Technical Data Sheet

# 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 needs 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/m2 |

**Labelling**

Lot-No. with 9-Digit Code
e.g.:

| LOT | 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

# DermaPlast® Cofix

Medical Device

MD

**Latest Date of Revision:** 2020-08-01