

McKESSON	McKesson Medical-Surgical Inc. Richmond, VA 23228	McKesson Medical-Surgical Brands Artwork Specifications		Doc. # BM-T-001	Rev. 05	
				Approver: Meghan Little		
				Effective Date: 07-15-2014		
Approval Process Requirements Printer Proofs: Please email artworks before creating printing plates to ensure all content is correct. Provide documentation if any additional changes were made. Press Proofs: Required for printing quality purposes. Please send a physical print proof, per artwork, through mail. <i>This is required only to New Suppliers, unless communicated otherwise.</i> Production Samples (FAI)*: Require one complete box unit per manufacturer number, pulled from a run, no less than one week prior to the scheduled ship date. Please Note: If either proofs or production samples were supplied with errors, changes will be made at no additional cost to MMS. <i>*Customer-ready FAIs complete with product in packaging, using artworks provided.</i>	Internal	Generated By		Luis Lugo		
		Information	File Name		122-LFC insert 2016-02	
			Product Description		Topical Skin Adhesive	
	Dimensions		297 x 210 mm			
	PMS Colors	Artwork	■	K		
		Text	■	K		
		Logo	■	K		
	Revisions	Revision		D		
		Description of Change		Removed Plymouth		
		Date		03-28-19		

McKESSON

LiquiBand® Flow Control Topical Skin Adhesive

n-BUTYL CYANOACRYLATE | STERILE

For use with McKesson MFR # 122-LFC.

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

IMPORTANT! This insert is designed to assist in using McKesson LiquiBand® Flow Control Topical Skin Adhesive. It is not a reference to surgical techniques.

DESCRIPTION

McKesson LiquiBand® Flow Control Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric [n-butyl-2-cyanoacrylate] formulation. It is provided in a single patient use applicator packaged in a blister pouch. The McKesson LiquiBand® Flow Control Topical Skin Adhesive product is comprised of a crushable glass ampoule contained within a plastic applicator with attached applicator tip. McKesson LiquiBand® Flow Control Topical Skin Adhesive remains liquid until it is applied to the skin. Upon application, McKesson LiquiBand® Flow Control Topical Skin Adhesive polymerizes within 30 seconds.

INDICATIONS

McKesson LiquiBand® Flow Control Topical Skin Adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma-induced lacerations. McKesson LiquiBand® Flow Control Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of active microbial, bacterial or fungal infections or gangrene.
- DO NOT use on mucosal surfaces or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- DO NOT apply internally, inject intravascularly, or ingest.
- DO NOT use on decubitus ulcers, animal or human bite wounds, or stab wounds.

WARNINGS

- McKesson LiquiBand® Flow Control Topical Skin Adhesive is a fast-setting adhesive capable of adhering to most body tissues and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, surface and/or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of McKesson LiquiBand® Flow Control Topical Skin Adhesive may be accelerated by water or fluids containing alcohol: McKesson LiquiBand® Flow Control Topical Skin Adhesive should not be applied to wet wounds.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye using McKesson LiquiBand® Flow Control Topical Skin Adhesive, adjust the patient's position so that any flow of the adhesive is away from the eye. The eye should be closed and protected with gauze. Strategic placement of petroleum jelly near the eye can be effective at preventing inadvertent flow of the adhesive into the eye. Use of adhesives near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these cases, general anesthesia and surgical intervention has been needed to open the eyelid.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where McKesson LiquiBand® Flow Control Topical Skin Adhesive is intended to adhere.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive should not be used in areas with high or increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period or the skin tension has been decreased by application of another wound closure device (e.g., sutures or skin staples) prior to application of McKesson LiquiBand® Flow Control Topical Skin Adhesive.
- Wounds treated with McKesson LiquiBand® Flow Control Topical Skin Adhesive should be monitored for signs of infection. Wounds with signs of infection such as erythema, edema, warmth, pain and/or drainage should be evaluated and treated accordingly to standard practice for infection.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive should be used only on wounds that have easily apposed edges which have been thoroughly cleaned, debrided, and otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive should always be applied sparingly,

either as minute drops or as a thin film bridging the wound and the aligned wound edges. Avoid pressure on the applicator to prevent wound edge separation, which could cause the topical skin adhesive to be interposed between the wound edges. Application and/or migration (leak) of the topical skin adhesive below the surface of the skin and between the wound edges may impair the healing process by forming a barrier.

- McKesson LiquiBand® Flow Control Topical Skin Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying McKesson LiquiBand® Flow Control Topical Skin Adhesive sparingly in minute drops or a thin film onto a dry wound, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if McKesson LiquiBand® Flow Control Topical Skin Adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive is packaged for single patient use. Discard remaining unopened material after each wound closure procedure.
- DO NOT re-sterilize McKesson LiquiBand® Flow Control Topical Skin Adhesive or include it in a procedure pack/tray that is to be sterilized prior to use. Exposure of McKesson LiquiBand® Flow Control Topical Skin Adhesive after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase viscosity and may render the product unusable.

PRECAUTIONS

- This product is meant for external dermal application only.
- Safety and effectiveness of McKesson LiquiBand® Flow Control Topical Skin Adhesive has not been evaluated for use on wounds of patients with uncontrolled diabetes mellitus, diseases or conditions that are known to interfere with the wound healing process, or a personal or family history of keloid formation or hypertrophic scarring.
- Safety and effectiveness has not been evaluated on wounds that have been treated with McKesson LiquiBand® Flow Control Topical Skin Adhesive and then exposed for prolonged periods of time to direct sunlight or tanning lamps.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive permeability by topical medications or other fluids is not known and has not been studied.
- Liquid, ointment, or cream medications should not be applied to the wound after closure with McKesson LiquiBand® Flow Control Topical Skin Adhesive, as these substances may weaken the polymerized film which may allow for wound dehiscence.
- If unintended bonding of intact skin with McKesson LiquiBand® Flow Control Topical Skin Adhesive should occur, removal may be accomplished by using either acetone or petroleum jelly. Typical cleansers such as soap and other agents such as water, saline, Betadine®, or chlorhexidine gluconate are not expected to loosen the bond. Peel, do not pull skin apart.
- McKesson LiquiBand® Flow Control Topical Skin Adhesive is a viscous liquid prior to polymerization. To prevent inadvertent flow of McKesson LiquiBand® Flow Control Topical Skin Adhesive to unintended areas: (1) the wound should be placed in a horizontal position, with McKesson LiquiBand® Flow Control Topical Skin Adhesive applied from above, and (2) McKesson LiquiBand® Flow Control Topical Skin Adhesive should be applied in minute drops or as a thin film rather than in a few large droplets.

ADVERSE REACTIONS

Clinical use of cyanoacrylate-based topical skin adhesives has suggested that the following adverse events may occur: wound dehiscence; infection; acute inflammation including erythema, edema, and drainage; bonding to unintended tissues such as the eye; thermal discomfort during polymerization; allergic reaction; foreign body reaction; and chronic non-healing of a wound.

CLINICAL STUDIES

Topical skin adhesives comprised of monomeric n-butyl-2-cyanoacrylate, including McKesson LiquiBand® Flow Control Topical Skin Adhesive, have been evaluated in controlled clinical studies in comparison to sutures, staples, adhesive strips and other cyanoacrylate-based topical skin adhesives to close incisions and trauma-induced lacerations. This Instructions for Use has been generated based on these studies.

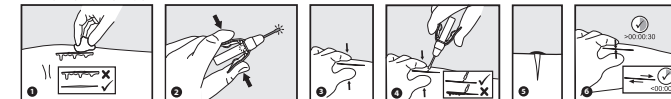
DIRECTIONS FOR USE

- Before using McKesson LiquiBand® Flow Control Topical Skin Adhesive, the wound must be thoroughly cleaned. When necessary, debride the wound.
- Use standard wound preparation procedures prior to using McKesson LiquiBand® Flow Control Topical Skin Adhesive.
- Dry the wound area with sterile gauze, removing all moisture to ensure proper bonding of McKesson LiquiBand® Flow Control Topical Skin Adhesive.
- To prevent inadvertent flow of McKesson LiquiBand® Flow Control Topical Skin Adhesive to the unintended areas of the body, the wound should be positioned horizontally and McKesson LiquiBand® Flow Control Topical Skin Adhesive should be applied from above the wound.
- Remove the applicator from the blister pouch. Hold the applicator with finger and thumb by the actuation wings with the tip pointed upward and away from the patient to avoid unintentional placement of the topical skin adhesive into the wound or on the patient. Squeeze the wings to apply sufficient pressure to crush the inner glass ampoule. Invert and gently squeeze the wings just sufficiently to express the liquid McKesson LiquiBand® Flow Control Topical Skin Adhesive adhesive to moisten the applicator tip. It will appear to darken as it is moistened by the adhesive. The adhesive will be seen travelling down the lumen to the tip.
- Approximate the wound edges together using either a gloved finger or sterile forceps. Maintain the wound edges in apposition during the application of McKesson LiquiBand® Flow Control Topical Skin Adhesive. Wounds that are subject to tension can be secured by subcuticular sutures prior to the topical application of the skin adhesive.
- Apply McKesson LiquiBand® Flow Control Topical Skin Adhesive very sparingly, either as minute drops or as a very thin film along the edges of the wound. Avoid heavy application.
- Maintain manual approximation of the apposed wound edges for approximately 30 seconds to allow the topical skin adhesive to polymerize. NOTE: Excessive pressure of the applicator tip

against the wound edges or surrounding skin can force the wound edges apart, allowing adhesive into the wound. Adhesive within the wound could act as a barrier and delay wound healing and/or result in adverse cosmetic outcomes. NOTE: McKesson LiquiBand® Flow Control Topical Skin Adhesive is expected to be completely polymerized and at full strength in approximately 1 minute, when the topical skin adhesive is no longer tacky.

- Following application the applicator should be discarded.
- Liquid, ointment or cream medications should not be applied onto wounds following closure with McKesson LiquiBand® Flow Control Topical Skin Adhesive.
- Protective dry dressings, such as gauze, may be applied over wounds closed with McKesson LiquiBand® Flow Control Topical Skin Adhesive once the adhesive has completely polymerized and is no longer tacky (approximately 2 minutes after application).
- If removal of McKesson LiquiBand® Flow Control Topical Skin Adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the McKesson LiquiBand® Flow Control Topical Skin Adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.

DIRECTIONS FOR USE



Thoroughly clean and dry wound, ensure wound edges are easily apposed.

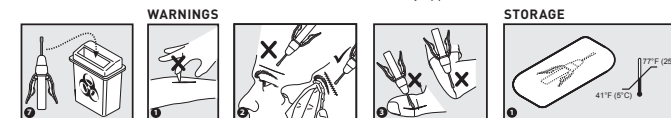
Squeeze the applicator wings with the tip pointing upward to activate the device.

Approximate the wound edges together, maintain the wound edges in apposition.

Apply topical skin adhesive sparingly either as minute drops or as a thin film along the edges of the wound. Avoid heavy application.

Apply topically - do not allow applicator tip or adhesive into the wound.

Hold together for approximately 30 seconds.



Dispose to clinical waste.

Avoid inadvertent contact with wet adhesive.

When closing facial wounds near the eye, adjust the patient's position. The eye should be closed and protected with petroleum jelly and gauze.

Do not use on wounds under high tension.

Store in original packaging at ambient room temperatures between 41°F (5°C) and 77°F (25°C).

PATIENT INSTRUCTIONS

No additional or special care is needed for wounds closed using McKesson LiquiBand® Flow Control Topical Skin Adhesive; however, it is recommended that the following information be shared with the patient as necessary. A dry protective dressing should be applied for children or other patients who may not be able to follow these instructions for proper wound care.

- Do not pull or pick at the wound or polymerized film of McKesson LiquiBand® Flow Control Topical Skin Adhesive. Picking at the film can disrupt it's adhesion to the skin and cause dehiscence of the wound.
- Light showering or bathing is permitted, however do not scrub, soak, or expose the wound site to prolonged wetness (including swimming) until after the film has sloughed off naturally (usually in 5-10 days).
- Do not apply any liquid, ointment or cream medication to the wound.
- Report any discomfort or other concerns regarding your wound to your doctor.

HOW SUPPLIED

McKesson LiquiBand® Flow Control Topical Skin Adhesive is supplied sterile, in a pre-filled, single use applicator. McKesson LiquiBand® Flow Control Topical Skin Adhesive is comprised of a crushable glass ampoule contained within a plastic applicator with tip attached. The applicator contains 0.5 g of the liquid adhesive. The applicator is packaged in a blister pouch to maintain the device sterile until opened or damaged. McKesson LiquiBand® Flow Control Topical Skin Adhesive is supplied in boxes of 12 applicators.

STORAGE

Recommended storage conditions: between 41°F and 77°F [5°C and 25°C] away from moisture, direct heat, and direct light. Avoid prolonged exposure to elevated temperatures.

McKesson LiquiBand® Flow Control Topical Skin Adhesive should always be stored in its original packaging. DO NOT use after the expiration date shown on the packaging, preceded by the expiration symbol.

STERILITY

McKesson LiquiBand® Flow Control Topical Skin Adhesive is terminally sterilized by irradiation. McKesson LiquiBand® Flow Control Topical Skin Adhesive is packaged for single patient use. Do not re-sterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.

LOT Batch code/Lot No.



Do not re-use.

EXP Use By.

STERILE R Sterilized by irradiation.

Questions? Call 1-800-777-4908

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