INSTRUCTION FOR USE

Product description

LIQUEEMAX® – Silicone Super Absorbent Dressing without border (Type I) is composed of release film, silicone net wound contact layer, PP distribution layer, the central absorbent core contains SAP polymer, SMS non-woven. It is indicated for the treatment of the wounds with moderate to heavily exudate, such as acute wounds (burns, post-operative, traumatic wounds) and chronic wounds (venous ulcer, pressure ulcer, diabetic foot ulcer, tumors). Silicone Super Absorbent Dressing without border (Type I) provides effective exudate control.

Intended purpose

- Silicone super absorbent dressing without border (Type I) is suitable for treatment of injured skin, acute and chronic wounds, with moderate to heavily exudate. It features a micro-adherent. The contact site was dermal tissue and the contact time was less than 28 days. It is used on adults only, by healthcare professionals in clinical or homecare environments and could be used with secondary dressings.

Functional principle

The multi-layer construction of silicone Super Absorbent Dressing achieves superior exudate management by combining adherent wound contact layer, a diversion layer, a superabsorbent core, and a backing layer. Non-adhesive wound contact layer and hydrophilic diversion layer can absorb wound exudate and transport it upward evenly. Combined with the central absorbent core containing SAP polymer, it can absorb and lock more exudate and prevent exudate from leaking out , so as to maintain a good wound healing environment, reduce the frequency of dressing changes, and promote wound healing.

Indications

Silicone super absorbent dressing without border(Type I) is suitable for the treatment of wounds with moderate to high levels of exudate: acute wounds (burns, post-operative, traumatic wounds) and chronic wounds (venous ulcer, pressure ulcer, diabetic foot ulcer, tumors).

Clinical benefit

For wound management: reduce the frequency of dressing changes.

- 1. Check the wound for signs of infection before use, if infection occurs, see a health careprofessional
- 2. Do not use on the patients with a known hypersensitivity to the product itself or to its components

Adverse reactions

Normally no complications are associated with the use of Silicone Super Absorbent Dressing. However, according to the analysis of existing clinical data and post-marketing data of competitive devices and benchmark devices, very occasionally, there will be some potential risks associated with the use of Silicone Super Absorbent Dressing with the following situations identified:

- Mechanical skin damage or resultant pain.

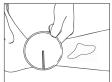
Intended user

The product shall be used by or under the supervision of a healthcare professi-

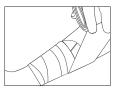
Intended patient population

Patient who has the indications: acute wounds (burns, post-operative, traumatic wounds) and chronic wounds (venous ulcer, pressure ulcer, diabetic foot ulcer, tumors)

Instructions for use







- Step 1: Select a dressing size that overlaps the wound edges by at least 2-3 cm.
- Step 2: Remove the PE film then gently apply the dressing directly on the wound site with the silicone layer of the dressing anto the wound surface
- Step 3: The dressing shall be fixed by an appropriate secondary dressing, such as Adhesive tape, elastic bandage or pressure bandage.

Note

The dressing can be left in place for up to 7days, but wearing time should be depended on level of exudate, because of excellent fluid handling capability of the dressing, it may produce pressure and require change, The dressing must be changed if clinically indicated or when exudate reaches the rim of the absorbent dressing.

Warning and Precautions

- Do not reuse. Reusing will cause cross-contamination.
- Do not use if package is damaged or open.
- Check the wound for signs of infection before use, if infection occurs, see a health careprofessional.
- 4. Do not cut the absorbent dressing.

Storage and transport conditions

The product should be stored in warehouse under normal room condition, temperature and humidity of room will not be specified strictly but require cool and dry. Direct sunlight shall be avoided. The transportation should prevent the weight, sun and rain and rain dripping.

Lifetime: 14 days, accumulate less than 28 days

Shelf life: 3 years

Disposal

Disposal should be handled according to local environment procedures.

Other information

If have any serious incident that has occurred in relation to the device, please reported to the manufacturer and the competent authority.

Distributor

L+F Medizinprodukte GmbH Am Gewerbepark 1a, 63594 Hasselroth, Germany Tel.: +49 6184 99 53 357 | Fax.: +49 6184 99 53 358 E-Mail: info@lf-med.de

Importer

Raguse Gesellschaft für medizinische Produkte mbH Südfeld 6, 59387 Ascheberg-Herbern, Germany

Manufacturer

Winner Medical Co., Ltd. Address: Winner Industrial Park, No 660 Bulong Road, Longhua District, 518109 Shenzhen, CHINA

European representation

Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestraße 80, 20537 Hamburg, Germany

Made in China

Meaning of symbols used



Do not re-use



Do not resterilize



Use-by date







Catalog number



Importer



Date of manufacture



Medical device



Keep away from sunlight



keep dry



STERILE EO Sterilized using ethylene oxide



Do not use if the packaging is damaged



Manufacturer



EU REP Authorized Representative in the European Community/Union



Consult instructions for use



Single sterile barrier system



Unique device identifier



this way up



Distributor