post-traumatic oedema, postoperative oedema, postoperative reperfusion oedema, idiopathic cyclic oedema, lipoedema from stage II, congestive states as a result of immobility (arthrogenic congestive syndrome, paresis and partial paresis of extremities), drug-induced oedema if not possible to switch)

Reference Numbers

REF	Name	Dimensions	Bandages per folding box	IfU per folding box
931582	Varolast® Plus	8 cm x 5 m	1	1
931583	Varolast® Plus	10 cm x 7 m	1	1
931585	Varolast® Plus	10 cm x 10 m	1	1
931587	Varolast® Plus	10 cm x 7 m	20	1
931588	Varolast® Plus	10 cm x 10 m	20	1
931589	Varolast® Plus	8 cm x 5m	16	1

Varolast® Plus

Contraindications

Varolast® Plus must not be used in cases of:

- 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

Precautions

Special precautionary measures are required in the event of:

- Severe weeping dermatosis
- Severe sensory disturbances of the extremity
- Advanced peripheral neuropathy (e.g. associated with diabetes mellitus)
- Primary chronic rheumatoid arthritis
- Compression material intolerance

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 Varolast® Plus 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 authorised representative and to your national authority.

Product Performance Characteristics

Property	First layer
Elongation	60%
Length stretched	500 cm, 700 cm, 1000 cm
Width	8 cm, 10 cm
Weight of bandages with core	8 cm x 5 m: 80 g 10 cm x 7 m: 140 g 10 cm x 10 m: 200 g

Varolast® Plus

Labelling

Lot-No. with 8-Digit Code

e.g.:



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.:



2021
year

04
month

01
day

Shelf Life: 2 years

Medical Device

MD

Unique Device Identifier (UDI)

UDI

Latest Date of Revision: 2020-06-04