

PRAYON

DENTAL DISPOSABLE NEEDLES

Single-use dental anesthesia needles | EO sterilized

PRODUCT FAMILY	INTENDED USER	STATUS
Dental injection needles	Dental professionals	EO sterilized / single use

1. Product Description

PRAYON Dental Disposable Needles are dental anesthesia needles designed for the injection of local anesthetic. The needle assembly comprises a tissue-puncture end, a cartridge-piercing end, a protective cap and a syringe hub.

2. Intended Use

Intended for the injection of anesthetic to achieve local anesthesia in dental procedures, for use with an anesthetic cartridge and a compatible dental syringe.

3. Models, Materials and Dimensions

Model / specification	Needle length	Packaging
27G x 21 mm	21 mm	100 pcs/box; 5,000 pcs/carton
27G x 25 mm	25 mm	100 pcs/box; 5,000 pcs/carton
30G x 21 mm	21 mm	100 pcs/box; 5,000 pcs/carton
30G x 25 mm	25 mm	100 pcs/box; 5,000 pcs/carton

Additional sizes mentioned: 12 mm and 32 mm needle lengths, and 25G. Available gauge/length combinations and packaging for these sizes are to be confirmed. Dimensional tolerances and needle diameters in mm are not specified.

Component	Material	Function
Tissue-puncture end	304 stainless steel	Tissue penetration and anesthetic delivery
Cartridge-piercing end	304 stainless steel	Connection to the anesthetic cartridge
Protective cap	Polypropylene (PP)	Protection of the sterile needle
Needle hub	Polypropylene (PP)	Connection to the syringe

4. General Characteristics

Three-bevel needle tip and medical silicone oil coating for smooth insertion. Triangular orientation mark to indicate the injection direction. Metric and imperial hub options are described; compatibility with the selected syringe is to be confirmed. Individually packaged and sterilized using ethylene oxide (EO).

5. Performance Requirements

Property	Requirement
Needle tubing	304 medical-grade stainless steel. GB 18457 is listed as the material requirement.
Needle tip	Sharp and free from burrs and hooks.
Lumen patency	Unobstructed flow for injection; no blockage.
Sterilization	EO sterilization validation is specified. Quantitative acceptance criteria are to be confirmed.
Product standard	GB 15811-2025 is listed in the product data. Applicability and supporting compliance documentation are to be confirmed.

6. Directions for Use

For use with an anesthetic cartridge and a compatible dental syringe. Detailed preparation, attachment, injection and disposal instructions are to be confirmed in the approved instructions for use.

7. Warnings and Precautions

For single use. Product-specific contraindications, warnings and precautions are to be confirmed in the approved instructions for use. Syringe compatibility shall be confirmed for the selected hub type.

8. Storage and Transport

Storage and transport conditions, including temperature and humidity limits, are not specified and are to be confirmed.

9. Shelf Life and Packaging

Individually packaged. For the four models listed in Section 3: 100 pcs/box and 5,000 pcs/carton. Shelf life, expiry dating, sterile-barrier specifications and carton dimensions are to be confirmed.

10. Label Symbols

The approved label artwork and symbol set are not provided. Applicable symbols and label details are to be confirmed before document release.

Document control note

Technical content is based on the supplied product data. CE and ISO 13485 are listed under qualifications; certificate validity, scope and product coverage are to be confirmed. This sheet does not establish verified regulatory compliance. Manufacturer details and approved labeling remain to be confirmed.