

DermaPlast® TEXTIL

General Product Description/Intended Purpose

DermaPlast® TEXTIL strips and woundplasters are non-active, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper.

The main constituents of this products are:

- The backing / carrier material:
 - Skin color Elastic fabric
- The medical grade adhesive:
 - White synthetic rubber based adhesive / Hotmelt
- The wound pad with 2 different layers:
 - Exudate-transmission layer made of viscose.
 - Absorption layer of non-woven with absorbent fibers.
- Protective paper / film for the protection of the wound pad and adhesive side of the product:
 - Silicone paper

The products do not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components.

Strips are sealed individually in peel-pouches and packed in cardboard folding boxes. Wound plasters are packed directly in cardboard folding boxes.

Application/Indication

DermaPlast® TEXTIL strips and woundplasters are non-active, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper, for the protection of minor injuries (including puncture wounds from injections) and absorption of exudate.

The products are intended for humans, without restrictions (in age group, weight range, health status or condition), for use by lay-users and healthcare professionals, in contact with intact skin (healthy skin) and breached skin, and short-term (60 minutes ≤ Duration ≤ 30 days, acc. to MDR) / prolonged use (24 hours < Duration ≤ 30 days, acc. to ISO 10993-1:2018) duration of use.

Reference Numbers

Packaging	Dimensions	Name	Reference number
P10	4x10cm	DermaPlast TEXTIL CH	522410
P10	6x10cm	DermaPlast TEXTIL CH	522420
P10	8x10cm	DermaPlast TEXTIL CH	522430

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P1	5mx4cm	DermaPlast TEXTIL CH	522470
P1	5mx6cm	DermaPlast TEXTIL CH	522480
P1	5mx8cm	DermaPlast TEXTIL CH	522490
P12	5x6cm	DermaPlast TEXTIL Finger CH	522510
P12	2x16cm	DermaPlast TEXTIL Finger CH	522650
P100	3x4cm	DermaPlast TEXTIL Centro CH	522710
P100	6x4cm	DermaPlast TEXTIL Centro CH	522720
P16	3x4cm 4x6cm	DermaPlast TEXTIL Centro CH	522810
P32	19x72mm 4x6cm 9x38mm	DermaPlast TEXTIL Family CH	522820
P15	19x72mm	DermaPlast TEXTIL Express CH	522840

Contra-Indications

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.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Dermaplast® TEXTIL should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

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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	Test method	Unit	Specifications
Visual examination	EN ISO 5350-02	Conform/not conform	Conform
Peel test (90° peel angle)	Evaluation based on DIN ISO 6133:2017-04, procedure B	N/25mm	26 +6 -7
Absorption capacity	(DIN) EN 13726-1:2002:06	g/100cm ²	>6

Labelling

Lot-No. with 8-Digit Code

e.g.:



0

12

XXXXX

year

week of production

for internal purposes only

Manufacturing Date

e.g.:



2020

03

01

year

month

day

Expiry Date

e.g.:



2025

03

01

year

month

day

Shelf Life: 5 years

Medical Device



Distributor Symbol



Latest Date of Revision: 2020-03-23

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