



CUANTUM SUTUREless
High viscosity topical tissue adhesive

Important: Please read.

Disclaimer:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Quantum Medical Cosmetics s.l. (CMC). Non-recommended use of products made by third parties in conjunction with CMC products will void any warranty or other obligation, express or implied, of CMC. The user of CMC products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. CMC disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of CMC products. The user is also obliged to study the latest developments in regard to this CMC product and its applications regularly. In cases of doubt, the user has to contact CMC. Since the utilization of this product is under the control of the user, it is his/her responsibility. CMC does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions For Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Quantum Sutureless is a sterile, high viscosity cyanoacrylate adhesive composed of n-hexyl cyanoacrylate. Quantum Sutureless is provided in single-use disposable medical grade polymeric barrels inserted in a high precision dispensing syringe in an aluminum sealed pouch. Quantum Sutureless remains liquid until it is applied to the target site. Upon contact with moisture and proteins found on surface areas, Quantum Sutureless cures to form a film that bonds to the underlying surfaces.

Indications:

Quantum Sutureless is a topical tissue adhesive intended to hold closed easily approximated edges of low-tension wounds from clean surgical incisions and small, thoroughly cleansed, trauma-induced lacerations. Quantum Sutureless may be used in conjunction with, but not in place of deep dermal sutures.

Contraindications:

Quantum Sutureless is not to be applied below the surface of the skin.
Quantum Sutureless is not to be applied to wounds subject to high skin tension.
Quantum Sutureless 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 Sutureless is delivered sterile for single use only. Discard in case of broken or damaged sterilization pouch.
- Quantum Sutureless 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 Sutureless 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 Sutureless 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 Sutureless.

Intended users and intended patients:

- This product is for sale and use only by medical specialists (professional use only) on low tension wounds.
- It is recommended that any person intending to use Quantum Sutureless has the necessary experience and tested the material outside of a patient to get used to the proper handling of the product.
- Keep out of reach of children.

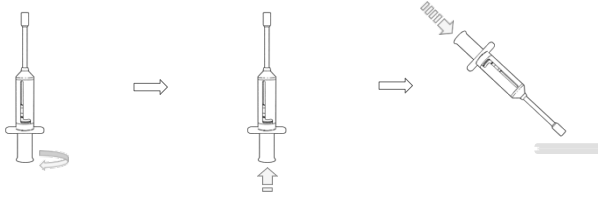
Directions for use / Handling procedure:

Previous to application:

Clean the affected area with water and dry.

Application:

- 1) Peel open the protective pouch and remove the syringe from the package. Discard the pouch in regular office waste.
- 2) Place the syringe upside taking the body syringe with your left hand and the cartridge with the right hand (reverse for lefthanded).
- 3) Unlock the applicator system by turning the cartridge to the left.
- 4) Prepare the dispensing system by pressing the cartridge upwards so that it starts to get inside the syringe body (noticing the lack of resistance).



- 5) Place then the syringe in your right hand (left for left handed) as any regular syringe (index and middle fingers in the wings of the syringe and thumb at the end of the cartridge) and get close to the application area.
- 6) Approximate the wound edges and hold them in position.
- 7) In case of adjuvant to suture, close the wound by suturing (using the technique you deem applicable to ensure uneventful wound healing).
- 8) For closing without suturing, dispense a small amount of adhesive over the wound edges by pushing smoothly the cartridge.
- 9) Spread the adhesive in a thin layer with the aid of the applicator tip of the syringe, moving it horizontally to completely cover the wound edges (thick layers will increase the setting time and could slough of prematurely).
- 10) Let the adhesive dry before releasing the wound edges.
- 11) Once finished the application, safely discard the syringe. The product may be used for multiple sites in the same patient but is not to be used on multiple patients. It will cure eventually due to the humidity in the air.

Materials:

Quantum Sutureless multipacks contain 5 individually pouched units of product.

Ingredients:

n-Hexyl cyanoacrylate, glyceryl triacetate, vinyl chloride/vinyl acetate copolymer, fumed silica, dibenzo-18-crown-6, cyanoacetic acid, 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 Sutureless 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		Consult instructions for use
	Use-by date		Sterilized using irradiation
	Do not re-use		For prescription use only
	Do not re-sterilize		



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