

Immerci Tulle

Medical device

wound care

Presentation from Immerci Tulle – Sterile paraffin dressing is in the form of a support impregnated with a neuter vaseline and paraffin base, packed in individual sterile envelope

Product code	Presentation form / Dimensions / Quantity	No. of pieces/ individual box	UDI-DI
42V4	Paraffin dressings 10 cm x 10 cm	10	5944729008228
45V4	Paraffin dressings 10 cm x 20 cm	10	5944729008242
43V4	Paraffin dressings 10 cm x 40 cm	10	5944729008259

Composition

- Support made of cotton lattice
- Protective sheets
- Impregnation: neuter base made of Vaseline and Paraffin

Clinical benefits

- On the wound, the dressing assure a contact interface that creates the favorable local microclimate for the cicatrization process (cicatrization in moist environment)
- It is not adherent (to tissues) to the wound; removal is easy and atraumatic
- Easy to apply in the case of wounds found in difficult areas (e.g. anatomical folds, mucocutaneous junctions, etc.)

Performance characteristics

- Using the products, helps to reduce:
 - the healing and treatment time
 - the treatment costs

Indications

- Local treatment of acute wounds: first, second a and b degree burns, excoriations, traumatic wounds
- Local treatment of bedsores and chronic vascular ulcers in: granulation and epithelization phases

Contra-Indications There are no contraindications

Instructions for use

- The wound must be cleaned with hypertonic solutions (physiological serum), before each use of the paraffin dressing
- In case of previous usage of an antiseptically, wash the wound with physiological serum before applying the paraffin dressing
- The paraffin dressing is applied in a single layer directly on the wound, after removal of protective sheets.
- This dressing can be cut according with the size and/or form of the wound, using a sterile instrument
- Cover the wound with a secondary compress (sterile gauze or non-woven compress) and fix it with an extensible or fix bandage, adhesive or not
- The dressing is replaced every day or every 1-2 days, depending of the wound healing process

Precautions for use

- If there are signs of local infection, treatment can be continued with the physician's approval

Additional precautions

- The presence of a deep wound does not involve the use of multiple dressings at the same time
- Single-use product; DO NOT re-sterilize
- Sterile only if the packaging is not damaged
- Storage:
 - Protected from humidity and sunshine
 - Temperature: max. 35°C.

Undesirable side-effects

- None known.

Warnings

- Products are single use medical devices, do not re-use! Otherwise it may appear: irritation /contamination/ infection of wound and/or skin
- The product is exclusively for external use; ingestion of the impregnation base may cause stomach problems
- For people with mental disabilities, the products should only be used under supervision of a mentally healthy person
- Do not use the product if the packaging is damaged
- The products should not be further used after the expiration date
- The products should be kept away from children and pets. Penetration in the wound of hair or stains from pets can cause wound contamination

NOTE Any serious incident that has occurred in relation to TAISSIS CONCEPT S.R.L. products should be reported to TAISSIS CONCEPT S.R.L. and the competent authority of the Member State in which the user and/or patient is established



Last revision: May 2023

Symbol	Significance	Symbol	Significance
	Single use product		Means that it is absolutely necessary for the user to read the leaflet before starting the utilization of the product
	The product is sterilized with Gamma radiations		Expiry date
	Single sterile barrier system		Keep dry!
	Non-sterile protective packaging with sterile barrier system inside		Keep away from sunlight!
	Do not resterilize!		Storage at a temperature up to 35°C
	Do not use if the package is damaged!		Symbol for warning regarding throwing the pack to the trash bin
	Medical device		Manufacturer
	Product reference (code)		Unique Device Identifier
	Product lot number		Compliance with Directive 93/42/EEC

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Regulatory status: IIa Class medical devices according to MDD 93/42/EEC

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