

## NOBAMED Paul Danz AG

### INSTRUMENTENBEZUG

**REF 324018** (as of LOT 130976)

#### **Product Description and Purpose**

Disposable single layer instrument covers, made of medically bleached knitted cotton fabric without bands, 10 mm x 80 mm, packed per 100 pcs with worked in X-Ray thread. For the sake of protection, the covers are put on the instruments prior to sterilization. If they are fixed to the instruments with tear-resistant material, they may be left on the instruments during surgery. If so, they will reduce reflections of the operating light on the instruments, while at the same time sensitive tissue will be protected against the sharp edges of the instruments.

Before use on open wounds the gauze balls must be sterilized with a validated procedure (moist heat at 121°C/134°C, 2 to 3 bar, in accordance with DIN EN ISO 17665, radiation in accordance with DIN EN ISO 11137, or ethylene oxide in accordance with DIN EN ISO 11135).

#### Composition

Cotton, X-Ray thread contains barium sulphate, PVC and DINP

# Normative and Legal Requirements

Instrumentenbezug (instrument cover) is a medical product according to the MDD 93/42/EEC and the MDR (EU) 2017/745 and is classified as class IIa, rule 7.

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: PE bag

Secondary packaging: carton made of

cellulose

#### Storage

To be stored in a dry and dust-free environment

The product bears the following symbols and marking:







0123

Sterilize before use

Date of information: March 01, 2019 [REV 6]

replaced: May 29, 2018 [REV 5]