



RUDA VEN[®]-universal

REF 072386

Product Description, Intended Use Application

The sterile special plaster RUDA VEN[®]-universal of size 7 cm x 8.5 cm made of a combination of white non-woven fabric and a breathable transparent polyurethane film with slit. The plaster has a hypoallergenic polyacrylate adhesive that allows secure fixation of the cannula. The edges of the plaster are rounded to prevent rolling. Easy application is ensured by the frame application technique. Two additional self-adhesive fixation strips are used for secure fixation of cannulas and/or tubes. RUDA VEN[®]-universal is used for the secure fixation of permanent cannulas or catheters on the skin. The vascular puncture wound is protected by covering it against germ penetration and contamination and particularly enabling wound observation. The disposable product is individually sterile packed.

Composition

Viscose, polyester, polyurethane film, polyacrylic adhesive

Contra-Indications

Do not use on infected wounds. Not suitable for wounds that bleed or exude heavily

The product should not be used in the case of a known allergy against the material.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical Device according to *MDD 93/42/EEC*, *MDR (EU) 2017/745*.

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging: paper-film packaging

Secondary packaging: folding box made of cellulose

Tertiary packaging: carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and Transport

Dry and dustfree

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.