

Bossklein®

ETCHgel syringe

MAXIETCHgel syringe



Phosphoric Acid Etching Gel 37% H3PO4

For professional use in dentistry only.

DESCRIPTION Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is 37% thixotropic phosphoric acid gel with optimum level of viscosity. Syringe presentation with special tips allows placement of the etching gel in any desired location.

COMPOSITION Diluent 40-60%, phosphoric acid 37%, silicon dioxide 10-20%, thickener 5-10%, pigment <1%.

Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel does not contain medicinal substance, including human blood or plasma derivative; tissues or cells, or their derivatives, of human origin; tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No. 722/2012; substances which are carcinogenic, mutagenic, toxic to reproduction or having endocrine-disrupting properties.

PERFORMANCE CHARACTERISTICS pH <1

INTENDED PURPOSE AND CLINICAL BENEFITS Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is intended to be used for tooth surface preparation procedures.

CLINICAL INDICATIONS Tooth enamel and / or dentin etching.

CONTRA-INDICATIONS Patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients.

RESTRICTIONS TO COMBINATIONS None known.

UNDESIRABLE SIDE EFFECTS In susceptible individuals, Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel may cause allergic or irritation reactions (skin, eye, mucosa, respiratory tract).

RESIDUAL RISKS Risk control measures have been implemented and verified, risk is reduced as far as possible, the overall residual risk is judged to be acceptable.

PATIENT TARGET GROUP No restrictions known regarding patient population, their age and general health conditions. There may be children, middle aged or elderly patient.

INTENDED PART OF THE BODY OR TYPES OF TISSUES OF BODY FLUIDS Part of the body – mouth. Tissues or body fluids contacted by the device – tooth.

INTENDED USER Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is developed for professional use in dentistry only. Its user only licensed doctor who has knowledge how to use common dental etchants. There is no need for specific training.

STERILITY Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is delivered non-sterile. There is no need of any preparatory sterilization, cleaning or disinfection, preventive, regular maintenance or calibration to ensure that the device operates properly and safely during its intended lifetime. However, do not use if primary package is damaged.

USE ENVIRONMENT Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is designed to be used in dental office where ambient temperature is 18-25°C. Dispensed amount of etchant is suitable for single use (only for one patient). Do not re-use. Dispensed amount kept not in original package may lead to loss of function.

CONSUMABLE COMPONENTS AND ACCESSORIES No accessories are supplied with the device. Consumables, such as application tips, are supplied with Bossklein Etching Gel Syringe. Consumables, such as empty syringes, application tips, adaptor are supplied with Bossklein MAXI Etching Gel

INSTRUCTION FOR USE

PREPARATION:

1. Prepare surface as always. The working area must be kept dry.
2. If the surface to be etched is not freshly exposed, cleaning with oil-free prophylaxis paste is recommended.
3. Twist application tip to the syringe.
4. Flow small amount of gel on mixing pad.

ETCHING:

1. Delicate push on plunger and apply layer of etch on all surface to be etched. Do not force plunger.
2. Leave etch gel in place for 15 seconds (dentine), 30 seconds (enamel).
3. Rinse with water and dry with air.
4. Verify etched surface is clean and dry.
5. Use an adhesive.

WARNINGS After the desired amount of material extruded, immediately remove application tip and close the syringe cap. Do not use Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel for patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients. Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel does not emit radiation and does not cause any electromagnetic interferences.

PRECAUTIONS It is recommended to use cofferdam during application of the product. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN OR MUCOSA: Wash with plenty of water. If skin/mucosa irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Subsequently, have the casualty drink 1 - 2 glasses of water immediately. Do not try to neutralize with bases, no charcoal. Call a Poison Centre or doctor/physician if you feel unwell. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Wash hands thoroughly after handling. Use only in a well-ventilated area. It is recommended to wear protective gloves/ protective clothing/eye protection/face protection for doctor and patient.

SHELF-LIFE Shelf-life of Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is 3 years from the date of manufacture. Do not use after the expiry date. The batch number should be quoted in all correspondence. See packaging for batch and expiry date.

STORAGE Keep product tightly closed in dry well-ventilated place at 4-28°C. Protect from direct sunlight and heat sources. Do not freeze. Keep out of the reach of children!

DISPOSAL Dispose of contents/container to as required by national regulatory requirements.

PRECAUTIONS TO BE TAKEN IN THE EVENT OF CHANGES IN THE PERFORMANCE OF THE DEVICE If you notice any discolouration and/or increased gloss of the patient's tooth tissue during use, sudden acute pain, strong pungent odour, foaming, uneven/run-off application, or any other abnormal behaviour of the product whilst manipulating the device, that is not mentioned above, discontinue use immediately. Rinse applied gel with plenty of water, use suction system and do not let the product enter the mouth and/or be swallowed. Ask patient how they are feeling. If patient notices any undesirable side-effects, immediately call a local poison centre. Collect all available remaining supplies, do not use and keep out of reach in a safe place until further notice. Contact the manufacturer immediately and report any noticed changes in the performance of the product.

VIGILANCE If any serious incident that has occurred in relation to the device report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE Bossklein Etching Gel Syringe/Bossklein MAXI Etching Gel is safe and performs as intended if it is used in accordance to manufacturer's instruction for use.

MANUFACTURERS RESPONSIBILITY Our products have been developed for professional use in dentistry. As the application of our products is beyond our control, the user is fully responsible for the application. Of course, we guarantee the quality of our products in accordance with the applied standards.

VALIDITY Upon publication of this instruction for use, all previous versions are superseded.



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Revised due to safety reasons

BOS9903 Contents: 12g syringe, 25 tips.

BOS9904 Contents: 60g (50cc) syringe, 5x3ml empty syringes, 50 tips, 1 adaptor