



RUDAFILM[®]-steril

REF 073585

Product Description and Purpose

The carrier material of the sterile wound dressing (size: 7 cm x 5 cm) consists of a transparent, elastic polyurethane film and is coated with a hypoallergenic polyacrylate adhesive. The wound pad does not adhere to the wound and is completely protected by the film, which is waterproof and water vapor permeable. The film protects the wound from germs and water. The patient is able to manage his daily body care without soaking the dressing with water. As the film is transparent the moisture status of the wound pad can be assessed without removing the dressing. The dressings is individually packed in sterile packaging.

Contraindications

Do not use on infected wounds or in case of known allergies to one of the ingredients listed below.

Composition

Polyurethane, viscose, polyester, polyethylene, polyacrylate adhesive

Normative and Legal Requirements

RUDAFILM[®]-steril is a medical product according to the MPG, the directive 93/42/EEC and the regulation MDR (EU 2017/745) and is classified as class Is according to rule 4.

Sterilization of the product complies with DIN EN 11135.

The product does not contain dangerous toxic substances according to REACH.

It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Packaging

Primary packaging:	paper-packaging
Secondary packaging:	folding box made of cellulose
Tertiary packaging:	carton made of cellulose

Storage

To be stored in a dry and dust-free environment

The product bears following labels and symbols:



Contents sterile unless package is damaged