

TRAUMA BANDAGE



General Product Description

TRAUMA BANDAGE is an emergency pressure bandage consisting of a wound-compatible absorbent dressing (Zetuvit® E, PAUL HARTMANN), which is applied to an elastic bandage. At the location of the wound dressing, a plastic pressure plate is attached on the outside of the bandage to apply compression on the wound. The pressure plate has a hook on each side that allows for looping the bandage in to build up pressure in a targeted manner.

A hooking fixation clamp is attached to the bandage end to allow for quick and easy fastening of the bandage.

The TRAUMA BANDAGE is sterilized with X-Ray and is sterile (SAL 10⁻⁶) according to ISO 11137-1/-2.

The TRAUMA BANDAGE comes in three widths: 10, 15 and 20 cm. The pressure plate has the same size for all bandages.

Intended Purpose

TRAUMA BANDAGE is a single use, sterile first aid bandage for short term treatment of all kind of acute wounds in emergency situations. It is used on humans by lay persons and health professionals in every environment except operation theater.

Application/Indication

Acute injuries and superficial wounds.

TRAUMA BANDAGE

Reference Numbers

Name	Width	REF
TRAUMA BANDAGE 10 cm	10 cm	831 273
TRAUMA BANDAGE 15 cm	15 cm	831 274
TRAUMA BANDAGE 20 cm	20 cm	831 275

Sterile Device

TRAUMA BANDAGE is sterile and vacuum packaged. Do not use if package is damaged (no vacuum present).

Single Use Device

TRAUMA BANDAGE is single use. Reuse is not intended. Information available on request.

Product Disposal

Dispose medical device together with regular hospital garbage.

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of TRAUMA BANDAGE 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.

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Product Characteristics

Material	Composition	Measures	Color
Bandage TRAUMA BANDAGE 10 cm	<ul style="list-style-type: none"> ▪ Cotton ▪ PA ▪ PU 	10 cm width 4.5 m length (stretched)*	green
Bandage TRAUMA BANDAGE 15 cm	<ul style="list-style-type: none"> ▪ Cotton ▪ PA ▪ PU 	15 cm width 4.5 m length (stretched)*	green
Bandage TRAUMA BANDAGE 20 cm	<ul style="list-style-type: none"> ▪ Cotton ▪ PA ▪ PU 	20 cm width 4.5 m length (stretched)*	green
Wound dressing TRAUMA BANDAGE 10 cm	<ul style="list-style-type: none"> ▪ Fluff ▪ PP 	10 x 20 cm	white
Wound dressing TRAUMA BANDAGE 15 cm	<ul style="list-style-type: none"> ▪ Fluff ▪ PP 	15 x 20 cm	white
Wound dressing TRAUMA BANDAGE 20 cm	<ul style="list-style-type: none"> ▪ Fluff ▪ PP 	20 x 20 cm	white
Pressure plate	<ul style="list-style-type: none"> ▪ PC 	L x W x H: 90 x 63 x 4 mm	grey
Fixation clamp TRAUMA BANDAGE 10 cm	<ul style="list-style-type: none"> ▪ PC 	L x W x H: 90 x 9 x 12 mm	grey
Fixation clamp TRAUMA BANDAGE 15 and 20 cm	<ul style="list-style-type: none"> ▪ PC 	L x W x H: 115 x 9 x 12 mm	grey
Packaging TRAUMA BANDAGE 10 cm	<ul style="list-style-type: none"> ▪ PET ▪ ALU ▪ PE 	L x W x H: approx. 110 x 85 x 35 mm **	blue
Packaging TRAUMA BANDAGE 15 cm	<ul style="list-style-type: none"> ▪ PET ▪ ALU ▪ PE 	L x W x H: approx. 160 x 85 x 35 mm **	blue
Packaging TRAUMA BANDAGE 20 cm	<ul style="list-style-type: none"> ▪ PET ▪ ALU ▪ PE 	L x W x H: approx. 210 x 85 x 35 mm **	blue

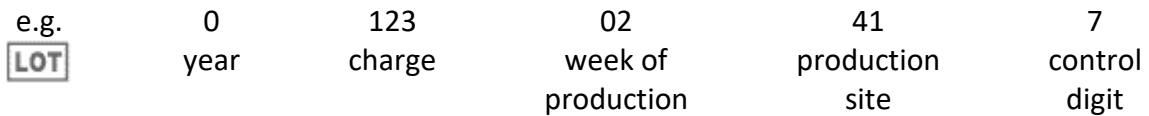
* Length of the bandage in unprocessed state at maximum stretch. A stretched length of approx. 3.75 m (+/- 0.25 m) can be assumed for the processed product.

** dimensions may vary due to production process (tolerance +/-10 mm)

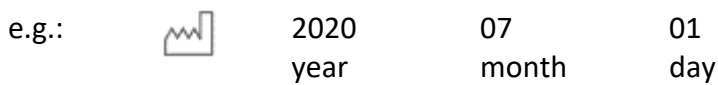
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Labelling

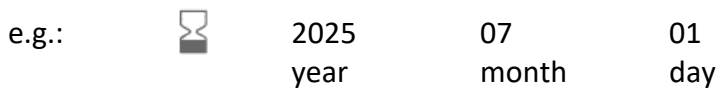
Lot-No. with 9-Digit Code



Manufacturing Date



Use-by-Date



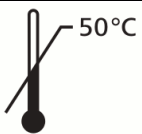
Shelf Life:

5 years

Medical Device:



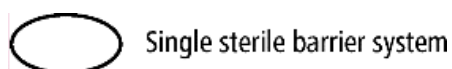
Temperature conditions:



Unique Device Identification (UDI)



Single Sterile Barrier System



Latest Date of Revision: 2023-06-14