

Extra-fast setting Plaster of Paris bandage

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1.0 Name of the product	Specialist ® E
2.0 Product description	
2.1 Description	Specialist® E is a plaster bandage which consists of 100% bleached cotton fabric with a plaster mixture
2.2 Characteristics	Initial setting time: 120-180 s Breaking load (30min): mini 5kg/dm and dry: 9kg/dm Maximum temperature 48 °C Plaster loss: maximum 11%
2.3 Intended use	Specialist® E plaster bandage are intended for use in any situation where rigid, external immobilization is required and judged suitable by a qualified professional-mainly for long and technical casts.
2.4 Instructions for use	Yes, leaflet available with product.
2.5 CE-class GMDN - code	Class I non sterile 33056- bandage-cast
2.6 Duration of application / Period of use	Few days to a long period depending on the indication
2.7 Composition	Backing material: 100% white cotton bleached by hydrogen peroxide Plaster mass: it's mainly composed of natural plaster and binders.
2.8 Latex in product and packaging material	Product composition: No latex content Packaging material: Not available
2.9 Phthalate in product and packaging material	Product : No phthalate content Packaging material: Not available
2.10 Controls	Raw materials: Fabric: weight, thread count, bleached quality and breaking load Plaster: setting time, fluidity, purity, particle size and specific area. Finished product: Setting time – water uptake - Breaking load-Plaster loss and exotherm
2.11 Product range	

Product Safety Data Sheet

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Product code	Sizes	Nb per box	Nb of box per shipper case	Total bandage per hipper case
72260-00000-01	2.7m*5cm	12 bandages	4	48
72260-00001-01	2.7m*7.5cm	12 bandages	4	48
72260-00002-01	2.7m*10cm	12 bandages	4	48
72260-00003-01	2.7m*12.5cm	12 bandages	2	24
72260-00004-01	2.7m*15cm	12 bandages	2	24
72260-00005-01	2.7m*20cm	12 bandages	2	24
72260-00001-02	2.7m*7.5cm	No box	-	12
72260-00002-02	2.7m*10cm	No box	-	12
72260-00003-02	2.7m*12.5cm	No box	-	12
72260-00004-02	2.7m*15cm	No box	-	12
72260-00005-02	2.7m*20cm	No box	-	12
2.12 Storage conditions	Keep away from moisture and heat			
2.13 Shelf life/Storage time	3 years			
2.14 Sterilization	Product is not sterile Sterilization not advisable			

3.0 Safety information of Specialist ® E

3.1 Warnings and precautions for use	<p>Exotherm: Plaster of Paris products generate heat during setting time reaction which can be felt by the patient The patient should be instructed to report any pain, numbness, irritation or "burning sensation". If the patient reports any of the above, remove the cast immediately. Inspect the cast to determine the cause of the complaint before recasting. Burn injury may result from improper cast application or failure to observe precautions during and after setting reaction. Factors that may lead to excessive exotherm include:</p> <ul style="list-style-type: none"> -Dip water above 24 °C/75 °F - Overly thick cast -Under-saturation of the plaster -Not changing dip water frequently -High room or dry bandage temperature -Inadequate air circulation: use of elastic bandage or blanket resting the cast on a pillow or mattress. <p>Caution must be used to ensure that the cast is not applied too tightly.</p>
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	<p>Constrictions may result in impair vascular flow and nerve function.</p> <p>Do not allow the patient to bear weight on a fresh cast; most casts require 48 hours to be weight bearing. Factors affecting the amount of time for the cast to be weight bearing are: humidity, weight of patient, thickness of cast, type of cast and physician instructions.</p> <p>Do not allow the patient to get cast wet or allow foreign objects enter into the cast.</p>
3.2 Flammable combustible properties	Combustible solid.
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contra Indications	None
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used
3.6 Transport Precautions	Not applicable
3.7 First Aid	<p>a) Inhalation: Not applicable</p> <p>b) Contact with skin: Not applicable</p> <p>c) Contact with eyes: Not applicable</p> <p>d) Ingestion: Not applicable</p>
3.8 Disposal	Controlled incineration/Landfill according to local environmental health guidelines.
4.0 General information	
4.1 Name, address and telephone number of supplier	<p>BSN medical SAS</p> <p>Rue du Millénaire-BP 22</p> <p>72320 Vibraye</p> <p>FRANCE</p> <p>Tel : +33 (0) 2 43 60 25 25</p> <p>Fax :+33 (0) 2 43 60 25 60</p>
4.2 Certificate	ISO 9001 / ISO 13485

History

Version/Date	Description of Change	Page /Item
01 06/2010	Creation	all
02 03/2013	Change with template 2012	all