NOBASET®

PEG-VERBAND-SET

REF 690221 (as of LOT 36105)

Contents of this procedure pack:

3 x NOBATOP®, 7,5 x 7,5 cm
NOBAMED Paul Danz AG, MD CE

2 x NOBADRAINAL®, 6 x 8 cm
NOBAMED Paul Danz AG, MD CE

1 x RUDAVLIES®, 12 x 15 cm
NOBAMED Paul Danz AG, MD CE

Product Description, Intended use, Application

The sterile procedure pack consists of 3 non-woven swabs NOBATOP®, 2 drainage swabs NOBADRAINAL® and one adhesive non-woven RUDAVLIES®. The procedure pack serves for appropriate change of dressing at the point of exit of the tube and place of entry of the catheter, in particular for percutaneous endoscopic gastrotomy (PEG) tubes for enteral feeding.

Composition

NOBATOP®: Viscose, polyester
NOBADRAINAL®: Polyethylene, aluminium, rayon, polyester
RIDAVLIES®: Polyester, polyacrylate adhesive

Contra-Indications

No contra-indications known.
The product should not be used in the case of a known allergy against the material.

This product is for single and temporary use on one patient and must be applied by specially trained medical personnel. Any information for use that is available for individual products must be observed!

Normative and Legal Requirements

Procedure Pack according to Art. 22, Medical Device Regulation (EU) 2017/745,
risk class Is.

The compatibility of the customized medical devices or other products has been assessed with due regard for the indications of the respective manufacturers, and operations have been performed in accordance with the aforementioned indications.

The manufacturers' intended use is not changed.

The systems and procedure packs are packed in compliance with a validated procedure.

All activity is properly monitored and controlled as part of our QM system, in accordance with DIN EN ISO 13485

A validated sterilization process is used for sterile procedure packs, taking into account the manufacturers' instructions, so that product functionality and product safety of the components are maintained after a system or procedure pack has been compiled and sterilized.

Sterilization and packaging are subject to supervision of our Notified Body TÜV Süd PS 0123 pursuant to Annex XI, Part A.

The gauze complies with the requirements of DIN EN 14079 type 20.
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.

Storage and Transport

To be stored in a dry and dust-free environment, protect from sunlight.

The product bears following labels and symbols