



Topical tissue adhesive

Important: Please read.

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Description:

Quantum SteriGlue is a sterile, high viscosity cyanoacrylate adhesive composed of n-butyl cyanoacrylate.

Quantum SteriGlue is provided in single-use disposable medical grade polymeric barrels in a sealed aluminum pouch.

Quantum SteriGlue remains liquid in its barrel until it is applied to the target site. Upon contact with moisture and proteins found on surface areas, Quantum SteriGlue cures to form a film that bonds to the underlying surfaces.

Indications:

Quantum SteriGlue is a topical tissue adhesive intended to be used as a mechanical barrier forming a protective layer on little wounds, superficial cuts, chafings and other little severe skin injuries.

Contraindications:

Quantum SteriGlue is not to be applied below the surface of the skin.

Quantum SteriGlue is not to be applied to wounds subject to high skin tension.

Quantum SteriGlue is not to be used on patients with known preoperative systemic infections, uncontrolled diabetes, or diseases or conditions that are known to interfere with the wound healing processes.

Warnings:

- Do not apply in patients with allergy to cyanoacrylates.
- Do not use the device if the packaging has been damaged or previously opened.
- In rare cases this material may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

Cautions:

Sterility and reusability information:

- Quantum SteriGlue is delivered sterile for single use only. Discard in case of broken or damaged sterilization pouch.
- Quantum SteriGlue must not be reused nor reprocessed. Re-used product would not be sterile and would lose its performance. Re-use could cause cross contamination. Any of its components may not be re-used and re-sterilized. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics.

Storage and handling:

- The product needs to be stored at room temperature in a dry place and out of direct light. Quantum SteriGlue should be handled using sterile gloves and / or with sterile instruments. Do not use after the use by date indicated on the package.
- The adhesive is capable of adhering to most body tissues (adheres skin and eyelids within seconds) and many other materials, such as latex gloves and stainless steel. Avoid contact with any tissue or equipment that is not disposable or that cannot be readily cleaned with a solvent, such as acetone. Do not use acetone or other chemicals to remove the product from undesired locations on the patient's skin.
- If accidental contact with the eye occurs, do not attempt to open the eye. Cover the eye with a soft dressing and consult an ophthalmologist immediately. The adhesive will lose its adhesive properties in a few days, and the eye will open spontaneously with no damage.
- The product is not absorbable and should only be used as a surface device. Do not allow it to ingress beneath surface tissues.
- A small amount of heat is generated during the process of polymerization. Apply thinly to make sure that no discomfort is caused to the patient.
- Do not use in the presence of gauze, cotton tipped applicators, basic substances or polyurethane foam applicators. These materials may cause excessive exothermic (heat generating) reaction.
- Quantum SteriGlue will not adhere to surfaces pre-coated with petrolatum, therefore avoid using this substance on any area where the product is intended to adhere.

- Do not apply any type of cream or lotion on the surface intended to be treated before or after using Quantum SteriGlue.

Intended users and intended patients:

- Keep out of reach of children.

Directions for use / Handling procedure:

Previous to application:

Clean the affected area with water and dry.

Application:

- 1) Peel open the protective pouch and remove the barrel. Discard the pouches in regular office waste.
- 2) Take the adhesive out of the barrel using a sterile syringe/needle or any other similar tool.
- 3) Apply a small amount of adhesive to the desired position and spread it to create a thin protective layer (thick layers will increase the setting time and could sloughs of prematurely).
- 4) Let the adhesive dry. Drying time is usually between 30 seconds and 1 minute, depending on the applied quantity.
- 5) Avoid contact of the applied area with any other object until the protection is fully dried. If product has been spilled on an unwanted area, it can be removed with cellulose paper.
- 6) Once the application is finished, safely discard the barrel and the used application tools.

Materials:

Quantum SteriGlue multipacks contain 5 individually pouched units of product.

Ingredients:

n-Butyl cyanoacrylate, glyceryl triacetate, vinyl chloride/vinyl acetate copolymer, fumed silica, D&C violet 2.

Cleaning instructions:















The liquid adhesive can be easily removed with the aid of a cellulose tissue. Tools that are contaminated with solidified Quantum SteriGlue may be cleaned with acetone.

Caution: please make sure that the tools can withstand this treatment without damage (i.e. some plastics such as PVC and polystyrene can be dissolved by acetone) and clean the instruments with repeated rinsing in water and subsequent autoclaving according to the manufacturer's recommendations

Disposal:

The product does not require specific waste treatment; it can be disposed of in normal office waste.

Symbols and Labels:

Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue number		Do not use if package is damaged
	Lot number		Keep dry
	Manufacturer		Keep away from sunlight
	Date of manufacture		Caution
	Use-by date		Consult instructions for use
	Do not re-use		Sterilized using irradiation
	Do not re-sterilize		For prescription use only



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