

INSTRUCTIONS FOR USE

Entellus Medical Reinforced Anesthesia Needle

Read all Instructions prior to use

- Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
Sterility: Provided Sterile, Gamma Irradiation Sterilization
Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse
Storage: Store in a cool, dry place.

Indication for Use

For use in injecting local anesthetics into a patient to provide regional anesthesia.

Description

The Entellus Medical Reinforced Anesthesia Needle is a 3.5" long disposable medical device that allows the user to transnasally administer anesthetic solutions. The Reinforced Anesthesia Needle device is a 27 gauge needle with a reinforcing sleeve which supports the needle to reduce needle flex during administration of anesthetic solutions. A slight bend at the distal end of the needle is designed to improve access to nasal anatomy. The Quincke tip extends approximately 2 mm past the reinforcing sleeve creating a distal stop. The needle hub features a standard luer-lock connector. The needle may be reshaped along its length. Refer to Figure 1 below.

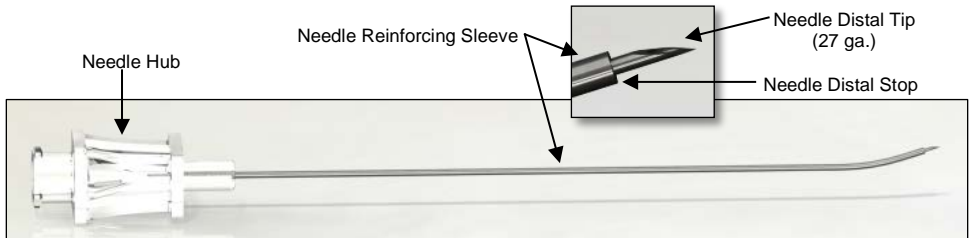


Figure 1: Entellus Medical Reinforced Anesthesia Needle

Contraindications

- None known.

Warnings

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Single use only. Do not resterilize or reuse, as it may result in compromised device performance and risk improper sterilization and cross contamination.
- Read all warnings and precautions in pharmaceutical literature prior to administration of anesthetic solutions; administer per state and local regulations.
- Do not over-insert the needle when injecting anesthetic – this may increase risk of delivering anesthetic solutions directly to blood stream.
- If the needle tip is bent during procedure, remove needle and replace with new device.
- When injecting anesthetic, if working channel is occluded, remove needle and replace with new device.
- To avoid infection, dispose of safely after single use, following local policies and procedures for disposal of sharps and/or biomedical waste.

Precautions

- Maintain aseptic conditions during preparation of the needle and throughout the procedure.
- Handle all used needles according to current blood borne pathogens procedures, such as Standard Precautions.
- Do not reshape needle beyond a 25 degree bend angle as this may cause device damage.
- Administration of anesthetic solutions may cause elevated heart rate – monitor patient accordingly.

Adverse Effects

Possible adverse effects include, but are not limited to, the following:

- Complications from anesthetic solutions
- Infection
- Tissue inflammation, irritation, swelling or trauma
- Bleeding
- Needle stick injury
- Orbital damage

Supplies

The following supplies are not provided with the Reinforced Anesthesia Needle and should be available for the procedure: medical syringes, injectable anesthetic solutions, sharps disposal container, and gloves.













Instructions for Use

1. Fill a medical syringe with anesthetic solution.
2. Remove the Reinforced Anesthesia Needle device from packaging.
3. Connect the needle hub onto filled syringe and discard clear needle protector.
4. Carefully insert needle transnasally into tissue at desired location.
 - The needle may be reshaped up to a 25 degree bend to access various anatomy
 - To avoid unnecessary tissue trauma, do not insert the needle into the tissue beyond the distal stop, which is 1.5 – 2 mm from the needle distal tip.
5. Administer anesthetic solution into desired location.
 - The same needle may be used multiple times within the same patient – repeat injections at additional sites within anatomy as necessary.
6. Remove the Reinforced Anesthesia Needle.
7. Discard used needle in accordance with local policies and procedures for disposal of sharps and/or biomedical waste.

Limited Warranty

Refer to *Entellus Medical, Inc. Standard Terms and Conditions.*

Symbols

 <p>Consult Instructions for use ISO 15223-1: 5.4.3</p>	 <p>Lot Number ISO 15223-1: 5.1.5</p>	 <p>Use By ISO 15223-1: 5.1.4</p>	 <p>Quantity</p>	 <p>Reorder Number ISO 15223-1: 5.1.6</p>	 <p>Model Number</p>
 <p>Do Not Reuse ISO 15223-1: 5.4.2</p>	 <p>Prescription Use Only</p>	 <p>Manufacturer ISO 15223-1: 5.1.1</p>	 <p>Sterilization with Radiation ISO 15223-1: 5.2.4</p>	 <p>Quinke Tip Type</p>	 <p>Do not use if package is damaged ISO 15223-1: 5.2.8</p>

Symbols Reference

ISO 15223-1:2012 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements

Not made with natural rubber latex.

patent <http://www.entellusmedical.com/patents>



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