

**Value Analysis Committee Product Information Kit** 

From the Covidien brand you trust.



Speed

**Ease of Use** 

**Precision** 







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#### **PRODUCT OVERVIEW**

#### One Product for All of Your Clinical Needs

Designed with patient comfort and safety in mind, SwiftSet<sup>™</sup> Topical Skin Adhesive offers everything you need in a topical skin adhesive – and more. The combination of unique formulation and proprietary application design makes it an essential skin closure device for use throughout the hospital including surgical incisions in the OR and trauma-induced lacerations in the ER.

#### **Enhanced Performance**

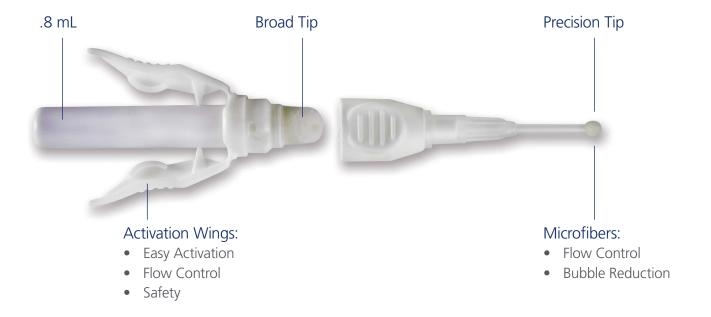
- Quick Drying 30 seconds¹
- Strong Adhesion Only one application required (Strength equivalent to a 4-0 suture<sup>2</sup>)
- Microbial Barrier Providing added protection where needed most<sup>3</sup>
- Waterproof For patient convenience and protection<sup>4</sup>
- Excellent Cosmesis For satisfied patients<sup>4</sup>

#### **More Control**

- Precise Application Precision Tip and Wide Tip options for controlled application
- Flow Control No mess and one-handed activation with specially designed applicator
- Easy to See Violet tint for enhanced visibility

#### **Better Value**

- More Adhesive More skin adhesive per vial than competitor brands
- Designed to Minimize Clogging Less chance of using multiple vials per procedure<sup>4</sup>
- Training and Support Best-in-class service and ongoing support from Covidien's highly trained sales force
- Easy to Store No refrigeration necessary



## Fast, Precise, Easy – How SwiftSet<sup>™</sup> Topical Skin Adhesive Compares

	SwiftSet <sup>™</sup> Topical Skin Adhesive	DermaBond <sup>™*</sup> Advanced	DermaBond™* Mini	
Set Time	30 seconds. Full apposition strength in 1 minute. <sup>1</sup>	Maintain manual approximation for 60 seconds. Full apposition strength in minutes. <sup>6</sup>	1 minute for 2 required applications, with full apposition strength in 2.5 minutes. <sup>7</sup>	
Application Required	1 <sup>1</sup>	1 <sup>5</sup>	2 <sup>7</sup>	
Adhesive per Vial	0.8 ml	0.7 ml	0.36 ml	
Precision Tip	Yes	No	No	
Designed to Minimize Clogging	Yes <sup>1</sup>	No <sup>6</sup>	No <sup>7</sup>	
Exothermic Reaction	Low <sup>5</sup>	High⁵	High⁵	
Microbial Barrier	Yes <sup>1</sup>	Yes <sup>6</sup>	Yes <sup>7</sup>	
Patient Can Shower Immediately	Yes <sup>1</sup>	Yes <sup>6</sup>	Yes <sup>7</sup>	
Violet Tint	Yes	Yes	Yes	
Ambient Storage	Yes	Yes	Yes	

#### **CLINICAL DATA**

### Swiftset<sup>™</sup> Adhesive Technology - Preferred in the ER

Why do clinicians depend on SwiftSet<sup>™</sup> Adhesive Technology in the ER? It's fast working, easy to use and remains strong and secure throughout the wound healing process. Plus, it's formulated for patient comfort and convenience.





1) Pre-closure

2) Post-closure

3) 24 Hours Post-closure



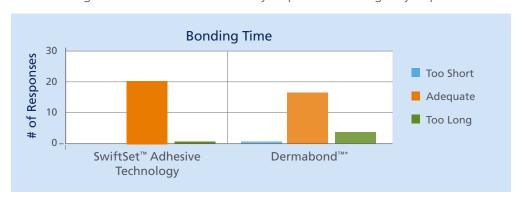


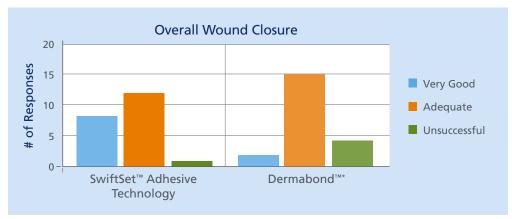


5) 4 Weeks Post-closure

Note: Adhesive used in photos does not include violet tint.

The following charts are based on a survey of pediatric emergency department nurses.  $^{8}$  (Sample Size = 63)





"Very accurate application, very little waste (single use) and successful closure – impressive!"

SwiftSet<sup>™</sup> Topical Skin Adhesive is safe and effective for use on scalp lacerations.<sup>4</sup>

The following chart is based on a study of 19 ER patients who received Swiftset<sup>™</sup> Adhesive Technology for closure of scalp wounds.<sup>4</sup>



#### **CLINICAL DATA** continued...

### Swiftset<sup>™</sup> Adhesive Technology – Proven in the OR

SwiftSet<sup>™</sup> is also conveniently designed for use in the OR, providing the strength, security and speed needed in closing surgical incisions.

In a prospective, randomized controlled trial, of 154 patients undergoing laparoscopic general surgical procedures, SwiftSet<sup>™</sup> Adhesive Technology showed potential time savings, comparable wound complication rates and comparable cosmetic outcomes compared to non-absorbable monofilament sutures.<sup>9</sup>

In a randomized study of 67 patients, SwiftSet<sup>™</sup> adhesive technology performed cosmetically as well as standard suture in the closure of columellar skin incisions used for external rhinoplasty, with a significantly shorter time to closure in the adhesive group.<sup>10</sup>



**Day of surgery:** A 46-year-old male smoker was admitted for left ileo femoral bypass for claudication of the left leg. The abdominal incision measured 18cm in length.



**Day of surgery:** Deep layer resorbable sutures were placed prior to skin closure with SwiftSet<sup>™</sup> skin adhesive.



**Five months post-surgery:** Despite the high tension position of the incision site and the patient being a high frequency smoker, the incision site healed well without complication.

Note: Adhesive used in photos does not include violet tint.

#### **TECHNICAL DATA**

In vitro testing shows that one layer of SwiftSet<sup>™</sup> Topical Skin Adhesive has a similar strength profile to standard suture.<sup>2</sup>

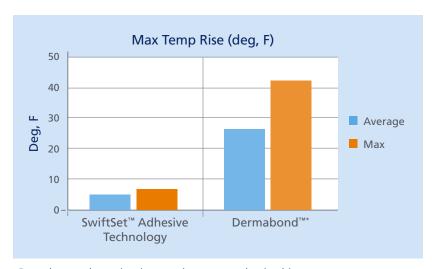
	Suture 3-0	Suture 4-0	SwiftSet™ Adhesive Technology
Average	12.14	11.65	11.37
ST Dev	4.84	5.59	5.44

SwiftSet<sup>™</sup> Topical Skin Adhesive provides an effective Microbial Barrier that could protect the wound from infection.<sup>3</sup>

Microbe	% Maintaining Microbial Barrier Propert Microbe (n=100 tests)		
	3 Day Time Point	7 Day Time Point	
Staphylococcus aureus	100%	100%	
Staphylococcus epidermidis	100%	99%	
Candida albicans	100%	100%	
Escherichia coli	100%	100%	
Pseudomonas aeruginosa	100%	99%	
MRSA	100%	100%	

#### Lower Heat Generation<sup>5</sup>

A lower exothermic reaction means less pain and more comfort for your patients.



Based on polymerization testing on synthetic skin.

### **MATERIALS MANAGEMENT INFORMATION**

### **Ordering Information**

Ordering Code	Description	Units per Box
SS6	SwiftSet™ Topical Skin Adhesive	6

Customer Service: 1-800-722-8772

#### **Packaging Overview**



### **Cross Reference**

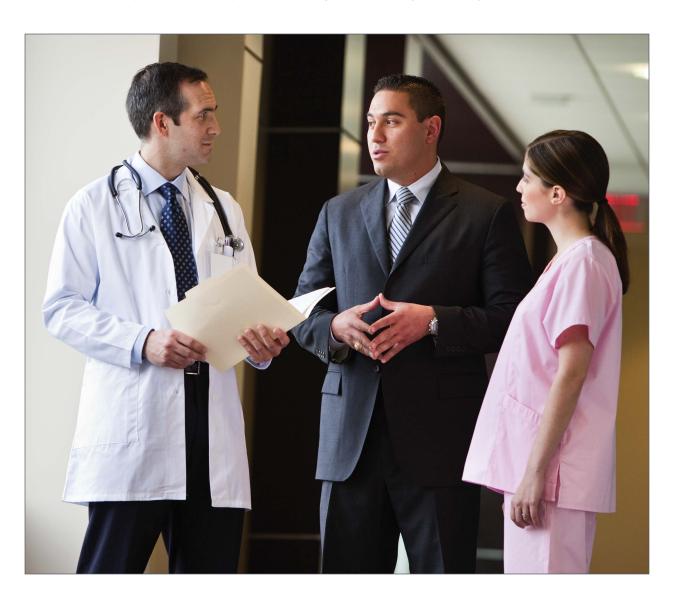
Reorder Code	Product Name	Units per Box	Reorder Code	Product Name	Units per Box
DNX12	Dermabond <sup>™*</sup> Advanced	12	SS6	SwiftSet™ Topical Skin Adhesive	6
DNX6	Dermabond™* Advanced	6	SS6	SwiftSet™ Topical Skin Adhesive	6
DHVM12	Dermabond™* Mini	12	SS6	SwiftSet™ Topical Skin Adhesive	6
DHV12	Dermabond <sup>™*</sup>	12	SS6	SwiftSet™ Topical Skin Adhesive	6
IND012	Indermil® Topical Skin Adhesive	12	SS6	SwiftSet™ Topical Skin Adhesive	6

### **SERVICE AND SUPPORT**

## **Making the Savings Stick**

### **Effective Clinical Service and Support**

- Our highly trained sales force will provide the clinical support you demand
- A committed partner, we will provide the long term service you can rely on



#### **REGULATORY CLEARANCE**

Letter



December 18, 2013

Dear Valued Customer:

SwiftSet™ Topical Skin Adhesive has been deemed substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act that do not require approval of a premarket approval application (PMA).

SwiftSet™ Topical Skin Adhesive has been cleared under 510k K122446 and the device listing is D187413.

Sincerely.

Senior Specialist, Regulatory Affairs

Covidien

COVIDIEN

60 MIDDLETOWN AVE NORTH HAVEN, CT 06473 203-492-5284 [T] 203-492-5029 [F]



#### INSTRUCTIONS FOR USE



SwiftSet™

#### **Topical Skin Adhesive**

SS6
INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

IMPORTANT! This insert is designed to assist in using SwiftSet™ topical skin adhesive. It is not a reference to surgical techniques.

#### DESCRIPTION

SwiftSet<sup>TM</sup> 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 paper/poly pouch. The SwiftSet<sup>TM</sup> topical skin adhesive product is comprised of a crushable glass ampule contained within a plastic applicator with attached broad tip and optional detached precision tip. SwiftSet<sup>TM</sup> topical skin adhesive remains liquid until it is applied to the skin. Upon application, SwiftSet<sup>TM</sup> topical skin adhesive product size applicator with attached broad tip and optional detached precision tip.

In vitro studies have shown that SwiftSet™ topical skin adhesive acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

SwiftSet™ 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. SwiftSet™ topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

- 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

- SwiftSet™ 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 can not be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of SwiftSet™ topical skin adhesive may be accelerated by water or fluids containing alcohol: SwiftSet™ topical skin adhesive should not be applied to wet wounds. SwiftSet™ 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 SwiftSet™ topical skin adhesive, adjust the patients 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.
- SwiftSet™ topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SwiftSet™ topical skin adhesive is intended to adhere.
- SwiftSet™ topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- SwittSet™ 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 would closure device (e.g., sutures or skin staples) prior to application of SwiftSet™ topical skin adhesive. Wounds treated with SwiftSet™ 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 according to standard practice for infection.
- SwiftSet™ topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction
- SwiftSet<sup>TM</sup> 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.
- standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.

  SwiftSet™ topical skin adhesive should always be applied sparingly, either as minute drops or as a thin fillm 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.

  SwiftSet™ topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SwiftSet™ 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 SwiftSet™ 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.

  SwiftSet™ topical skin adhesive is packaged for a single patient use. Discard remaining opened material after each wound closure procedure.
- DO NOT re-sterilize SwiftSet™ topical skin adhesive or include it in a procedure pack/tray that is to be sterilized prior to use. Exposure of SwiftSet™ 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

- This product is meant for external dermal application only.
- This product is meant for external dermal application only.
  Safety and effectiveness of SwiftSet™ 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 have not been evaluated on wounds that have been treated with SwiftSet™ topical skin adhesive and then exposed for prolonged periods of time to direct sunlight or tanning lamps.
- SwiftSet™ 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 SwiftSet™ topical skin adhesive, as these substances may weaken the polymerized film which may allow for wound dehiscence.
- allow for wound openscence.

  If unintended bonding of intact skin with SwiftSet™ 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.

  SwiftSet™ topical skin adhesive is a viscous liquid prior to polymerization. To prevent indovertent flow of SwiftSet™ topical skin adhesive to unintended areas: (1) the wound should be placed in a horizontal position, with SwiftSet™ topical skin adhesive should be applied in minute drops or as a thin film rather than
- in a few large droplets.

  Do not attach precision tip after using broad tip as adhesive may get transferred to hand and applicator body

## SwiftSet™ Topical Skin Adhesive

#### INSTRUCTIONS FOR USE

#### 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.

Topical skin adhesives comprised of monomeric n-butyl-2-cyanoacrylate, including SwiftSet<sup>TM</sup> 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.

- Before using SwiftSet™ topical skin adhesive, the wound must be thoroughly cleansed. When necessary, debride the wound
- Use standard wound preparation procedures prior to using SwiftSet™ topical skin adhesive.

  Dry the wound area with sterile gauze, removing all moisture to ensure proper bonding of SwiftSet™ topical skin adhesive.
- To prevent inadvertent flow of SwiftSet™ topical skin adhesive to the unintended areas of the body, the wound should be positioned horizontally and SwiftSet™ topical skin adhesive should be applied from above the wound.
- Remove the applicator from the paper/poly pouch. Select preferred tip, if desired attach precision tip by fitting and twist clockwise until secure. 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 ampule. Invert and gently squeeze the wings just sufficiently to express the liquid SwiftSet<sup>TM</sup> topical skin 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 Precision tip.
- Approximate the wound edges together using either a gloved finger or sterile forceps. Maintain the wound edges in apposition during the application of SwiftSet™ 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 SwiftSet™ topical skin adhesive very sparingly, either as minute drops or as a very thin film along the edges of the wound. Avoid heavy application.

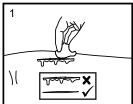
- Apply switted: "optical skin adhesive very spaningly, entire as limited tolbs of as a very timi limit along the edges of the would. Avoid heavy application. Midintain manual approximation of the apposed wound edges for approximately 30 seconds to allow the topical skin adhesive to polymerize.

  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.

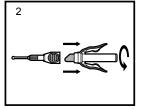
  NOTE: SwiftSet<sup>TM</sup> topical skin adhesive is expected to be completely polymerized and at full strength in approximately 1 minute, when the topical skin adhesive is no longer tacky.
- Following application the applicator should be discarded.
- Liquid, ointment or cream medications should not be applied onto wounds following closure with SwiftSet™ topical skin adhesive.

  Protective dry dressings, such as gauze, may be applied over wounds closed with SwiftSet™ topical skin adhesive once the adhesive has completely polymerized and is no longer tacky (approximately 2 minutes after application).
- (approximates) grammates that approximately approximately

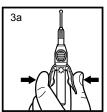
#### **Directions for Use**

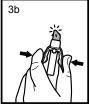


Thoroughly clean and dry wound, ensure wound edges are easily apposed.



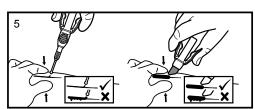
If desired select precision tip and attach by twisting clockwise







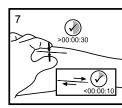
Approximate the wound edges together, maintain the wound edges in apposition.



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.

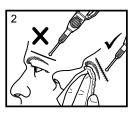


Dispose to clinical waste

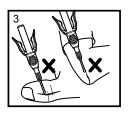
#### Warnings



Avoid inadvertent contact with wet adhesive.

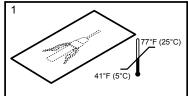


When closing facial wounds near the eye, adjust the patients position. The eye should be closed and protected with petroleum jelly and gauze



Do not use on wounds under high tension.

#### Storage



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 SwiftSet™ 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 SwiftSet™ topical skin adhesive. Picking at the film can disrupt its 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
  - Do not apply any liquid, ointment or cream medication to the wound.
  - Report any discomfort or other concerns regarding your wound to your doctor.

SwiftSet™ topical skin adhesive is supplied sterile, in a pre-filled, single use applicator. SwiftSet™ topical skin adhesive is comprised of a crushable glass ampule contained within a plastic applicator with a broad tip attached and precision tip separate. The applicator contains 0.8mL of the liquid adhesive. The applicator is packaged in a paper/poly pouch to maintain the device sterile until opened or damaged. SwiftSet™ topical skin adhesive is supplied in boxes of 6 applicators.

Recommended storage conditions: between 41°F and 77°F away from moisture, direct heat, and direct light.

Avoid prolonged exposure to elevated temperatures.

SwiftSet 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.

#### STERII ITY:

SwiftSet<sup>TM</sup> topical skin adhesive is terminally sterilized by dry heat and ethylene oxide. SwiftSet<sup>TM</sup> topical skin adhesive is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.



Use-by date. Indicates the date of expiry of the device



Caution: Consult accompanying documents. Refer to Instructions for use



Batch Code - Indicates the manufacturers lot number



Do Not Reuse. Indicates that the device is for single patient use only



Do Not Resterilize



Catalog Number



Temperature Limit



Sterilized using ethylene oxide



Sterilized using dry heat



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



Do not use if package is damaged



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#### REFERENCES

- <sup>1</sup> SwiftSet™ Topical Skin Adhesive Product IFU.
- <sup>2</sup> Report on Comparing N-butyl Cyanoacrylate Skin Adhesive Wound Closure Strength Against Competitors. M059 VR 180.
- <sup>3</sup> McAuliffe J et al. Microbial barrier properties of n-butyl cyanoacrylate topical skin adhesive: an in vitro study. IRM 06 0128.
- <sup>4</sup> Hendry, et al. (2011) A Prospective, Single-Center Study to Evaluate the Use of N-butyl Cyanoacrylate Skin Adhesive in the Closure of Scalp Wounds. University of Florida Health Science Center Jacksonville, Department of Emergency Medicine.
- <sup>5</sup> A report on measuring the heat of polymerization of n-butyl cyanoacrylate monomer. Doc No. MLGL-08019-R1.

- <sup>6</sup> Dermabond<sup>™\*</sup> Advanced Product IFU.
- <sup>7</sup> Dermabond<sup>™\*</sup> Product IFU.
- 8 Charters, A (2000) Wounds glue: A comparative study of tissue adhesives: Accident & Emergency Nursing: 8:223-7.
- <sup>9</sup> Dowson et al. (2006) A prospective, randomised controlled trial comparing n-butyl cyanoacrylate tissue adhesives with sutures for skin closure after laparoscopic general procedures, Surgical Laparoscopy Endoscopy and percutaneous Techniques.
- <sup>10</sup> Ozturan et al. (2001) Butyl cyanoacrylates tissue adhesive for columellar incision closure, The Journal of Laryngology & Otology Vol 115: 535-40.

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