



NOBAMED Paul Danz AG

RUDANAHT®

REF 061012

Product Description, Intended use, Application

Reliably adhesive and elastic, beige-coloured wound suture strips, **size 13 mm x 100 mm**, packed per **6 pieces** in sterile packaging. The wound suture strips are used for an atraumatic primary closure of small, smooth, superficial lacerations or cuts, surgical incisions, as a complement to/relief for subcutaneous and intra-cutaneous sutures or for wounds that have been closed with staples, for the fixation of skin grafts, and if staples and sutures are prematurely removed. RUDANAHT® are for single use only.

Composition

Polyamide, polyester, polyacrylate adhesive

Contra-Indications

Wounds under tension, infected wounds, deeper wounds, and heavily bleeding wounds should not be closed with wound suture strips.

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

Note

RUDANAHT® is not intended for the fixation of e.g., dialysis cannulae.

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 Regulatory Requirements, Common Standards

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

Sterilization of the product complies with DIN EN ISO 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.