

Varolast®


Spec.-No.: D 2.6860

Department: KOB

Date: 2012-01-13

CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 dated 2012-01-13	new	New Technical Data Sheet

Department	Date	Signature
Development KOB	2012-01-13	<i>for Ha Fules</i>

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1. General Product Description

Two-way stretch elastic zinc paste bandage, ready for use, the two-dimensional stretch of the fabric facilitates accurate bandaging without any slitting or cutting of the bandage, even around the difficult contours of the limbs, this will result in an evenly graduated decrease in pressure up the leg and away from the ankle; kind to the skin, will dry quickly.

Varolast® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Varolast® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Varolast®, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

As a permanent compression bandage in the treatment of phlebitis in the deep and superficial veins, for follow-up treatment after thrombosis, leg ulcers and dry, stasis dermatitis; as a support bandage in general orthopaedics and in orthopaedic aftercare.

3. Presentations

Size bandage	contents per pack	packs per case
individually packed in folding box		
10cm x 5m (stretched length)	1 bandage	16
10cm x 7m (stretched length)	1 bandage	20
10cm x 10m (stretched length)	1 bandage	20
individually wrapped		
10cm x 5m (stretched length)	16 bandages	1
10cm x 7m (stretched length)	20 bandages	1
10cm x 10m (stretched length)	20 bandages	1

4. Product Characteristics

Material:	bandage: app. 66% cotton, app. 34% viscose
	zinc paste
	aluminium compound foil pouch

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5. Product Requirements

Elasticity

longitudinal app. 70%
transverse app. 35%

6. Labelling

The lot-number consists of a 7-digit-code.

For Example:

12	23	XXX
Two last digits of the Calendaryear	Calendarweek	Batchnumber

Date of expiry:  2012-01

Shelf life: 3 years

7. Packaging

Varolast® is sealed into aluminium compound foil pouch, folding box, instructions for use, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

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