



# Safix<sup>®</sup> plus

## General Product Description/Intended Purpose

Safix Plus plaster of Paris bandage consists of natural gypsum ( $\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$ ) and a carrier material made from a specially woven cotton cloth. Safix Plus are single-use, non-sterile plaster of Paris bandages and slabs for short- and long-term treatment of external immobilization on humans using circular plaster of Paris bandaging techniques and for splints, used by healthcare professionals in a clinical environment applied in combination with products that are used as underlays.

## Application/Indication

Safix plus is activated after having been immersed in water for about 3 seconds at approximately 20 °C (it is possible to cut the product before immersing it in water). It should then be wrung out thoroughly and moulded immediately. The moulding time is approximately 2 – 4 minutes. Safix plus plaster casts and splinting bandages can support light loads after 30 minutes. After 12-24 hours the product is completely hardened, depending on the number of applied layers. Protect the entire part of the body being treated with suitable padding (synthetic wadding, tube, foam).

## Reference Numbers

Description	Reference numbers
Safix plus Plaster Bandage, 6 cm x 2 m P2	332 730/1
Safix plus Plaster Bandage, 8 cm x 2,7 m P2	332 731/1
Safix plus Plaster Bandage, 10 cm x 2,7 m P2	332 732/1
Safix plus Plaster Bandage 12 cm x 2,7 m P2	332 733/1
Safix plus Plaster Bandage, 15 cm x 2,7 m P2	332 734/1
Safix plus Plaster Bandage, 20 cm x 2,7 m P2	332 735/1
Safix plus Plaster Bandage, 5 cm x 3 m P2	332 739/1
Safix plus Plaster Bandage, 8 cm x 3 m P2	332 740/1
Safix plus Plaster Bandage, 10 cm x 3 m P2	332 741/1
Safix plus Plaster Bandage, 12 cm x 3 m P2	332 742/1
Safix plus Plaster Bandage, 14 cm x 3 m P2	332 743/1
Safix plus Plaster Bandage, 15 cm x 3 m P2	332 744/1
Safix plus Plaster Bandage, 20 cm x 3 m P2	332 745/1
Safix plus Slabs, 10 cm x 20 m (x4) P1	332 790/1
Safix plus Slabs, 12 cm x 20 m (x4) P1	332 791/1
Safix plus Slabs, 15 cm x 20 m (x4) P1	332 792/1
Safix plus Slabs, 20 cm x 20 m (x4) P1	332 793/1

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

While setting Safix plus, heat is released which is tolerated by the patient if the instructions for use are followed.

There is danger of burns due to excessive heat release under the following circumstances:

- water temperature higher than 27 °C during immersion
- bandage applied too dry
- multi-layered cast
- obstruction of air circulation during setting by covering with a towel and other material

Please pay attention to these situations! Avoid covering completely!



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Only for use on intact skin.

Patients should be warned not to be in contact with excessive amounts of moisture through submersion, for example while swimming or bathing!

## 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. More information about this is available on request.

No risk was evaluated in the risk analysis.

Reuse is not possible based on the functional principle. As far as the product is concerned, it can only be used once. There is no possibility to reuse it because the hardening process is finished.

## Product Disposal

To minimise the risk of potential infection hazards, or environmental pollution, disposable components of Safix plus 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 Performance Characteristics

Property	Test method	Test results
Short immersion time	PH 155/001	1,5 - 4,5 second
High quality natural gypsum	TM00 0001	> 89 % of natural gypsum
Easy application	DIN EN 62366	min. 70% of healthcare professionals said that the application is easy according to IFU
Short setting time	PH 104/002	2 - 3,5 min
High stability	PH 105/002	final strength after 30 min. $\geq$ 250 N
Cutable - before application and water immersion	IEC 62366	min. 70 % helthcare professionals said that they are able to cut the product before its application
Easy to remove with cast scissors or cast saw	IEC 62366	min. 70 % healthcare professionals said that they are able to remove the product with cast saw and scissors



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## Product Characteristics

Property	Test method	Test results
Maximum of heat	PH 151/001	max. 41°C
Product's area weight	PH 014/005	area weight 370 - 450 g/m <sup>2</sup>
Product is free from any impurity	TM00 0001	no impurities, wave cut, clear cutting edges, crease-free, no conic winding

## Labelling

### Lot-No. with 8-digit code

e.g.:



0  
Last figure of  
the current  
year

1 9 3  
Internal order  
number

1 5  
Week

9 9  
Plant code

1  
Control  
digit

### Manufacturing date

e.g.:



2019  
year

-

01  
month

-

23  
day

### Expiry date

e.g.:



2022  
year

-

01  
month

-

01  
day

Shelf life: 3 years

### Medical Device



### Unique Device Identification (UDI)



Not yet

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## Distributor



Distributor

AE – PAUL HARTMANN Middle East FZE · Dubai, U.A.E.  
AT – PAUL HARTMANN Ges.m.b.H. · 2355 Wiener Neudorf  
BG – ТП Хартманн-Рико · 1113 София  
CH – IVF HARTMANN AG · 8212 Neuhausen  
CZ – HARTMANN-RICO a.s. · 66471 Veverská Bítýška  
FR – Lab. PAUL HARTMANN S.à.r.l. · Châtenois  
67607 Sélestat CEDEX  
GR – PAUL HARTMANN Hellas A.E. · 16674 Glyfada/Athina  
HR – PAUL HARTMANN d.o.o. · 10020 Zagreb  
HU – HARTMANN-RICO Hungária Kft. · 2051 Biatorbágy, Budapest  
NL – PAUL HARTMANN B.V. · 6546 BC Nijmegen  
PL – PAUL HARTMANN Polska Sp. z o.o. · 95-200 Pabianice  
PT – PAUL HARTMANN LDA · 2685-378 Prior Velho  
RO – S.C. PAUL HARTMANN S.R.L. · 020194 București  
RU – PAUL HARTMANN OOO · 115114 Moskwa  
SI – PAUL HARTMANN Adriatic d.o.o. · 1000 Ljubljana  
SK – HARTMANN-RICO spol. s r.o. · 85101 Bratislava

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