

DermaPlast® Cofix

General Product Description/Intended Purpose

DermaPlast® Cofix is a cohesive conforming bandage for retention of all kinds of primary and secondary dressings, splints, casts, catheters and cannulas (etc.) particularly on joints as well as on conical and round parts of the body. It is used for the stabilization of muscles, tendons, ligaments, joints with low immobilization effect as well. It is manufactured from 43% cotton, 37% viscose and 20% polyamide. It is for single-use and can be used by instructed lay persons and health professionals on intact skin in clinical and home environment.

Application/Indication

DermaPlast® Cofix is a cohesive conforming bandage that may be used in medical interventions when acute and chronic wounds need to be treated short or long term or when slight immobilization is needed in combination with medical device. It is suitable for fixation of:

- primary and secondary dressings
- cannulae, catheters, tubes and similar medical devices
- splints, casts and similar medical devices

Reference Numbers

REF	Name	Size	Bandages per folding box	Individually wrapped
4347103	Dermaplast CoFix weiß	1,5cmx4m	2	No
4347204	Dermaplast CoFix weiß	4cmx4m	1	No
4347304	Dermaplast CoFix weiß	6cmx4m	1	No
4347403	Dermaplast CoFix weiß	8cmx4m	1	No
4347503	Dermaplast CoFix weiß	10cmx4m	1	No
4347803	Dermaplast CoFix weiß	2,5cmx4m	2	No
4348203	Dermaplast CoFix weiß	4cmx20m	1	No
4348303	Dermaplast CoFix weiß	6cmx20m	1	No
4348403	Dermaplast CoFix weiß	8cmx20m	1	No
4348503	Dermaplast CoFix weiß	10cmx20m	1	No

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Not known.

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.

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Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of DermaPlast® Cofix 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 Characteristics

Property	Requirements
Width	2,5 cm; 4,0 cm; 6,0 cm; 8,0 cm; 10,0 cm; 12,0 cm
Length, stretched	4 m; 20 m
Elongation, MD	80 %
Cohesive force	45 cN/cm
Unwinding force	15-125 cN/cm
Weight per area (stretched)	39,5 g/m ²

Labelling

Lot-No. with 9-Digit Code

e.g.:

	9	999	01	00	1
explanation	[9 = 2019]	[999-000]			
definition	year	serial production order			for internal purposes onl

Manufacturing Date

e.g.: 	2015	04	07
	year	month	day

Expiry Date

e.g.: 	2018	04	07
	year	month	day

Shelf Life: 3 years

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Medical Device



Latest Date of Revision: 2020-08-01