



1. General Product Description

DermaPlast® CoolFix is an elastic bandage which is moistened with cooling fluid. The cooling bandage is packaged in an air- and agent proof packaging made of laminated film.

DermaPlast® CoolFix 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 DermaPlast® CoolFix and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of DermaPlast® CoolFix, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

DermaPlast® CoolFix is used for cooling after bruises, strains, crushes and sprains and restricted insect bites.

3. Presentation

Size (width x length dilated)	Bags/Folded box	Folded boxes/Transport cardboard box
6 cm x 4 m	13 pcs/FB	18 FB/OK

4. Product Characteristics

Material composition: 66% cotton
33% polyamide
1% polyurethane

Color: ice-blue

Amount cooling fluid: approx. 30 ml

Composition cooling fluid:

Cooling effect: approx. 2 hours

Longitudinal elongation: approx. 90%

water, e

5. Labelling

LOT-Number, 9-digit

Expiration date:
Date specification with hourglass

e.g.:  2004 - 12

Shelf life: 3 years

6. Packaging

DermaPlast® CoolFix are packaged in bags and folded boxes. The transport cardboard carton according to DIN is sealed with adhesive tapes. Packaging onto europallet.

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Marketing

CHANGE CONTROL REPORT

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05.10.06		new	2
27.08.08	05.10.06	Kapitel 5: Erklärung der LOT-Nummer gestrichen	2
26.06.2011	27.08.08	Produktbild abgeändert	3
19.02.2013	26.06.2011	Auditmassnahme	3

Date/Signature Written by:	Date/Signature Approved by:
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