



NOBASPONGE®-Border

REF 777111

Product Description, Intended use, Application

Individually packed, sterile silicone foam dressing, 10 cm wide and 10 cm long. Silicone Foam Dressing are absorbent foam dressings featuring a hydrocellular pad with a low-friction, breathable polyurethane film backing and an atraumatic silicone wound contact layer. Silicone Foam Dressings can be used as a low-trauma primary dressing on fragile skin to absorb wound exudate and provide an optimal wound healing environment, even under compression.

For chronic and acute wounds with light to moderate levels of exudate such as Skin abrasions, pre-tibial lacerations, Pressure ulcers, Diabetic foot ulcers, Leg ulcers, post-operative wounds, Superficial burns Donor sites, Traumatic wounds, 2. Shallow, granulating wounds.

Composition

Polyurethane film, silicone gel, polyurethane foam, release film

Contraindications

Arterial bleeds, allergies against the material.

Warnings and precautions:

- NOBASPONGER-border is not suitable for arterial bleeds.
- Do not overlay multiple foam dressings or overlap them
- Do not stretch the skin or dressings during application. Silicone is hydrophobic and will not adhere to wet skin.
- Do not use with oxidizing solutions such as hypochlorite or hydrogen peroxide.

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 and Regulative Requirements, Common Standards

Medical Device according to MDD 93/42/EEC. The product does not contain dangerous toxic substances according to REACH. Sterilization of the product complies with DIN EN ISO 11135.

Packaging

Primary packaging:	paper-film packaging
Secondary packaging:	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 ISO 20417.

Storage and Transport

Dry and dustfree, protect from sunlight.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a 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.