



Reach Needle™

CAT1614

Model: FG1686

Instructions for Use

English (US)



Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Aerin Medical relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.



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Rx ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician.

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DEFINITIONS OF SYMBOLS USED

	Manufacturer
	Country of Manufacture
	Medical Device
	Catalogue number
	Quantity
	Consult instructions for use
	Batch Code
	Unique Device Identifier
	Single Sterile Barrier System
	Sterilized using Irradiation
	Do not use if package is damaged
	Do not re-sterilize
	Do not reuse
	Use-by Date
	Quincke Tip
	Keep Dry
	Caution: Federal law restricts this device to sale by or on the order of a physician.

1. DEVICE DESCRIPTION

The Reach Needle is a 4" long reinforced disposable needle that allows the user to administer anesthetic solutions. The Reach Needle is a 27-gauge needle with a reinforcing sleeve which supports the needle to reduce needle flex during administration of anesthesia solutions. The short bevel Quincke tip extends approximately 2mm past the reinforcing sleeve providing a distal stop. The distal end has a bend to provide easier access around anatomical structures. The needle hub features a standard luer-lock connector. The Reach Needle may be reshaped along its length if needed. The Reach Needle is supplied sterile and for single use only. (Figure 1.0 and Figure 2.0):

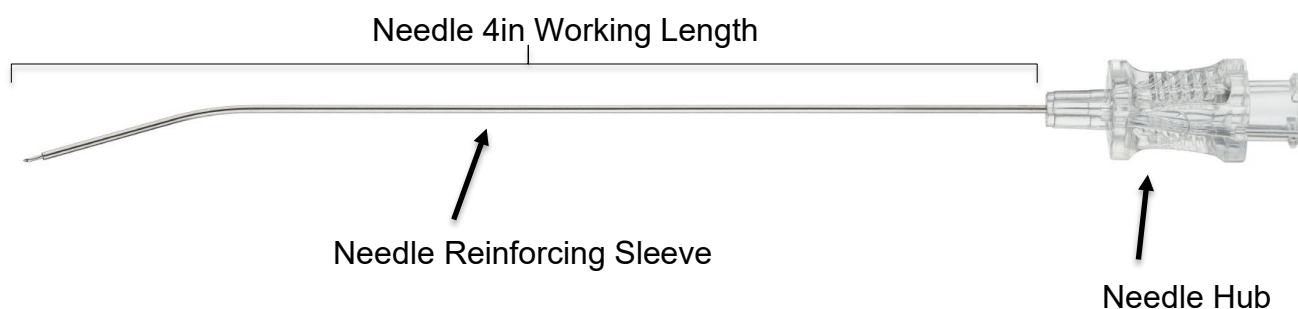


Figure 1.0 – Reach Needle

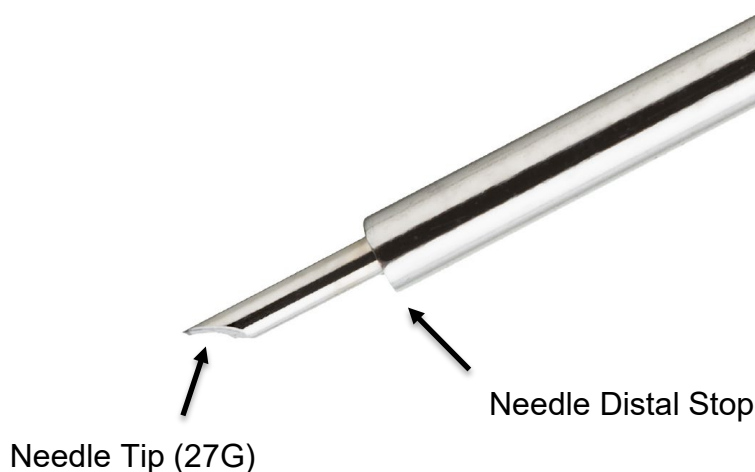


Figure 2.0 – Tip of Reach Needle

2. ADDITIONAL SUPPLIES NEEDED

Medical Syringes, injectable anesthesia solution, sharps disposal container, and gloves.

3. INDICATIONS FOR USE

The Reach Needle is used for injecting local anesthetics into a patient to provide regional anesthesia.

4. PATIENT POPULATION

- The Reach Needle is intended for use in adults (≥ 22 years).

5. CONTRAINDICATIONS

- None

6. WARNINGS & PRECAUTIONS

- The Reach Needle is for single use only. **Do not re-sterilize** or reuse. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device that may lead to infection or illness.
- DO NOT USE if packaging is breached or damaged as the sterility of the device may be compromised and may result in infection.
- DO NOT USE if the needle and/or tip is damaged or bent, replace with a new needle as this may result in ineffective or painful delivery of anesthesia to the target site.
- If the needle channel is occluded, replace with a new needle.
- After use, dispose of the needle safely after single use, following local policies and procedures for disposal of sharps and biomedical waste to avoid accidental needle stick injury.
- Do not reshape the needle beyond a 25 degrees bend angle as this could cause damage to the device.
- Maintain aseptic handling techniques when handling the needle and during procedure.
- Handle all used needles according to current blood borne pathogens procedures, such as Standard Precautions.

- Administration of anesthetic solutions may cause elevated heart rate – monitor patient accordingly.
- Do not recap the needle with the needle protector in order to reduce the risk of needle stick injuries.

7. MRI SAFETY INFORMATION

- The Reach Needle has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Reach Needle in the MR environment is unknown. Performing an MR exam on a person while using this medical device may result in injury or device malfunction.

8. CALIFORNIA PROPOSITION 65 WARNING

- WARNING: This product contains a chemical known to the State of California to cause cancer.
- WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

9. ADVERSE EFFECTS

- Complications from anesthesia
- Tissue inflammation, irritation, swelling or trauma
- Bleeding
- Infection
- Injury from accidental needle stick

10. INSTRUCTIONS FOR USE

- 1) Fill medical syringe with desired anesthesia solution.
- 2) Inspect the needle package and use-by date prior to opening. Do not use if the package is opened, damaged, or past use-by date.
- 3) Inspect the device to ensure the needle protector is on the tip of the needle. If the tip protector has fallen off, discard and use a new needle to avoid risk of accidental needle stick.
- 4) Remove the needle from the packaging using sterile technique.
- 5) Inspect the needle to ensure that it has no visible signs of damage.

6) Connect the needle hub to the syringe filled with anesthesia solution.

7) Remove the needle protector carefully and discard.

Note: The needle may be re-shaped up to a 25-degree bend angle prior to removing the needle protector.

8) Insert needle into tissue at desired location and inject anesthesia solution.

Note: The same needle may be used multiple times within the same patient – repeat injections at additional sites within anatomy, as necessary.

CAUTION: To avoid tissue trauma, do not insert the needle into the tissue beyond the distal stop.

9) Remove the needle and dispose of it in accordance to applicable local and national legislation procedures and requirements.

CAUTION: Do not recap the used needle with the needle protector in order to reduce the risk of needle stick injuries.

11. SAFE DISPOSAL

Disposal of the Reach Needle shall be in accordance with applicable local and national legislation procedure and requirements.

12. DISCLAIMER AND LIMITATION OF LIABILITY

No agent, employee or representative of Aerin Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product. This warranty is valid only to the original purchaser of Aerin Medical products directly from an Aerin Medical authorized agent. The original purchaser cannot transfer the warranty.