Cellona® gipsbinda

Cellona gipsbinda

Överlägset finkrämig högvärdig gipsmassa

Cellona gipsbindor är lindade på specialhylsor vilka genomfuktas snabbt och jämnt med kort doppningstid. Gipset är genom sin finkrämighet mycket lätt att modellera.

Dopptiden är 1 sekund / meter binda.

Bindetiden uppgår till 3 1/2 min. vid en doppvatten temperatur på 20°C. Efter 30 min kan man belasta gipset och transportera patienten. Efter 24 timmar kan man belasta gipset fullt ut.

Bindorna är förpackad i plastförpackningar med 5 st bindor per förpackning

Finns också som 4-lagriga splints – Cellona splints.

Pos.nr	Storlek	Lev.artnr	Avdfp	Trpfp
	Gipsbinda (rulle)			
168	6cm x 2m	25400	60	60
169	8cm x 3m	25411	40	40
170	10cm x 3m	25412	40	40
171	12cm x 3m	25413	40	40
172	15cm x 3m	25414	40	40
173	20cm x 3m	25415	30	30
	Splints (4-lagers)			
164	10cm x 20m	25500	1	1
165	12cm x 20m	25501	1	1
166	15cm x 20m	25502	1	1
167	20cm x 20m	25503	1	1

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P R O D U C T D A T A S H E E T

C E L L O N A (R) Plaster-of-Paris Bandages
REF: 20110 - 20115, 24999
25000 - 25005, 25011 - 25015
25021 - 25025, 25400 - 25405
25411 - 25415, 25421 - 25425
91162 - 91165, 91380 – 91385

C E L L O N A (R) Wide Material
REF: 20301 – 20303

C E L L O N A (R) Splints
REF: 25500 – 25503, 25510 - 25513

February 2003 Translation: C.M.Kelly/MVW

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1. Composition of the product:

Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints consist of:

- α- and β-calcium sulphate hemihydrates
- cotton gauze, bleached

Cellona ® Plaster-of-Paris Bandages REF 91261, 91264, 91275, 91612, 91613, 91621 – 91625 and Cellona ® Plaster-of-Paris Bulk Bandage Roll REF 92601 and 92602 comply with the requirements of the current version of the finished product specification no. 28-00142-.. CELLONA ® GIPSBINDEN, CELLONA ® LONGUETTEN with the exception of the dimensions in some cases.

2. Packaging, structure and composition of:

Cellona (R) Plaster-of-Paris Bandages
- REF: **20110 – 20115, 25000 – 25005, 25011 – 25015, 25021 – 25025**
91162 – 91165, 91380 – 91385

2.1 Unit container
- polypropylene core
- cellulose sleeve
- tubular bag of coated paper (cellulose/polyethylene)

2.2 Shelf container
- folding box (cellulose)
- instructions for use (cellulose

2.3 Transit container
- corrugated cardboard carton

- REF: **25400 – 25405, 25411 – 25415, 25421 – 25425**

2.1 Unit container
- polypropylene core
- cellulose sleeve
- tubular bag of coated paper (cellulose/polyethylene)
- instructions for use (cellulose)

2.2 Shelf container
- see 2.3

2.3 Transit container
- corrugated cardboard carton

- REF: **24999**

2.1 Unit container
- polypropylene core
- wrapping of cellulose/aluminium/PVC varnish

2.2 Shelf container
- folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container
- corrugated cardboard carton

Cellona ® Wide Material

- REF : **20301 – 20303**

2.1 Unit container
- wrapping of polyester/polyethylene film
- instructions for use (cellulose)

2.2 Shelf container
- see 2.3

2.3 Transit container
- corrugated cardboard carton

Cellona ® Splints

- REF: **25500 – 25503**

2.1 Unit container
- shrink-wrapped in bag of polyethylene film
- a polystyrene clip

2.2 Shelf container
- see 2.3

2.3 Transit container
- dispenser carton of cellulose
- instructions for use

- REF: **25510 – 25513**

2.1 Unit container
- a flat bag of opaque white polyethylene film

2.2 Shelf container
- folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container
- corrugated cardboard carton

3. Manufacture

Bleached cotton gauze is impregnated with α- and β-calcium sulphate hemihydrates, cut and wound on cores (bandages), cut and wound onto itself (wide material) or cut and formed into 4-ply splints, all in the dimensions required. The products are wrapped as described above and placed in boxes and/or cartons for transportation.

4. Description

These are white plaster-of-Paris bandages, wide material and splints presented in various dimensions. The coat of calcium sulphate hemihydrates is white, porous and with an even transverse structure, fully enclosing the gauze threads except at the cut edges.

5. Properties

High quality plaster-of-Paris consisting of the finest "α" and "ß" calcium sulphate hemihydrates, coated onto a 17-thread gauze, is the material from which Cellona ® Plaster-of-Paris Bandages, Wide Material and Splints are produced.

These products are ready for immersion absorbing water rapidly and evenly in a very short time. The plaster-of-Paris used is easy to mould. Finished casts are strong enough to take some weight after approx. 30 min when it is also safe to transport the patients. A cast is fully set after 24 hours. Fully set Cellona ® casts are resilient, they have a smooth surface and allow X-rays to pass through.

6. Intended purpose

Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints are intended for the immobilization of parts of the body after injury or fracture.

7. Medical device classification

As a non-invasive medical device intended for the post-traumatic immobilization of the body or parts thereof, Rule 1, Annex IX of the Council Directive 93/42/EEC concerning medical devices applies:
Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints are in Class I.

8. Biological evaluation and biocompatibility (DIN EN ISO 10 993)

Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints should not be applied to the unprotected skin.

For both starting materials - cotton as well as calcium sulphate hemihydrates - there exist monographs in national and international pharmacopoeia.
Cotton is known to be pharmacologically harmless and indifferent. Biocompatibility being good, cotton is also used widely in the textile industry manufacturing underwear.

The starting materials used to produce Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints are of such purity that the use of these products is considered completey safe for the purposes intended.

To date this company has received no notification of incidents involving Cellona (R) Plaster-of-Paris Bandages, Wide Material or Splints, neither has there been a need for a re-call of these products for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of **Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints** and that - as it says in the essential requirements of the Council Directive 93/42/EEC concerning Medical Devices - **Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints** "are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons when used under the conditions and for the purposes intended".

9. Stability

Stored appropriately in dry conditions Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints have a minimum shelf life of 5 years.

10. Disposal

Incineration or landfill disposal of Cellona (R) Plaster-of-Paris Bandages, Wide Material and Splints will generate CO_2, H_2O and $CaSO_4$, of the packaging material CO_2, H_2O and in the case of REF 24999 additionally traces of HCl and Al_2O_3.

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signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)