



Dental Application Tips

EN Dental Application Tips



INSTRUCTION FOR USE EN

DESCRIPTION

dline Dental Application Tips are a non-sterile medical device Application Tips for syringes, which are bended in 45° angle. Application Tips helps the application of small controlled amounts of material in limited access areas. dline Dental Application Tips come in 2 colors: black and blue.

COMPOSITION

Plastic, stainless steel.

Product does not contain medicinal substance, including human blood or plasma derivate; 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

size	0,5x13 mm; 0,9x10 mm
angle	45°
colour	black, blue

INTENDED PURPOSE AND CLINICAL BENEFITS

dline Dental application tips are medical devices mainly used to apply various dental materials to a treatment site in the mouth.

CLINICAL INDICATIONS

- For application of dental materials.

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

None known.

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, saliva, mucosa.

INTENDED USER

dline Dental application tips are developed for professional use in dentistry only. Its user only licensed doctor who has knowledge how to use common dental materials. There is no need for specific training.

STERILITY

dline Dental application tips are 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

dline Dental application tips are designed to be used in dental office where ambient temperature is 18-25°C. Do not re-use.

CONSUMABLE COMPONENTS AND ACCESSORIES

No consumable components and accessories are supplied with the device.

INSTRUCTION FOR USE

1. Twist the application tip into the syringe to lock the tip in place.
2. Gently push on plunger and test the flow.
3. Perform application on prepared tooth.
4. Dispose used application tip as required by national regulatory requirements.

WARNINGS

Do not use product for patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients. Product does not emit radiation and does not cause any electromagnetic interferences.

PRECAUTIONS

Wear protective gloves/protective clothing/eye protection/face protection for doctor and patient.

SHELF-LIFE

Shelf-life of disposable micro applicators is 5 years from the date of manufacture. Do not use after the expiry date. See packing for expiry date. Do not re-use.

STORAGE

Keep product tightly closed in dry well-ventilated place at 4-28°C. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from direct sunlight. Dispose of contents/container to as required by national regulatory requirements. Keep out of the reach of children!

DISPOSAL

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

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

dline Dental Application Tips are safe and perform 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.

PACKAGING

REF 25601	Bent 45°, 23G, 0,5 x 13 mm, blue, 50 pcs.
REF 25602	Bent 45°, 20G, 0,9 x 10 mm, black, 50 pcs.

SIGNS EXPLANATION

	Caution
	Temperature limit
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	Non-sterile
	Medical device
	Use-by-date
	Catalogue number
	Batch code
	Manufacturer



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