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|-------|-----------------------------|-------------------|
| 30968 | Cellacast® Splint - Pre-cut | 10,0 cm x 76,0 cm |
| 30969 | Cellacast® Splint - Pre-cut | 12,5 cm x 76,0 cm |

2. Packaging, structure and composition

2.1 Unit container

1 piece = 1 tubular bag
made of polyester, aluminium and polyethylene

2.2 Shelf container

1 tubular bag = 1 folding box made of cellulose
1 instructions for use (cellulose)

| REF | pcs | folding boxes |
|-----------------|-----|---------------|
| 139960 - 139964 | 1 | 1 |
| 139965 - 139967 | 10 | 1 |
| 139968 - 139969 | 5 | 1 |
| 30966 - 30967 | 10 | 1 |
| 30968 - 30969 | 5 | 1 |

2.3 Transit container

1 corrugated cardboard box made of cellulose

| REF | pcs | folding boxes |
|-----------------|-----|---------------|
| 139960 | 4 | 4 |
| 139961 - 139964 | 2 | 2 |
| 139965 - 139967 | 40 | 4 |
| 139968 - 139969 | 20 | 4 |
| 30966 - 30967 | 40 | 4 |
| 30968 - 30969 | 20 | 4 |

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3. Manufacture

Cellacast® Splints are produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

4. Description

Protected and supported — and with double the comfort: the Cellacast Splint is the solution for both patients and users. The Ready-for-use Padded Splint with padding on both sides is simple to use and versatile, provides a high degree of stability and is comfortable to wear. The ease of use ensures efficient work practice in hospitals and medical practices.

The Ready-for-use Padded Splint meets users' individual requirements and is comfortable against patients' skin. Different widths, available as pre-cuts or by the meter in practical cardboard dispensers, make for economic use of the materials. A reseal-

able, airtight foil pouch prevents drying out. The splint is secured with a conforming bandage such as Mollelast haft and can be removed easily, if necessary (e.g. to inspect the wound). The fibreglass core, which is composed of seven layers, provides the required stability.

5. Properties

- rigide Cast-Schiene
- fibreglass core made up of 7 individual layers
- individually sealed pre-cuts for standard treatment
- soft padding material
- good lamination of layers

6. Intended purpose (please see valid instructions for use)

Cellacast® Splints are intended for the preparation of splints for partial immobilization of body parts.

7. Medical device classification

Cellacast® Splint Splints are medical devices of Class I in terms of Rule 1. (according to Directive 93/42/EEC and Regulation (EU) 2017/45).

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of Cellacast® Splints are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical devices Cellacast® Splint and that they 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 and other persons when used under the conditions and for the purposes intended.

9. Requirements regarding the safety / harmlessness of the constituents

The polurethan resin contains the following substances:
Active isocyanates max. 7 wt% "disappears" during reaction with water.

10. Stability

Stored at temperatures below 30°C, keep dry, protected from dust and sun – Cellacast® Splints have a shelf life of 2 years from the date of manufacture.

11. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG
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signed by

Peter Grillitsch
Head of Global Marketing