ROSIDAL® TCS

Two-Component Compression System

REF 26484

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1. Composition of the product

The ROSIDAL® Dual Component Compression System consists of:

- Padding liner compression bandage made of polyurethane foam flame-laminated with a textile fabric made of polyamide and cotton
- Compression dressing, cohesive and free of natural latex with a fabric made of polyamide, polyurethane and cotton, coated with synthetic latex free of natural latex and a sleeve made of white laminated paper

This product data sheet covers the following item:

REF 26484 Rosidal® TCS Two-Component Compression System

2. Packaging, structure and composition

2.1 Unit container

- see 2.2

2.2 Shelf container

- cellulose cardboard sleeve
- instructions for use (cellulose)
- cellulose folding box

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

ROSIDAL® TCS Two-Component Compression System is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

4. Description

The Two-Component Compression System consists of a padding polyurethane foam dressing and a cohesive compression dressing free of natural latex.

5. Properties

The foam dressing is fine-pored, lightweight and elastic. The material is permeable to air and water vapor and has the required elasticity.
The adhesive dressing that is **free of natural latex** is a cohesive and elastic dressing with a lengthwise elasticity of approximately 70%.
The cohesive finish allows the wrapped dressing to adhere to itself and not to skin, hair or clothing; in addition, it prevents the wrapped dressing from slipping.
The product can be sterilized by steam or ethylene oxide as needed, in compliance with DIN EN ISO 17665-1 and DIN EN ISO 11135-1.
In the case of cohesive compression dressings, steam sterilization increases the unrolling resistance during unwinding and reduces elasticity.

6. Intended purpose (see valid instructions for use)

ROSIDAL® TCS Two-Component Compression System is indicated for the treatment of ulcus cruris venous and its secondary disorders as well as chronic edema.

7. Medical device classification

ROSIDAL® Dual-Component Compression System is a medical device of Class I (EU) in terms of Rule 1.
(Council Directive 93/42/EEC concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of ROSIDAL® Dual-Component Compression System 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 device ROSIDAL® Dual-Component Compression System and that it is designed, manufactured and packaged in such a way that it 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. Stability

Stored appropriately the dual-component compression system has a shelf life of 3 years.

10. 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.

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