NOBAMED Paul Danz AG

JODOTAMP®

REF 632401

Product Description, Intendend use, Application

The **sterile** ribbon gauze strip (**1 cm x 5 m**) is made of cotton and is medicated with 50 mg/g iodoform. It serves as antiseptic ribbon gauze and drainage of body cavities, fistulas and wound loculations **after surgical sanitation of infections.** Strong antifungal, antibacterial and antiviral activity based on *in vitro* studies (test germs *Staphylococcus aureus*, *Klebsiella pneumonia*, *Candida albicans*, *Aspergillus brasiliensis* and *bacteriophage MS2*).

Composition

Cotton, iodoform, paraffin

Contra-Indications

The product may not be used in the case of pregnancy or during the nursing period, nor for newborns, babies, infants, and young children. Iodine passes into the breast milk and is there enriched. Hypersensitivity to iodine or any other component of this medical device; hyperthyroidism; autonomous ademona or other thyroid disorders; untreated infected wounds or wounds with a high risk of infection.

Residual Risks, Undesirable Side Effects, Warnings

Contents sterile as long as the packaging is undamaged.
Product is for single use **after surgical sanitation of infections.**
Do not resterilize.
Do not use in conjunction with oxidizing agents.
As with all products containing iodine, undesirable effects may occur even after a latency of 5-6 weeks.

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 und regulative Requirements, Common Standards

JODOTAMP® is a medical device. It is classified as class III, rule 13, annex IX of the MDD 93/42 EEC and as class III product, rule 14, chapter III, annex VIII according to the MDR (EU) 2017/745.

Iodoform is considered as wound antiseptic agent and is therefore classified as medicinal product.

Sterilization of the product complies with DIN EN 11137.

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

It has DIN EN ISO 15223-1 and EN 1041 labels on all its packaging.

Packaging

Primary packaging	aluminium composite
Secondary packaging:	packaging and folding box made of cellulose
Tertiary packaging:	carton made of cellulose

Symbols used in labelling explanations at www.nobamed.com

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN 1041.

Storage and Transport

To be stored in a dry and dust-free environment, temperature not exceeding 25°C and protected from sunlight. The products must not be used after the expiry date. The expiry date is mentioned on all packaging levels.

Single use device

Reusing aa 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.