

Flamaderm

Medical device First aid for burns

Presentation form

Sterile impregnated dressing/sterile bandage for burns of a support from polyurethane foam impregnated with hydrogel, packed in individual envelope.

Product code	Presentation form/dimensions	UDI-DI
3.100GM	Sterile impregnated dressing for burns, 10 cm x 10 cm	5944729006798
3.410GM	Sterile impregnated dressing for burns, 10 cm x 40 cm	5944729006804
3.200GM	Sterile impregnated dressing for burns, 20 cm x 20 cm	5944729006835
3.420GM	Sterile impregnated dressing for burns, 20 cm x 40 cm	5944729006842
3.M245GM	Sterile impregnated dressing for burns, 20 cm x 45 cm, Child Facial Mask	5944729006880
3.255GM	Sterile impregnated dressing for burns, 20 cm x 55 cm, with finger cutouts	5944729006859
3.400GM	Sterile impregnated dressing for burns, 40 cm x 40 cm	5944729006910
3.640GM	Sterile impregnated dressing for burns, 40 cm x 60 cm	5944729006811
3.M640GM	Sterile impregnated dressing for burns, 40 cm x 60 cm, Facial Mask	5944729006866
3.800GM	Sterile impregnated dressing for burns, 80 cm x 80 cm	5944729006873
3.1612GM	Sterile impregnated dressing for burns, 120 cm x 160 cm	5944729006828
3.1518GM	Sterile impregnated dressing for burns, 152 cm x 185 cm	5944729006903
3DGM	Sterile bandage for burns, 2.5 cm x 50 cm, Finger	5944729006989
3MGM	Sterile bandage for burns, 5 cm x 100 cm, Hand	5944729006972
3.107GM	Sterile bandage for burns, 7 cm x 100 cm	5944729006996

Composition

Composition of Flamaderm – Sterile impregnated dressing/sterile bandage for burns

- Support made of alveolar polyurethane (foam)
- The hydrogel contains: Glycerin, Propylene Glycol, Carbopol, Sodium Hydroxide 10%, Menthol 0.05%, Purified water
- Reduces pain and decrease the edema
- Minimize the burn evolution
- The cooling of the burn with water is not necessary anymore, because the progressive evaporation of the water molecules from the hydrogel allows the absorption of calories by heat transfer. This evaporation lasts about 45 minutes
- Ensure the favorable microclimate for burn healing
- Limit the risk of hypothermia; placing the Flamaderm dressing/bandage directly over the affected area cools the burn and avoids rapid cooling on other body surface area as does showering or hosing the patient
- Sterile impregnated dressings/sterile bandages for burns do not adhere on the tissue and can be removed without pain and trauma
- Easy to use; fresh smell of menthol
- Using the products, helps to reduce:
 - the healing and treatment time
 - the treatment costs

Performance characteristics

Indications

- First aid for thermal burns, including sunburns and chemical burns, I, II and III degree

Contra-Indications

- DO NOT USE the sterile impregnated dressing/sterile bandages for burns if the patients are allergic to any of the hydrogel components

Instructions for use

Thermal burns, including sunburns:

- Wash your hands thoroughly
- Open the envelope and remove the dressing/bandage. Gently lay the dressing/bandage on the site of the burn, ensuring that the whole of the wound is covered
- Carefully squeeze the rest of the gel from the envelope over the top of the dressing/bandage
- Wrap the dressing/bandage for burns to keep it in place with a non-absorbent bandage, such as a cohesive bandage or conforming bandage and fix it with an adhesive tape (if necessary). Take care to ensure that pressure is not applied to the area when bandaging
- The dressing/bandage for burns must be kept on the burned area for 30-45 minutes while the patient is driven to a hospital unit

Chemical burns

- It is recommended to use only after limiting chemical contact with tissues and decreasing chemical concentration
- After water jetting for 20 to 30 minutes, it is possible to neutralize the chemical and continue to give first aid as a thermal burn

Precautions for use

- If there are signs of local infection, treatment can be continued with the physician's approval
- Products are exclusively for external use
- When first aid is given in the case of chemical burns, chemical neutralizing agents are used only with the consent of the physician.

Additional precautions

- The products should not be further used after the expiration date
- The products should be kept away from children
- Single-use product; DO NOT re-sterilize
- Sterile only if the packaging is not damaged
- Storage:
 - Protected from humidity and sunshine
 - Temperature: max. 35°C.

Undesirable side-effects

- None known

Warnings

- The use of products is restricted only to practitioners (doctors, paramedics, first aid personnel)
- Products are single use medical devices, do not re-use! Otherwise it may appear: irritation/ contamination/ infection of burn and/or skin
- The product is exclusively for external use; ingestion of the hydrogel may cause stomach problems
- Do not use the product if the packaging is damaged
- The products should not be further used after the expiration date
- The products should be kept away from children and pets. Penetration in the burn of hair or stains from pets can cause burn contamination
- Care should be taken to avoid hypothermia especially in those patients who are most at risk; infants, elderly and those with large surface area burns. It is recommended that hydrogel dressings are not used on children and the elderly if it covers more than 10% of the Total Body Surface Area (TBSA), and for adults no more than 20% TBSA. In these situations, follow your protocols in force (e.g. wrap the patient in an emergency foil thermal blanket over their wet dressings, so as to hold the evaporation to a minimum)

NOTE

Any serious incident that has occurred in relation to TAISSIS CONCEPT S.R.L. products should be reported to TAISSIS CONCEPT S.R.L. and the competent authority of the Member State in which the user and/or patient is established



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Symbol	Significance	Symbol	Significance
	Single use product		Means that it is absolutely necessary for the user to read the leaflet before starting the utilization of the product
	The product is sterilized with Gamma radiations		Expiry date
	Single sterile barrier system		Keep dry!
	Non-sterile protective packaging with sterile barrier system inside		Keep away from sunlight!
	Do not resterilize!		Storage at a temperature up to 35°C
	Do not use if the package is damaged!		Symbol for warning regarding throwing the pack to the trash bin
	Medical device		Fragile. Handle with care!
	Product reference (code)		Manufacturer
	Product lot number		Unique Device Identifier
			Compliance with Directive 93/42/EEC



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according to MDD 93/42/EEC

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