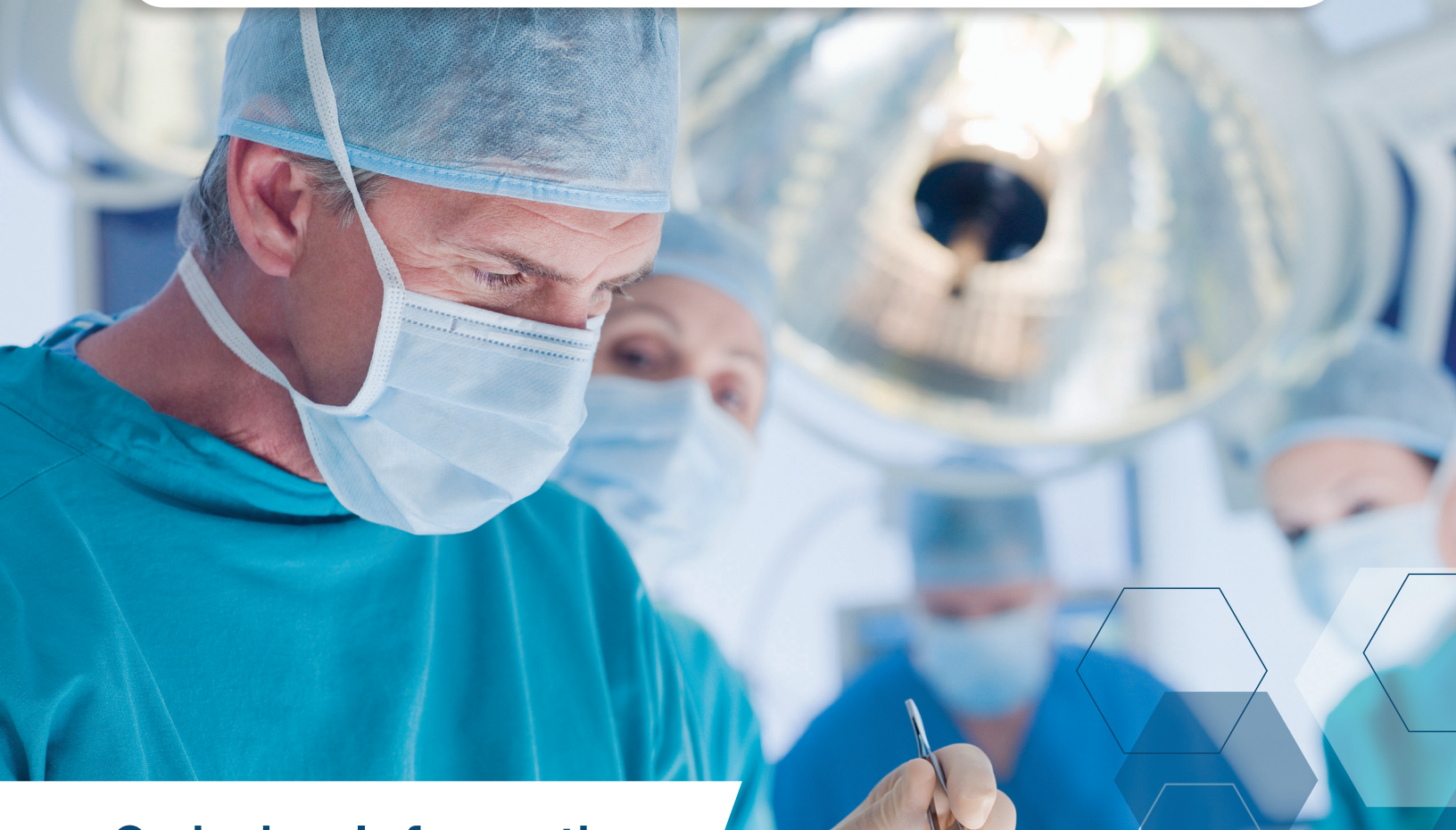


SurgiSeal®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

SurgiSeal Twist®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

SurgiSeal Stylus®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



Ordering Information

Contact your Pfizer Sales Rep or call

1-877-946-7747 Option #2

for pricing or to order SurgiSeal® Topical Skin Adhesive products.

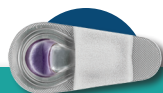
INDICATION FOR SURGISEAL, SURGISEAL STYLUS, AND SURGISEAL TWIST

SURGISEAL topical skin adhesives are 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. SURGISEAL topical skin adhesives may be used in conjunction with, but not in place of, deep dermal sutures.

*Please see Important Safety Information on the following pages.
Please see Instructions for Use at the end of this document.*



Ordering Information



	SurgiSeal® Topical Skin Adhesive (2-octyl cyanoacrylate)	SurgiSeal Twist® Topical Skin Adhesive (2-octyl cyanoacrylate)	SurgiSeal Stylus® Topical Skin Adhesive (2-octyl cyanoacrylate)
Readable Bar Code on Outer Box	0901-2004-22	0901-2004-33	0069-0901-20
List Number	90120-22	90120-33	90120-01
Catalog ID	9012022	9012033	9012001
Product Number on Tray/ SurgiSeal Stylus	SS-035T	ST-050S	SS-050S
Product Number on Sleeve	SST-IB02-1600	STS-IB02-1600	SSS-IB02-15IR
Packaging Information	1 unit contains 12 SurgiSeal; 1 case contains 48 units	1 unit contains 12 SurgiSeal Twist; 1 case contains 24 units	1 unit contains 12 SurgiSeal Stylus; 1 case contains 48 units
Shelf Life	24 months	24 months	24 months

**Contact your Pfizer Sales Rep or call
1-877-946-7747 Option #2
for pricing or to order SurgiSeal.**

IMPORTANT SAFETY INFORMATION FOR SURGISEAL, SURGISEAL STYLUS, AND SURGISEAL TWIST

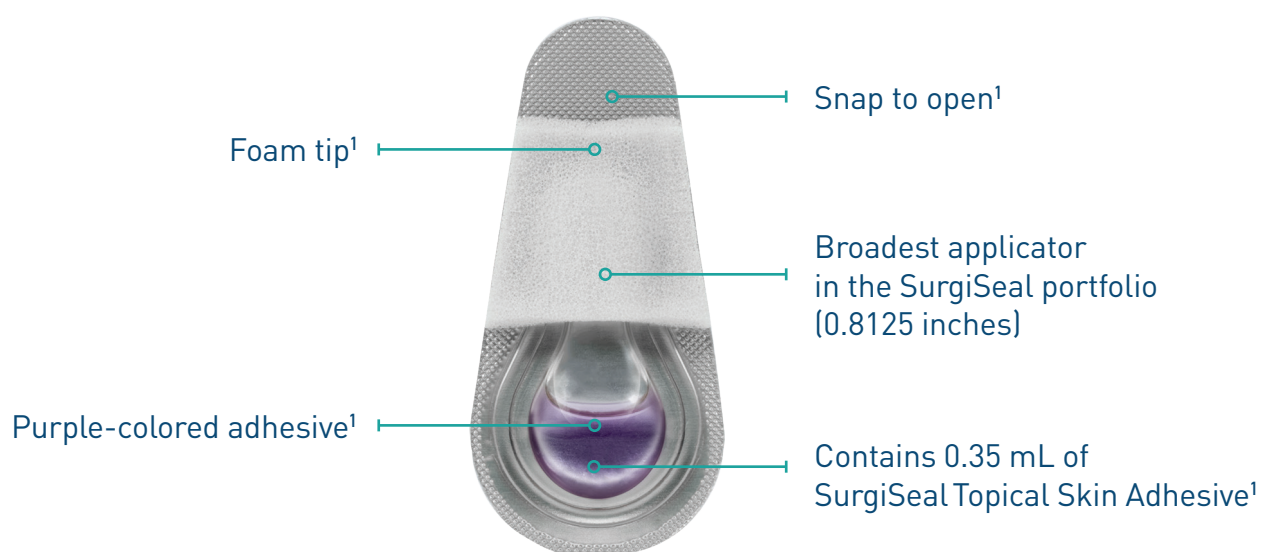
SURGISEAL topical skin adhesives are contraindicated on:

- any wounds with evidence of microbial, bacterial, or fungal infections or gangrene
- mucosal surfaces or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids or with dense natural hair
- patients that have a hypersensitivity to cyanoacrylates or formaldehyde

Please see additional Important Safety Information on the following pages.

Please see Instructions for Use at the end of this document.

**SurgiSeal® Topical Skin Adhesive (2-octyl cyanoacrylate)
comes in a teardrop-shaped applicator
containing 0.35 mL of 2-octyl cyanoacrylate.¹**



A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days^{1,2}

IMPORTANT SAFETY INFORMATION FOR SURGISEAL, SURGISEAL STYLUS, AND SURGISEAL TWIST (CONTINUED)

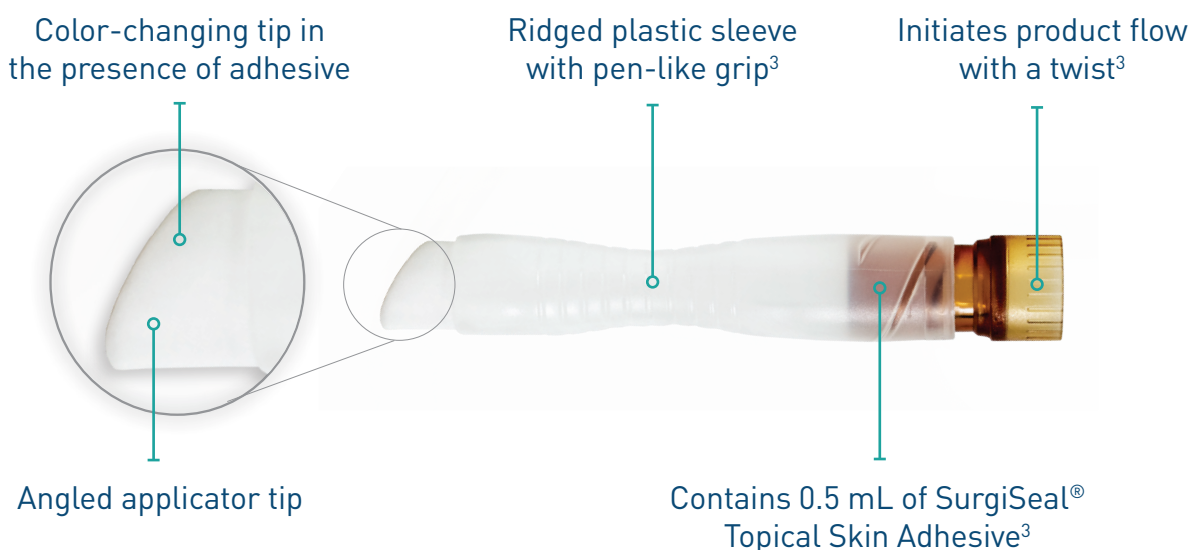
Do not use SURGISEAL topical skin adhesives on wounds or skin surfaces that are wet, complex, non-acute, poorly perfused, or subject to repeated or prolonged moisture or friction, or in the presence of ongoing bleeding or incomplete debridement.

Please see Instructions for Use at the end of this document.

SurgiSeal Twist[®]

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

**SurgiSeal Twist[®] Topical Skin Adhesive (2-octyl cyanoacrylate)
has distinct features for adhesive flow initiation,
grip, and application.**



A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days^{2,3}

IMPORTANT SAFETY INFORMATION FOR SURGISEAL, SURGISEAL STYLUS, AND SURGISEAL TWIST (CONTINUED)

Do not use SURGISEAL topical skin adhesives below the skin, in decubitus ulcers, or in the eye. Avoid ingestion, internal application, and inadvertent contact with or intravascular injection of SURGISEAL topical skin adhesives.

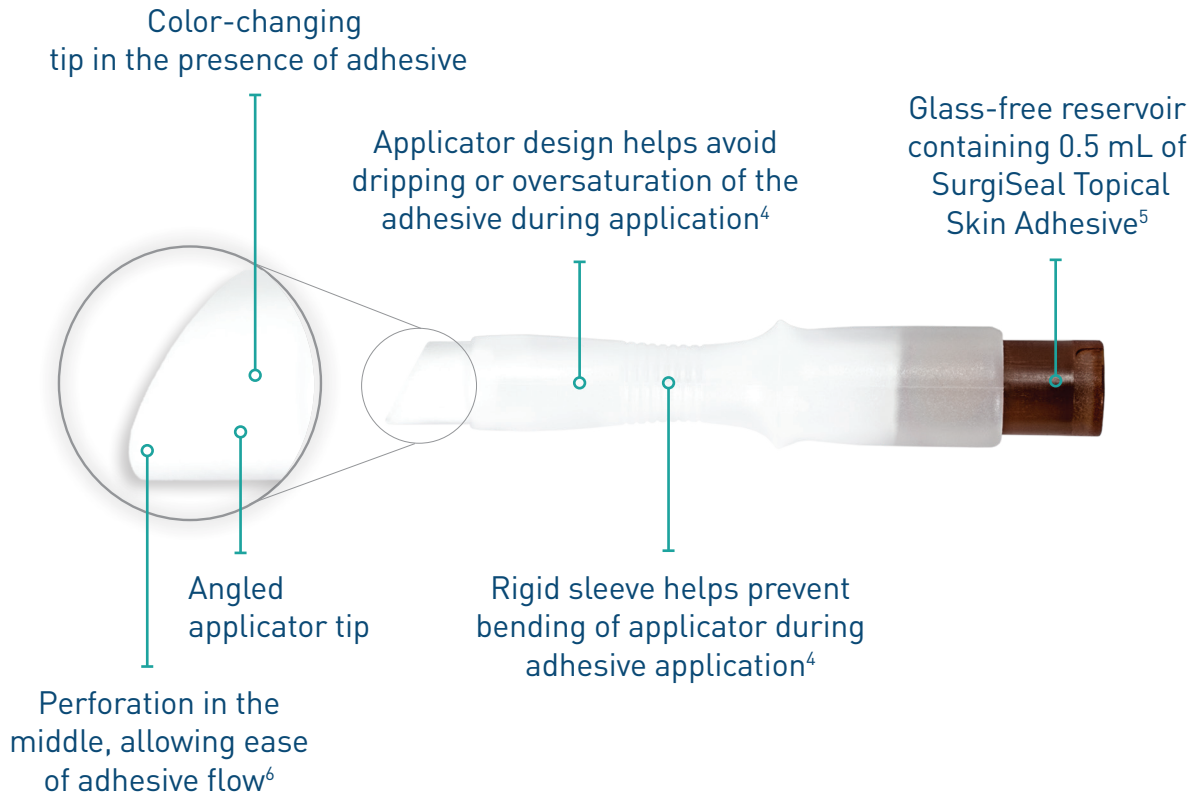
Use of SURGISEAL topical skin adhesives may result in localized sensitization or irritation reactions. Large, unspread droplets of SURGISEAL topical skin adhesives may cause a sensation of heat or discomfort.

Please see Instructions for Use at the end of this document.

SurgiSeal Stylus[®]

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

SurgiSeal Stylus[®] Topical Skin Adhesive (2-octyl cyanoacrylate) applicator has distinct design characteristics.



A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days^{2,5}

IMPORTANT SAFETY INFORMATION FOR SURGISEAL, SURGISEAL STYLUS, AND SURGISEAL TWIST (CONTINUED)

Instruct patients not to pick at SURGISEAL topical skin adhesives and not to scrub, soak, or otherwise expose the wound site to prolonged wetness.

Monitor and evaluate wounds treated with SURGISEAL topical skin adhesives for signs of infection.

Please see Instructions for Use at the end of this document.

SurgiSeal®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

SurgiSeal Twist®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

SurgiSeal Stylus®
TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



Contact your Pfizer Sales Rep or call
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for pricing or to order SurgiSeal.

References: 1. SURGISEAL Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; March 2016. 2. Singer AJ, Quinn JV, Hollander JE. The cyanoacrylate topical skin adhesives. *Am J Emerg Med.* 2008;26(4):490-496. 3. SURGISEAL Twist Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; March 2016. 4. Zhang S; Adhezion Biomedical. Evaluation of overall function performance of Stylus SURGISEAL. August 18, 2011. Report 2011-ABM-022. 5. SURGISEAL Stylus Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; July 2015. 6. Adhezion Biomedical. SURGISEAL Stylus and Stylus Twist Topical Skin Adhesive abbreviated 510(k); May 2013.

SurgiSeal®, SurgiSeal Stylus®, and SurgiSeal Twist® are registered trademarks of Adhezion Biomedical, LLC.

Please see Important Safety Information on the previous pages.
Please see Instructions for Use at the end of this document.

SurgiSeal®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

English

Español



Manufactured by:
Adhezion Biomedical, LLC
506 Pine Mountain Rd
Hudson, NC 28638 USA

SST-IFU02-1600
(03-2016)



Caution, see instructions for use



Do not reuse



Do not sterilize



Do not use if package is damaged or opened



Keep away from sunlight



Not made with natural rubber latex



30°C, 86°F



STERILE



0.35ml x12

US Patent Nos. 6,667,031; 8,729,121; 8,980,947 and 9,018,254

English

DESCRIPTION

SURGISEAL® Topical Skin Adhesive is a sterile, professional liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. Each applicator consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. This applicator with sponge tip is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes. In vitro studies have shown that SURGISEAL acts as a physical 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 has not been established.

INDICATIONS

SURGISEAL is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of 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 or with dense natural hair.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

WARNINGS

- SURGISEAL topical skin adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of SURGISEAL topical skin adhesive may be accelerated by water or fluids containing alcohol: SURGISEAL topical skin adhesive should not be applied to wet wounds.
- SURGISEAL 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 with a tissue adhesive for topical approximation of skin, position the patient so that any runoff of adhesive is away from the eye.
- The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective at preventing inadvertent flow of adhesive into the eye.
- SURGISEAL topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SURGISEAL adhesive is intended to adhere.
- SURGISEAL topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- SURGISEAL topical skin adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period, or unless skin tension has been removed by application of another wound closure device (e.g., sutures or skin staples) prior to application of SURGISEAL topical skin adhesive.
- SURGISEAL topical skin adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- SURGISEAL topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- SURGISEAL topical skin adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- SURGISEAL should always be applied as a light coating bridging the wound and the aligned approximated wound edges. Avoid pressure on the applicator or wound edge separation, which could cause the topical adhesive to be interposed between wound edges. Topical adhesive between wound edges interfere with wound healing.
- SURGISEAL topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if SURGISEAL 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.
- SURGISEAL topical skin adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize SURGISEAL topical skin adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of SURGISEAL 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 its viscosity and may render the product unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
- SURGISEAL topical skin adhesive should not be applied to decubitus ulcers.
- SURGISEAL topical skin adhesive should be used only on wounds that have been thoroughly cleaned debrided and have easily apposed wound edges.
- Application and/or migration (leak) of either version of the product below the surface of the skin will impair the healing process by forming a barrier between tissue edges. Potential systemic toxicity of this product is unknown.
- If Chlorhexidine gluconate (CHG) is used preoperatively on the affected area, it must be completely dry before applying SURGISEAL adhesive. The adhesive may not cure properly and prematurely flake if the adhesive is applied before the Chlorhexidine gluconate is completely dry¹.

PRECAUTIONS

- Tissue adhesives for the topical approximation of skin should also not be used on wounds that are: wet, dirty, complex, not easily approximated, under dynamic stress (e.g. knuckles or elbows), non-acute, poorly perfused, located in areas where device run-off into unintended sites cannot be prevented.
- Tissue adhesives intended for the topical approximation of skin should not be used in the presence of infection, ongoing bleeding, incomplete debridement and on mucosal or hair covered surfaces.
- This product should not be ingested, applied internally, or injected intravascularly.
- DO NOT apply liquid or ointment medications to the wound after closure with SURGISEAL, as these substances weaken the polymerized film and allow for wound dehiscence.
- SURGISEAL topical skin adhesive permeability by topical medications has not been studied.
- If mistaken placement of SURGISEAL should occur then removal may be accomplished by using either acetone or petroleum jelly. Typical cleaners such as soap do not work well. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
- SURGISEAL topical skin adhesive as a liquid, is viscous. To prevent inadvertent flow of liquid SURGISEAL topical skin adhesive to unintended areas: (1) the wound should be held in a horizontal position, with SURGISEAL topical skin adhesive applied from above, and (2) SURGISEAL topical skin adhesive should be applied in one thick, continuous layer or two thin layers rather than in a few large droplets.
- SURGISEAL topical skin adhesive should be used immediately after breaking along the perforated opening as the liquid adhesive will not flow freely from the applicator sponge tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, Chlorhexidine gluconate (CHG), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of SURGISEAL topical skin adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness of SURGISEAL topical skin adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness on wounds that have been treated with SURGISEAL topical skin adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Vermillion surfaces have not been tested for effectiveness and safety.

ADVERSE REACTIONS

- Adverse reactions may occur if adhesive makes contact with the eye.
- Adverse reactions may occur to patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- SURGISEAL topical skin adhesive should always be applied in one thick, continuous layer or two thin layers so that large amounts of liquid are not allowed to collect, resulting in thermal discomfort for the patient.

SurgiSeal®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



1. Fold over the SURGISEAL® applicator at the sponge. You will hear a snap.



2. Hold with the sponge facing downward. No squeezing is necessary in normal application. If you require greater flow, you may very gently squeeze.



3. Hold the wound together & apply in either one thick layer or two thin layers. If two thin layers applied, allow 30 seconds dry time in between layers.

DIRECTIONS FOR USE

- Before the use of SURGISEAL the wound must be thoroughly cleaned.
 - Use normal surgical protocol for wound preparation before treatment of SURGISEAL topical skin adhesive and be certain to suture deep subcutaneous layers.
 - Dry the injured area with sterile gauze, removing all moisture for proper tissue bonding of SURGISEAL to the skin.
 - To prevent inadvertent flow of SURGISEAL topical skin adhesive to unintended areas of the body, the wound should be held in a horizontal position and the SURGISEAL topical skin adhesive should be applied from above the wound.
 - Remove the applicator from the blister pouch. Hold the applicator with the thumb and forefinger away from patient to prevent any unintentional placement of the liquid SURGISEAL topical skin adhesive into the wound or on the patient.
 - While holding the applicator, and with the applicator sponge facing upward, snap at tip along the perforated line and fold over.
 - Gently squeeze the liquid SURGISEAL adhesive from the applicator bubble while saturating the sponge.
 - Approximate the wound edges together using either gloved fingers or sterile forceps.
 - Slowly apply the liquid SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers. If two thin layers are applied, allow 30 seconds dry time in between layers.
 - Maintain manual approximation of the opposed wound edges together for approximately 60 seconds once the final coat of SURGISEAL is applied.
- NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing SURGISEAL topical skin adhesive into the wound. SURGISEAL topical skin adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.
- NOTE: Full apposition strength is expected to be achieved about 1.0 minute after the final layer is applied. Full polymerization is expected when the top SURGISEAL topical skin adhesive layer is no longer tacky.
- Protective dry dressings, such as gauze, may be applied only after SURGISEAL topical skin adhesive film is completely solid/polymerized and not tacky to the touch (approximately five minutes after application). Allow the top layer to fully polymerize before applying a bandage. If a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film. The film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur.
 - Patients should be instructed to not pick at the polymerized film of SURGISEAL topical skin adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.
 - Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
 - Patients should be instructed that until the polymerized film of SURGISEAL topical skin adhesive has sloughed naturally (usually in 5-10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.
 - If removal of SURGISEAL topical skin adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the SURGISEAL topical skin adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.
 - Once the surface is tack-free, full polymerization has generally occurred.

HOW SUPPLIED

SURGISEAL is a sterile, easy to use, single-dose applicator, packaged in a thermal formed blister pouch. The applicators are packaged in a box that fits precisely on the skin shelf. The applicator has a perforation in the middle allowing for ease of application. The applicator contains a topical skin adhesive. Supplied: 1 box of 12 applicators/0.35ml adhesive.

STORAGE

Recommended storage conditions are at or below 30°C (86 °F) away from moisture, direct heat and direct light. DO NOT use after expiration date.

STERILITY

SURGISEAL topical skin adhesive is sterilized by ethylene oxide to reduce Bioburden. SURGISEAL adhesive is then terminally sterilized by irradiation. STERILE SINGLE USE ONLY

CAUTIONS

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

¹ Adhezion Biomedical, LLC Data on File.

REFERENCES

- Bernard, L., et al., A prospective comparison of octyl cyanoacrylate tissue adhesive and suture for the closure of excisional wounds in children and adolescents Arch Dermatol, 2001. 137 (9): s. 1177-80.
- Penoff, J., Skin closures using cyanoacrylate tissue adhesives Plastic Surgery Educational Foundation DATA Committee. Device och Technique Assessment, Plast Reconstr Surg, 1999. 103(2): s. 730-1.
- Singer, A.J. och H.C. Thode, Jr., A review of the literature on octylcyanoacrylate adhesive. Am J Surg, 2004. 187(2): s. 238-48.
- Narang, U., et al., In-vitro analysis for microbial barrier properties of 2-octyl cyanoacrylate-derived wound treatment films J Cutan Med Surg, 2003. 7 (1): s. 13-9.

SurgiSeal Stylus®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

EN English

DESCRIPTION

SURGISEAL Stylus® Topical Skin Adhesive is a sterile, professional liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. The applicator is comprised of a plastic button contained within a plastic vial with an attached applicator tip. This Stylus applicator is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes. In vitro studies have shown that SURGISEAL acts as a physical 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 has not been established.

INDICATIONS

SURGISEAL is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of 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 or with dense natural hair.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

WARNINGS

- SURGISEAL topical skin adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of SURGISEAL topical skin adhesive may be accelerated by water or fluids containing alcohol: SURGISEAL topical skin adhesive should not be applied to wet wounds.
- SURGISEAL 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 with a tissue adhesive for topical approximation of skin, position the patient so that any runoff of adhesive is away from the eye.
- The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective at preventing inadvertent flow of adhesive into the eye.
- SURGISEAL topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SURGISEAL adhesive is intended to adhere.
- SURGISEAL topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- SURGISEAL topical skin adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period, or unless skin tension has been removed by application of another wound closure device (e.g., sutures or skin staples) prior to application of SURGISEAL topical skin adhesive.
- SURGISEAL topical skin adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- SURGISEAL topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- SURGISEAL topical skin adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- SURGISEAL should always be applied as a light coating bridging the wound and the aligned approximated wound edges. Avoid pressure on the applicator or wound edge separation, which could cause the topical adhesive to be interposed between wound edges. Topical adhesive between wound edges interfere with wound healing.
- SURGISEAL topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if SURGISEAL 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.
- SURGISEAL topical skin adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize SURGISEAL topical skin adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of SURGISEAL 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 its viscosity and may render the product unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
- SURGISEAL topical skin adhesive should not be applied to decubitus ulcers.
- SURGISEAL topical skin adhesive should be used only on wounds that have been thoroughly cleaned debrided and have easily apposed wound edges.
- Application and/or migration (leak) of either version of the product below the surface of the skin will impair the healing process by forming a barrier between tissue edges. Potential systemic toxicity of this product is unknown.
- If Chlorhexidine gluconate (CHG) is used preoperatively on the affected area, it must be completely dry before applying SURGISEAL adhesive. The adhesive may not cure properly and prematurely flake if the adhesive is applied before the Chlorhexidine gluconate is completely dry¹.

PRECAUTIONS

- Tissue adhesives for the topical approximation of skin should also not be used on wounds that are: wet, dirty, complex, not easily approximated, under dynamic stress (e.g. knuckles or elbows), non-acute, poorly perfused, located in areas where device run-off into unintended sites cannot be prevented.
- Tissue adhesives intended for the topical approximation of skin should not be used in the presence of infection, ongoing bleeding, incomplete debridement and on mucosal or hair covered surfaces.
- This product should not be ingested, applied internally, or injected intravascularly.
- DO NOT apply liquid or ointment medications or other substances to the wound after closure with SURGISEAL, as these substances weaken the polymerized film and allow for wound dehiscence.
- SURGISEAL topical skin adhesive permeability by topical medications has not been studied.
- If mistaken placement of SURGISEAL should occur then removal may be accomplished by using either acetone or petroleum jelly. Typical cleaners such as soap do not work well. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
- SURGISEAL topical skin adhesive as a liquid, is viscous. To prevent inadvertent flow of liquid SURGISEAL topical skin adhesive to unintended areas: (1) the wound should be held in a horizontal position, with SURGISEAL topical skin adhesive applied from above, and (2) SURGISEAL topical skin adhesive should be applied in one thick, continuous layer or two thin layers rather than in a few large droplets.
- SURGISEAL topical skin adhesive should be used immediately after breaking along the perforated opening as the liquid adhesive will not flow freely from the applicator sponge tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, Chlorhexidine gluconate (CHG), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of SURGISEAL topical skin adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness of SURGISEAL topical skin adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness on wounds that have been treated with SURGISEAL topical skin adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Vermillion surfaces have not been tested for effectiveness and safety.

ADVERSE REACTIONS

- Adverse reactions may occur if adhesive makes contact with the eye.
- Adverse reactions may occur to patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- SURGISEAL topical skin adhesive should always be applied in one thick, continuous layer or two thin layers so that large amounts of liquid are not allowed to collect, resulting in thermal discomfort for the patient.



Manufactured by:
Adhezion Biomedical, LLC
506 Pine Mountain Rd
Hudson, NC 28638 USA

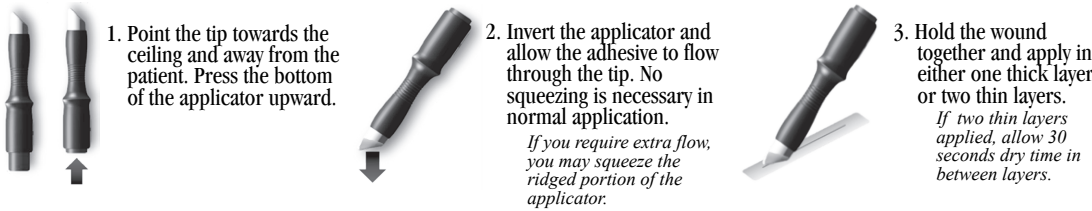
SSS-IFU02-15IR
(07-2015)



US Patent Nos. 6,667,031; 8,729,121;
8,550,737 and D641,469

SurgiSeal Stylus®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



DIRECTIONS FOR USE

- Before the use of SURGISEAL the wound must be thoroughly cleaned.
 - Use normal surgical protocol for wound preparation before treatment of SURGISEAL topical skin adhesive and be certain to suture deep subcutaneous layers.
 - Dry the injured area with sterile gauze, removing all moisture for proper tissue bonding of SURGISEAL to the skin.
 - To prevent inadvertent flow of SURGISEAL topical skin adhesive to unintended areas of the body, the wound should be held in a horizontal position and the SURGISEAL topical skin adhesive should be applied from above the wound.
 - Remove the Stylus applicator from the blister pouch. Hold the applicator with the thumb and forefinger away from patient to prevent any unintentional placement of the liquid SURGISEAL topical skin adhesive into the wound or on the patient.
 - While holding the Stylus applicator towards the ceiling and away from the patient, press the bottom of the applicator upward.
 - Invert the applicator and allow the adhesive formula to flow through the tip. No squeezing is necessary in normal application. If greater flow is required, the ridged portion of the applicator may be very gently squeezed.
 - Approximate the wound edges together using either gloved fingers or sterile forceps.
 - Slowly apply the liquid SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers. If two thin layers are applied, allow 30 seconds dry time in between layers.
 - Maintain manual approximation of the opposed wound edges together for approximately 60 seconds once the final coat of SURGISEAL is applied.
- NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing SURGISEAL topical skin adhesive into the wound. SURGISEAL topical skin adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.
- NOTE: Full apposition strength is expected to be achieved about 1.0 minute after the final layer is applied. Full polymerization is expected when the top SURGISEAL topical skin adhesive layer is no longer tacky.
- Protective dry dressings, such as gauze, may be applied only after SURGISEAL topical skin adhesive film is completely solid/polymerized and not tacky to the touch (approximately five minutes after application). Allow the top layer to fully polymerize before applying a bandage. If a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film. The film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur.
 - Patients should be instructed to not pick at the polymerized film of SURGISEAL topical skin adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.
 - Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
 - Patients should be instructed that until the polymerized film of SURGISEAL topical skin adhesive has sloughed naturally (usually in 5-10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.
 - If removal of SURGISEAL topical skin adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the SURGISEAL topical skin adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.
 - Once the surface is tack-free, full polymerization has generally occurred.

HOW SUPPLIED

SURGISEAL is a sterile, easy to use, single-dose Stylus applicator, packaged in a thermal formed blister pouch. The applicators are packaged in a box that fits precisely on the skin shelf. The Stylus applicator has a button on the top that is depressed for ease of application. The applicator contains a topical skin adhesive. Supplied: 1 box of 12 applicators/0.50ml adhesive.

STORAGE

Recommended storage conditions are at or below 30°C, 86 °F, away from moisture, direct heat and direct light. DO NOT use after expiration date.

STERILITY

SURGISEAL topical skin adhesive is terminally sterilized by ethylene oxide. SURGISEAL Stylus filled ampoule component is terminally sterilized by irradiation. STERILE SINGLE USE ONLY

CAUTIONS

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

¹ Adhezion Biomedical, LLC Data on File.

REFERENCES

- Bernard, L., et al., A prospective comparison of octyl cyanoacrylate tissue adhesive and suture for the closure of excisional wounds in children and adolescents Arch Dermatol, 2001. 137 (9): s. 1177-80.
- Penoff, J., Skin closures using cyanoacrylate tissue adhesives Plastic Surgery Educational Foundation DATA Committee. Device och Technique Assessment, Plast Reconstr Surg, 1999. 103(2): s. 730-1.
- Singer, A.J. och H.C. Thode, Jr., A review of the literature on octylcyanoacrylate adhesive. Am J Surg, 2004. 187(2): s. 238-48.
- Narang, U., et al., In-vitro analysis for microbial barrier properties of 2-octyl cyanoacrylate-derived wound treatment films J Cutan Med Surg, 2003. 7 (1): s. 13-9.

SurgiSeal Stylus®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

ES Español

DESCRIPCIÓN

El adhesivo tópico para la piel SURGISEAL Stylus® es un adhesivo líquido estéril y profesional, que contiene una formulación monomérica (2-octil cianoacrilato) y el pigmento D & C Violeta n.º 2. El aplicador consta de un botón de plástico contenido en un vial de plástico que lleva unida una punta aplicadora. Esta aplicador Stylus se incluye en una bolsa Tyvek externa. Al aplicar SURGISEAL en la piel, la polimerización se produce en minutos. Estudios in vitro han mostrado que SURGISEAL actúa como una barrera física frente a la penetración microbiana, en tanto que la película adhesiva permanezca intacta. No se han realizado estudios clínicos para demostrar las propiedades de barrera antimicrobiana y no se ha establecido una correlación entre las propiedades de barrera antimicrobiana y una reducción de las infecciones.

INDICACIONES

SURGISEAL está indicado para aplicaciones tópicas únicamente con el fin de mantener cerrados los extremos próximos de la piel en heridas provocadas por incisiones quirúrgicas, incluidas punciones de cirugías mínimamente invasivas y laceraciones simples y completamente limpias causadas por traumatismos. SURGISEAL se puede utilizar junto con suturas dérmicas profundas, pero no como sustituto de las mismas.

CONTRAINDICACIONES

- NO utilizar en heridas que presenten pruebas de infecciones de microbios, bacterias u hongos, o en caso de gangrena.
- NO utilizar en superficies mucosas, en ninguna de las uniones mucocutáneas o en la piel que pueda estar expuesta con regularidad a fluidos corporales o que tenga pelo natural abundante.
- NO utilice en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehído.

ADVERTENCIAS

- El adhesivo tópico para la piel SURGISEAL es un adhesivo que actúa rápidamente, capaz de adherirse a la mayoría de tejidos corporales y a muchos otros materiales como, por ejemplo, guantes de látex y acero inoxidable. Se debe evitar el contacto involuntario con cualquier tejido corporal y con superficies o equipos que no sean desechables o que no se puedan limpiar fácilmente con un disolvente como la acetona.
- La polimerización del adhesivo tópico para la piel SURGISEAL se puede acelerar mediante agua o fluidos que contengan alcohol: el adhesivo tópico para la piel SURGISEAL no debe aplicarse en heridas húmedas.
- El adhesivo tópico para la piel SURGISEAL no debe aplicarse en los ojos. Si entra en contacto con los ojos, enjuáguelos abundantemente con solución salina o con agua. Si quedan restos de adhesivo, aplique pomada ocular para que ayude a rebajar la adherencia y póngase en contacto con un oftalmólogo.
- Cuando cierre heridas faciales próximas a un ojo con un adhesivo de tejidos para aproximación tópica de la piel, sitúe al paciente de forma que si se escurre algo del adhesivo, éste quede alejado del ojo.
- El ojo debe estar cerrado y protegido con gasa. La aplicación profiláctica de vaselina alrededor del ojo, para que actúe como barrera o contención mecánica, puede ser eficaz para evitar el flujo accidental de adhesivo hacia el ojo.
- El adhesivo tópico para la piel SURGISEAL no se adherirá a la piel que se haya cubierto previamente con vaselina. Por tanto, evite utilizar vaselina en zonas de la piel en las que desee que el adhesivo SURGISEAL se adhiera.
- El adhesivo tópico para la piel SURGISEAL no es absorbible, por tanto, no debe utilizarse bajo la piel, ya que podría provocar una reacción corporal ante un cuerpo extraño.
- El adhesivo tópico para la piel SURGISEAL no debe utilizarse sobre zonas de la piel de mucha tensión, ni en zonas donde la tensión aumente, como nudillos, codos o rodillas, a menos que se inmovilice la articulación durante el período de curación de la piel o que se haya eliminado la tensión de la piel mediante otro dispositivo para el cierre de heridas (por ejemplo, suturas o grapas) antes de la aplicación del adhesivo tópico para la piel SURGISEAL.
- Las heridas tratadas con adhesivo tópico para la piel SURGISEAL se deben controlar por si aparecen signos de infección. Las heridas que presenten signos de infección como, por ejemplo, eritema, edema, calor, dolor y pus se deben evaluar y tratar según la práctica estándar para infecciones.
- El adhesivo tópico para la piel SURGISEAL no debe utilizarse en lugares de la herida que van a estar sometidos a humedad o fricción repetida y prolongada.
- El adhesivo tópico para la piel SURGISEAL solo debe utilizarse después de que las heridas se hayan limpiado, desbridado y cerrado de otro modo según la práctica quirúrgica estándar. Cuando sea necesario, se debe utilizar anestesia local para garantizar una limpieza y desbridamiento adecuados.
- SURGISEAL siempre debe aplicarse en forma de una ligera capa que sirva de puente entre la herida y los extremos próximos alineados de la herida. Evite ejercer presión sobre el aplicador o sobre la separación del extremo de la herida, ya que podría provocar que el adhesivo tópico se interponga entre los extremos de la herida. El adhesivo tópico entre los extremos de la herida interfiere con la curación de la herida.
- El adhesivo tópico para la piel SURGISEAL se polimeriza a través de una reacción exotérmica en la que se libera una pequeña cantidad de calor. Utilizando la técnica apropiada de aplicación del adhesivo tópico para la piel SURGISEAL en una capa gruesa continua, o dos capas finas, sobre una herida seca y dejando un tiempo para la polimerización entre aplicaciones, se libera calor lentamente y se minimiza la sensación de calor o dolor que experimenta el paciente. No obstante, si el adhesivo tópico para la piel SURGISEAL se aplica de tal forma que permita la acumulación de una gran cantidad de gotas de líquido, el paciente puede experimentar una sensación de calor o malestar.
- El adhesivo tópico para la piel SURGISEAL se presenta en paquetes para uso de un solo paciente. Deseche el material abierto restante después de cada proceso de cierre de heridas.
- No reesterilice el adhesivo tópico para la piel SURGISEAL en un paquete/bandeja de procedimiento que deba esterilizarse antes del uso. Se sabe que la exposición del adhesivo tópico para la piel SURGISEAL, después de su fabricación final, a calor excesivo (como la esterilización en autoclaves o con óxido de etileno) o a radiación (como haz de electrones o rayos gamma) aumenta la viscosidad del mismo y puede dejar el producto inservible. El uso del adhesivo de tejidos puede provocar sensibilización localizada o reacciones de irritación.
- El adhesivo tópico para la piel SURGISEAL no debe aplicarse en úlceras de decúbito.
- El adhesivo tópico para la piel SURGISEAL solo debe utilizarse en heridas que se hayan limpiado y desbridado a fondo, y que tengan los extremos de la herida apuestos con facilidad.
- La aplicación y/o migración (fuga) de cualquiera de las versiones del producto bajo la superficie de la piel perjudicará el proceso de curación al formar una barrera entre los extremos del tejido. Se desconoce la posible toxicidad sistémica de este producto.
- Si se emplea gluconato de clorhexidina (CHG) preoperativamente sobre la zona afectada, debe estar completamente seca antes de aplicar el adhesivo SURGISEAL. Es posible que el adhesivo no cure debidamente y se desprenda de forma prematura si se aplica antes de que la gluconato de clorhexidina esté completamente seca¹.

PRECAUCIONES

- Los adhesivos de tejidos para la aproximación tópica de la piel tampoco deben usarse en heridas: húmedas, sucias, complejas, de aproximación difícil, sometidas a esfuerzo dinámico (p. ej., en nudillos o codos), no agudas, deficientemente perfundidas, localizadas en zonas donde el escurrimiento del producto hacia partes no previstas no se pueda evitar.
- Asimismo, los adhesivos de tejidos para la aproximación tópica de la piel no deben usarse en presencia de infección, si el sangrado continúa, en casos de desbridamiento incompleto o en superficies cubiertas por mucosas o vello.
- Este producto no debe ingerirse, aplicarse internamente ni inyectarse intravascularmente.
- NO aplique medicamentos líquidos ni pomadas, ni ninguna otra sustancia, en la herida después de cerrarla con SURGISEAL, ya que dichas sustancias debilitan la película polimerizada y provocan la dehiscencia de la herida.
- No se ha estudiado la permeabilidad del adhesivo tópico para la piel SURGISEAL mediante medicamentos tópicos.
- Si SURGISEAL se aplica en un lugar equivocado, puede retirarse utilizando acetona o vaselina. Los productos de higiene habituales, como el jabón, no sirven para este fin. Sin embargo, con vaselina o acetona podrá retirar inmediatamente el adhesivo de la piel.
- El adhesivo tópico para la piel SURGISEAL es un líquido viscoso. Para evitar el derramamiento accidental del líquido SURGISEAL adhesivo cutáneo tópico en zonas no deseadas: (1) se debe mantener la herida en posición horizontal y aplicar el adhesivo tópico para la piel SURGISEAL desde arriba y (2) aplicar el adhesivo SURGISEAL en una capa gruesa continua, o dos capas finas, y no en gotas grandes.
- El adhesivo tópico para la piel SURGISEAL se debe utilizar inmediatamente después de abrirlo a lo largo de la abertura perforada, ya que el adhesivo líquido no fluirá copiosamente de la punta de esponja del aplicador después de transcurridos unos cuantos minutos.
- Si se produce adherencia no deseada en piel intacta, despéguela pero no separe la piel. La vaselina o la acetona pueden ayudar a reducir la adherencia. No es de esperar que otros agentes como agua, solución salina, Betadine® Antibiotics, gluconato de clorhexidina (CHG), o jabón rebajen la adherencia inmediatamente.
- No se ha estudiado la seguridad ni la eficacia del adhesivo tópico para la piel SURGISEAL en heridas de pacientes con enfermedad vascular periférica, con diabetes mellitus dependientes de insulina, con afecciones de coagulación sanguínea, con historial personal o familiar de formación de queloides o hipertrofia o con laceraciones estrelladas reventadas.
- No se ha estudiado la seguridad ni la eficacia del adhesivo tópico para la piel SURGISEAL para las siguientes heridas: mordeduras de animales o de personas, heridas con arma blanca o punciones.
- No se ha estudiado la seguridad ni la eficacia en heridas que han sido tratadas con adhesivo tópico para la piel SURGISEAL y luego se han expuesto durante períodos prolongados a la luz solar directa o a lámparas de bronceado.
- No se ha comprobado la seguridad ni la eficacia sobre superficies rojo bermellón.



Manufactured by:
Adhezion Biomedical, LLC
506 Pine Mountain Rd
Hudson, NC 28638 USA

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(07-2015)



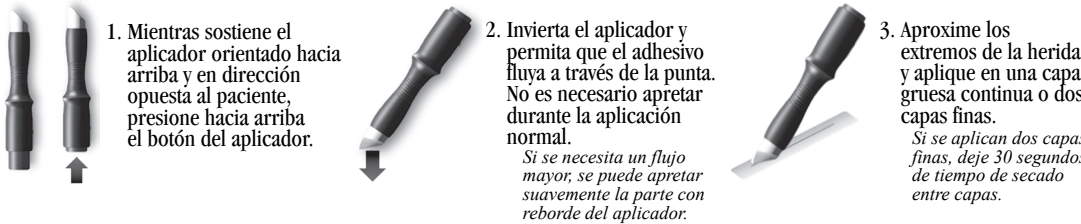
US Patent Nos. 6,667,031; 8,729,121;
8,550,737 and D641,469

REACCIONES ADVERSAS

- Se pueden producir reacciones adversas si el adhesivo entra en contacto con el ojo.
- Se pueden producir reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehído.
- El adhesivo tópico para la piel SURGISEAL siempre se debe aplicar en una capa gruesa continua, o dos capas finas para que no se acumulen grandes cantidades de líquido, lo que provocaría malestar térmico al paciente.

SurgiSeal Stylus®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



MODO DE EMPLEO

1. Antes de utilizar SURGISEAL, la herida debe limpiarse completamente.
2. Lleve a cabo el protocolo quirúrgico habitual para la preparación de la herida antes del tratamiento con el adhesivo tópico para la piel SURGISEAL y asegúrese de suturar las capas subcutáneas profundas.
3. Seque la zona herida con gasa esterilizada, eliminando toda la humedad para permitir la adherencia apropiada del tejido a la piel mediante SURGISEAL.
4. Para evitar el derrame involuntario del adhesivo tópico para la piel SURGISEAL en zonas no deseadas del cuerpo, se debe mantener la herida en posición horizontal y SURGISEAL se debe aplicar desde por encima de la herida.
5. Saque el aplicador Stylus de la bolsa alveolada. Mantenga el aplicador con el dedo pulgar y el índice alejado del paciente para evitar cualquier aplicación involuntaria del adhesivo líquido tópico para la piel SURGISEAL dentro de la herida o sobre el paciente.
6. Mientras sostiene el aplicador Stylus orientado hacia arriba y en dirección opuesta al paciente, presione hacia arriba el botón del aplicador.
7. Invierta el aplicador y permita que el adhesivo fluya a través de la punta. No es necesario apretar durante la aplicación normal. Si se necesita un flujo mayor, se puede apretar suavemente la parte con reborde del aplicador.
8. Aproxime los extremos de la herida utilizando guantes o un fórceps estéril.
9. Aplique lentamente el líquido adhesivo tópico para la piel SURGISEAL en una capa gruesa continua o dos capas finas. Si se aplican dos capas finas, deje 30 segundos de tiempo de secado entre capas.
10. Mantenga la aproximación de los extremos opuestos de la herida de manera manual durante unos 60 segundos una vez que haya aplicado la capa final de SURGISEAL. NOTA: una presión excesiva de la punta del aplicador contra los extremos de la herida o de la piel circundante puede forzar la separación de los extremos de la herida y permitir que el adhesivo tópico para la piel SURGISEAL penetre en la herida. La penetración en la herida del adhesivo tópico para la piel SURGISEAL puede retrasar la curación de la herida y/o provocar un resultado cosmético adverso.
11. Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tópico para la piel SURGISEAL esté completamente sólida/polimerizada: que no esté pegajosa al tocarla (aproximadamente cinco minutos después de la aplicación). Deje que la capa superior se polimerice completamente antes de poner una venda. Si un apósito, vendaje, cinta o refuerzo adhesivo se aplica antes de la polimerización completa, el apósito puede adherirse a la película. La película puede separarse de la piel al retirar el apósito, provocando su dehiscencia.
12. Se les debe indicar a los pacientes que no toquen la película polimerizada del adhesivo tópico para la piel SURGISEAL. Si lo hacen, la película puede perder adhesión a la piel, provocándose la dehiscencia de la herida. Puede prevenirse que se toque la película cubriéndola con un apósito.
13. Aplique un apósito seco de protección para niños u otros pacientes que no sean capaces de seguir las recomendaciones para el cuidado apropiado de la herida.
14. A los pacientes se les debe indicar que solo se podrá humedecer ligeramente el lugar del tratamiento, hasta que la película polimerizada del adhesivo tópico para la piel SURGISEAL se haya asentado con naturalidad (generalmente entre 5 y 10 días). Los pacientes pueden duchar y bañar la zona con suavidad. La zona no debe restregarse, mojarse o exponerse a humedad prolongada hasta que la película se haya asentado con naturalidad y la herida esté cerrada y curada. A los pacientes se les debe informar que no pueden nadar durante este período.
15. Si por algún motivo es necesario retirar el adhesivo tópico para la piel SURGISEAL, aplique suavemente vaselina o acetona en la película de adhesivo tópico para la piel SURGISEAL para reducir la adherencia. Despegue la película, pero no separe la piel.
16. Generalmente, una vez que la superficie esté completamente libre del adhesivo, ya se ha producido la polimerización completa.

CÓMO SE SUMINISTRA

SURGISEAL Stylus® es un aplicador monodosis, estéril y fácil de usar, que se presenta en una bolsa alveolada termoformada. Los aplicadores se presentan en una caja que cabe exactamente en el estante destinado al instrumental quirúrgico. El aplicador Stylus tiene un botón que se presiona en la parte superior, lo que permite una aplicación sencilla. El aplicador contiene un adhesivo tópico para la piel. Suministrada: 1 caja de 12 aplicadores/0,50 ml de adhesivo.

ALMACENAMIENTO

Se recomienda almacenarlo en unas condiciones igual o inferior de 30 °C, alejado de la humedad y del calor y la luz directos. NO utilice después de la fecha de caducidad.

ESTERILIDAD

El adhesivo tópico para la piel SURGISEAL está esterilizado en forma terminal con óxido de etileno. SURGISEAL Stylus® componente ampolla llena se esteriliza por irradiación terminal.

SOLO PARA UN USO ÚNICO, ESTÉRIL

PRECAUCIONES

Las leyes federales de EE. UU. restringen la venta de este dispositivo por parte de un médico o por orden facultativa.

¹ Adhezion Biomedical, LLC Data on File.

REFERENCIAS:

1. Bernard, L., et al., A prospective comparison of octyl cyanoacrylate tissue adhesive and suture for the closure of excisional wounds in children and adolescents. Arch Dermatol, 2001. 137 (9):p 1177-80.
2. Penoff, J., Skin closures using cyanoacrylate tissue adhesives. Plastic Surgery Educational Foundation DATA Committee. Device and Technique Assessment, Plast Reconstr Surg. 1999. 103(2): p. 730-1
3. Singer, A.J. y H.C. Thode, Jr., A review of the literature on octylcyanoacrylate tissue adhesive. Am J Surg, 2004. 187(2):p. 238-48
4. Narang, U., et al., In-vitro analysis for microbial barrier properties of 2-octyl cyanoacrylate-derived wound tretment films. J Cutan Med Surg. 2003. 7 (1): p 13-9.

SurgiSeal *Twist*®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

EN English

DESCRIPTION
SURGISEAL Twist® Topical Skin Adhesive is a sterile, professional liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. The applicator is comprised of a plastic ampoule, which houses the adhesive, contained within the longer plastic sleeve with an attached applicator tip. This Twist applicator is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes. In vitro studies have shown that SURGISEAL acts as a physical 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 has not been established.

INDICATIONS
SURGISEAL is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of 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 or with dense natural hair.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

WARNINGS

- SURGISEAL topical skin adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of SURGISEAL topical skin adhesive may be accelerated by water or fluids containing alcohol: SURGISEAL topical skin adhesive should not be applied to wet wounds.
- SURGISEAL 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 with a tissue adhesive for topical approximation of skin, position the patient so that any runoff of adhesive is away from the eye.
- The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective at preventing inadvertent flow of adhesive into the eye.
- SURGISEAL topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SURGISEAL adhesive is intended to adhere.
- SURGISEAL topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- SURGISEAL topical skin adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period, or unless skin tension has been removed by application of another wound closure device (e.g., sutures or skin staples) prior to application of SURGISEAL topical skin adhesive.
- SURGISEAL topical skin adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- SURGISEAL topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- SURGISEAL topical skin adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- SURGISEAL should always be applied as a light coating bridging the wound and the aligned approximated wound edges. Avoid pressure on the applicator or wound edge separation, which could cause the topical adhesive to be interposed between wound edges. Topical adhesive between wound edges interfere with wound healing.
- SURGISEAL topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if SURGISEAL 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.
- SURGISEAL topical skin adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize SURGISEAL topical skin adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of SURGISEAL 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 its viscosity and may render the product unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
- SURGISEAL topical skin adhesive should not be applied to decubitus ulcers.
- SURGISEAL topical skin adhesive should be used only on wounds that have been thoroughly cleaned debrided and have easily apposed wound edges.
- Application and/or migration (leak) of either version of the product below the surface of the skin will impair the healing process by forming a barrier between tissue edges. Potential systemic toxicity of this product is unknown.
- If Chlorhexidine gluconate (CHG) is used preoperatively on the affected area, it must be completely dry before applying SURGISEAL adhesive. The adhesive may not cure properly and prematurely flake if the adhesive is applied before the Chlorhexidine gluconate is completely dry¹.

PRECAUTIONS

- Tissue adhesives for the topical approximation of skin should also not be used on wounds that are: wet, dirty, complex, not easily approximated, under dynamic stress (e.g. knuckles or elbows), non-acute, poorly perfused, located in areas where device run-off into unintended sites cannot be prevented.
- Tissue adhesives intended for the topical approximation of skin should not be used in the presence of infection, ongoing bleeding, incomplete debridement and on mucosal or hair covered surfaces.
- This product should not be ingested, applied internally, or injected intravascularly.
- DO NOT apply liquid or ointment medications or other substances to the wound after closure with SURGISEAL, as these substances weaken the polymerized film and allow for wound dehiscence.
- SURGISEAL topical skin adhesive permeability by topical medications has not been studied.
- If mistaken placement of SURGISEAL should occur then removal may be accomplished by using either acetone or petroleum jelly. Typical cleaners such as soap do not work well. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
- SURGISEAL topical skin adhesive as a liquid, is viscous. To prevent inadvertent flow of liquid SURGISEAL topical skin adhesive to unintended areas: (1) the wound should be held in a horizontal position, with SURGISEAL topical skin adhesive applied from above, and (2) SURGISEAL topical skin adhesive should be applied in one thick, continuous layer or two thin layers rather than in a few large droplets.
- SURGISEAL topical skin adhesive should be used immediately after breaking along the perforated opening as the liquid adhesive will not flow freely from the applicator sponge tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, Chlorhexidine gluconate (CHG), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of SURGISEAL topical skin adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness of SURGISEAL topical skin adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness on wounds that have been treated with SURGISEAL topical skin adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Vermillion surfaces have not been tested for effectiveness and safety.

ADVERSE REACTIONS

- Adverse reactions may occur if adhesive makes contact with the eye.
- Adverse reactions may occur to patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- SURGISEAL topical skin adhesive should always be applied in one thick, continuous layer or two thin layers so that large amounts of liquid are not allowed to collect, resulting in thermal discomfort for the patient.



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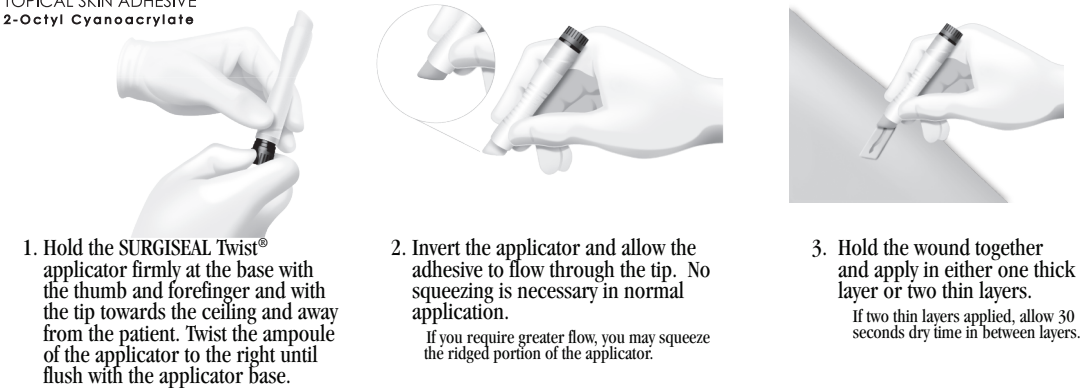
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US Patent Nos. 6,667,031; 8,729,121;
8,980,947; 9,018,254; 9,066,711 and
D663,836

SurgiSeal *Twist*®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



DIRECTIONS FOR USE

1. Before the use of SURGISEAL the wound must be thoroughly cleaned.
2. Use normal surgical protocol for wound preparation before treatment of SURGISEAL topical skin adhesive and be certain to suture deep subcutaneous layers.
3. Dry the injured area with sterile gauze, removing all moisture for proper tissue bonding of SURGISEAL to the skin.
4. To prevent inadvertent flow of SURGISEAL topical skin adhesive to unintended areas of the body, the wound should be held in a horizontal position and the SURGISEAL topical skin adhesive should be applied from above the wound.
5. Remove the SURGISEAL Twist® applicator from the blister pouch. Hold the applicator tip away from patient to prevent any unintentional placement of the liquid SURGISEAL topical skin adhesive into the wound or on the patient.
6. Hold the SURGISEAL Twist® applicator firmly at the base with the thumb and forefinger and with the tip towards the ceiling and away from the patient. Twist the ampoule of the applicator to the right until flush with the applicator base.

NOTE: To decrease tension on the applicator sleeve, DO NOT twist the applicator sleeve but only the ampoule that contains the adhesive formula.

7. Invert the applicator and allow the adhesive formula to flow through the tip. No squeezing is necessary in normal application. If greater flow is required, you may very gently squeeze the ridged portion of the applicator.
8. Approximate the wound edges together using either gloved fingers or sterile forceps.
9. Slowly apply the liquid SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers. If two thin layers are applied, allow 30 seconds dry time in between layers.
10. Maintain manual approximation of the opposed wound edges together for approximately 60 seconds once the final coat of SURGISEAL is applied.

NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing SURGISEAL topical skin adhesive into the wound. SURGISEAL topical skin adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.

NOTE: Full apposition strength is expected to be achieved about 1.0 minute after the final layer is applied. Full polymerization is expected when the top SURGISEAL topical skin adhesive layer is no longer tacky.

11. Protective dry dressings, such as gauze, may be applied only after SURGISEAL topical skin adhesive film is completely solid/polymerized and not tacky to the touch (approximately five minutes after application). Allow the top layer to fully polymerize before applying a bandage. If a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film. The film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur.
12. Patients should be instructed to not pick at the polymerized film of SURGISEAL topical skin adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.
13. Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
14. Patients should be instructed that until the polymerized film of SURGISEAL topical skin adhesive has sloughed naturally (usually in 5-10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.
15. If removal of SURGISEAL topical skin adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the SURGISEAL topical skin adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.
16. Once the surface is tack-free, full polymerization has generally occurred.

HOW SUPPLIED
SURGISEAL Twist® is a sterile, easy to use, single-dose Stylus applicator, packaged in a thermal formed blister pouch. The SURGISEAL Twist® applicator has an ampoule that is twisted for ease of application. The applicator contains a topical skin adhesive. 12 applicators per box. Minimum fill volume is 0.5ml.

STORAGE
Recommended storage conditions are at or below 30°C (86 °F) away from moisture, direct heat and direct light.
DO NOT use after expiration date.

STERILITY
SURGISEAL topical skin adhesive is terminally sterilized by ethylene oxide. SURGISEAL Twist® filled ampoule component is terminally sterilized by irradiation.
STERILE SINGLE USE ONLY

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

¹ Adhezion Biomedical, LLC Data on File.

REFERENCES

1. Bernard, L., et al., A prospective comparison of octyl cyanoacrylate tissue adhesive and suture for the closure of excisional wounds in children and adolescents Arch Dermatol. 2001. 137 (9): s. 1177-80.
2. Penoff, J., Skin closures using cyanoacrylate tissue adhesives Plastic Surgery Educational Foundation DATA Committee. Device och Technique Assessment, Plast Reconstr Surg. 1999. 103(2): s. 730-1.
3. Singer, A.J. och H.C. Thode, Jr., A review of the literature on octylcyanoacrylate adhesive. Am J Surg. 2004. 187(2): s. 238-48.
4. Narang, U., et al., In-vitro analysis for microbial barrier properties of 2-octyl cyanoacrylate-derived wound treatment films J Cutan Med Surg. 2003. 7 (1): s. 13-9.

SurgiSeal *Twist*®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate

ES Español

DESCRIPCIÓN

El adhesivo tóxico para la piel SURGISEAL Twist® es un adhesivo líquido estéril y profesional, que contiene una formulación monomérica (2-octil cianoacrilato) y el pigmento D & C Violeta n.º 2. El aplicador está constituido por una ampolla de plástico, que alberga el adhesivo, contenida en el interior de la funda de plástico más larga con una punta aplicadora. Este aplicador Twist está contenido en una bolsa exterior Tyvek. Al aplicar SURGISEAL en la piel, la polimerización se produce en minutos. Estudios in vitro han mostrado que SURGISEAL actúa como una barrera física frente a la penetración microbiana, en tanto que la película adhesiva permanezca intacta. No se han realizado estudios clínicos para demostrar las propiedades de barrera antimicrobiana y una reducción de las infecciones.

INDICACIONES

SURGISEAL está indicado para aplicaciones tópicas únicamente con el fin de mantener cerrados los extremos próximos de la piel en heridas provocadas por incisiones quirúrgicas, incluidas punciones de cirugías mínimamente invasivas y laceraciones simples y completamente limpias causadas por traumatismos. SURGISEAL se puede utilizar junto con suturas dérmicas profundas, pero no como sustituto de las mismas.

CONTRAINDICACIONES

- NO utilizar en heridas que presenten pruebas de infecciones de microbios, bacterias u hongos, o en caso de gangrena.
- NO utilizar en superficies mucosas, en ninguna de las uniones mucocutáneas o en la piel que pueda estar expuesta con regularidad a fluidos corporales o que tenga pelo natural abundante.
- NO utilice en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehído.

ADVERTENCIAS

- El adhesivo tóxico para la piel SURGISEAL es un adhesivo que actúa rápidamente, capaz de adherirse a la mayoría de tejidos corporales y a muchos otros materiales como, por ejemplo, guantes de látex y acero inoxidable. Se debe evitar el contacto involuntario con cualquier tejido corporal y con superficies o equipos que no sean desechables o que no se puedan limpiar fácilmente con un disolvente como la acetona.
- La polimerización del adhesivo tóxico para la piel SURGISEAL se puede acelerar mediante agua o fluidos que contengan alcohol: el adhesivo tóxico para la piel SURGISEAL no debe aplicarse en heridas húmedas.
- El adhesivo tóxico para la piel SURGISEAL no debe aplicarse en los ojos. Si entra en contacto con los ojos, enjuáguelos abundantemente con solución salina o con agua. Si quedan restos de adhesivo, aplique pomada ocular para que ayude a rebajar la adherencia y póngase en contacto con un oftalmólogo.
- Quando cierre heridas faciales próximas a un ojo con un adhesivo de tejidos para aproximación tópica de la piel, sitúe al paciente de forma que si se escurre algo del adhesivo, éste quede alejado del ojo.
- El ojo debe estar cerrado y protegido con gasa. La aplicación profiláctica de vaselina alrededor del ojo, para que actúe como barrera o contención mecánica, puede ser eficaz para evitar el flujo accidental de adhesivo hacia el ojo.
- El adhesivo tóxico para la piel SURGISEAL no se adherirá a la piel que se haya cubierto previamente con vaselina. Por tanto, evite utilizar vaselina en zonas de la piel en las que desee que el adhesivo SURGISEAL se adhiera.
- El adhesivo tóxico para la piel SURGISEAL no es absorbible, por tanto, no debe utilizarse bajo la piel, ya que podría provocar una reacción corporal ante un cuerpo extraño.
- El adhesivo tóxico para la piel SURGISEAL no debe utilizarse sobre zonas de la piel de mucha tensión, ni en zonas donde la tensión aumente, como nudillos, codos o rodillas, a menos que se inmovilice la articulación durante el período de curación de la piel o que se haya eliminado la tensión de la piel mediante otro dispositivo para el cierre de heridas (por ejemplo, suturas o grapas) antes de la aplicación del adhesivo tóxico para la piel SURGISEAL.
- Las heridas tratadas con adhesivo tóxico para la piel SURGISEAL se deben controlar por si aparecen signos de infección. Las heridas que presenten signos de infección como, por ejemplo, eritema, edema, calor, dolor y pus se deben evaluar y tratar según la práctica estándar para infecciones.
- El adhesivo tóxico para la piel SURGISEAL no debe utilizarse en lugares de la herida que van a estar sometidos a humedad o fricción repetida y prolongada.
- El adhesivo tóxico para la piel SURGISEAL solo debe utilizarse después de que las heridas se hayan limpiado, desbridado y cerrado de otro modo según la práctica quirúrgica estándar. Cuando sea necesario, se debe utilizar anestesia local para garantizar una limpieza y desbridamiento adecuados.
- SURGISEAL siempre debe aplicarse en forma de una ligera capa que sirva de puente entre la herida y los extremos próximos alineados de la herida. Evite ejercer presión sobre el aplicador o sobre la separación del extremo de la herida, ya que podría provocar que el adhesivo tóxico se interponga entre los extremos de la herida. El adhesivo tóxico entre los extremos de la herida interfiere con la curación de la herida.
- El adhesivo tóxico para la piel SURGISEAL se polimeriza a través de una reacción exotérmica en la que se libera una pequeña cantidad de calor. Utilizando la técnica apropiada de aplicación del adhesivo tóxico para la piel SURGISEAL en una capa gruesa continua, o dos capas finas, sobre una herida seca y dejando un tiempo para la polimerización entre aplicaciones, se libera calor lentamente y se minimiza la sensación de calor o dolor que experimenta el paciente. No obstante, si el adhesivo tóxico para la piel SURGISEAL se aplica de tal forma que permita la acumulación de una gran cantidad de gotas de líquido, el paciente puede experimentar una sensación de calor o malestar.
- El adhesivo tóxico para la piel SURGISEAL se presenta en paquetes para uso de un solo paciente. Deseche el material abierto restante después de cada proceso de cierre de heridas.
- No reesterilice el adhesivo tóxico para la piel SURGISEAL en un paquete/bandeja de procedimiento que deba esterilizarse antes del uso. Se sabe que la exposición del adhesivo tóxico para la piel SURGISEAL, después de su fabricación final, a calor excesivo (como la esterilización en autoclaves o con óxido de etileno) o a radiación (como haz de electrones o rayos gamma) aumenta la viscosidad del mismo y puede dejar el producto inservible. El uso del adhesivo de tejidos puede provocar sensibilización localizada o reacciones de irritación.
- El adhesivo tóxico para la piel SURGISEAL no debe aplicarse en úlceras de decúbito.
- El adhesivo tóxico para la piel SURGISEAL solo debe utilizarse en heridas que se hayan limpiado y desbridado a fondo, y que tengan los extremos de la herida apuestos con facilidad.
- La aplicación y/o migración (fuga) de cualquiera de las versiones del producto bajo la superficie de la piel perjudicará el proceso de curación al formar una barrera entre los extremos del tejido. Se desconoce la posible toxicidad sistémica de este producto.
- Si se emplea gluconato de clorhexidina (CHG) preoperativamente sobre la zona afectada, debe estar completamente seca antes de aplicar el adhesivo SURGISEAL. Es posible que el adhesivo no cure debidamente y se desprenda de forma prematura si se aplica antes de que la gluconato de clorhexidina esté completamente seca¹.

PRECAUCIONES

- Los adhesivos de tejidos para la aproximación tópica de la piel tampoco deben usarse en heridas: húmedas, sucias, complejas, de aproximación difícil, sometidas a esfuerzo dinámico (p. ej., en nudillos o codos), no agudas, deficientemente profundas, localizadas en zonas donde el escurrimiento del producto hacia partes no previstas no se pueda evitar.
- Asimismo, los adhesivos de tejidos para la aproximación tópica de la piel no deben usarse en presencia de infección, si el sangrado continúa, en casos de desbridamiento incompleto o en superficies cubiertas por mucosas o vello.
- Este producto no debe ingerirse, aplicarse internamente ni inyectarse intravascularmente.
- NO aplique medicamentos líquidos ni pomadas, ni ninguna otra sustancia, en la herida después de cerrarla con SURGISEAL, ya que dichas sustancias debilitan la película polimerizada y provocan la dehiscencia de la herida.
- No se ha estudiado la permeabilidad del adhesivo tóxico para la piel SURGISEAL mediante medicamentos tópicos.
- Si SURGISEAL se aplica en un lugar equivocado, puede retirarse utilizando acetona o vaselina. Los productos de higiene habituales, como el jabón, no sirven para este fin. Sin embargo, con vaselina o acetona podrá retirar inmediatamente el adhesivo de la piel.
- El adhesivo tóxico para la piel SURGISEAL es un líquido viscoso. Para evitar el derramamiento accidental del líquido SURGISEAL adhesivo cutáneo tóxico en zonas no deseadas: (1) se debe mantener la herida en posición horizontal y aplicar el adhesivo tóxico para la piel SURGISEAL desde arriba y (2) aplicar el adhesivo SURGISEAL en una capa gruesa continua, o dos capas finas, y no en gotas grandes.
- El adhesivo tóxico para la piel SURGISEAL se debe utilizar inmediatamente después de abrirlo a lo largo de la abertura perforada, ya que el adhesivo líquido no fluirá copiosamente de la punta de esponja del aplicador después de transcurridos unos cuantos minutos.
- Si se produce adherencia no deseada en piel intacta, despéguela pero no separe la piel. La vaselina o la acetona pueden ayudar a reducir la adherencia. No es de esperar que otros agentes como agua, solución salina, Betadine® Antibiotics, gluconato de clorhexidina (CHG), o jabón rebajen la adherencia inmediatamente.
- No se ha estudiado la seguridad ni la eficacia del adhesivo tóxico para la piel SURGISEAL en heridas de pacientes con enfermedad vascular periférica, con diabetes mellitus dependientes de insulina, con afecciones de coagulación sanguínea, con historial personal o familiar de formación de queloides o hipertrofia o con laceraciones estrelladas reventadas.
- No se ha estudiado la seguridad ni la eficacia del adhesivo tóxico para la piel SURGISEAL para las siguientes heridas: mordeduras de animales o de personas, heridas con arma blanca o punciones.
- No se ha estudiado la seguridad ni la eficacia en heridas que han sido tratadas con adhesivo tóxico para la piel SURGISEAL y luego se han expuesto durante períodos prolongados a la luz solar directa o a lámparas de bronceado.
- No se ha comprobado la seguridad ni la eficacia sobre superficies rojo bermellón.



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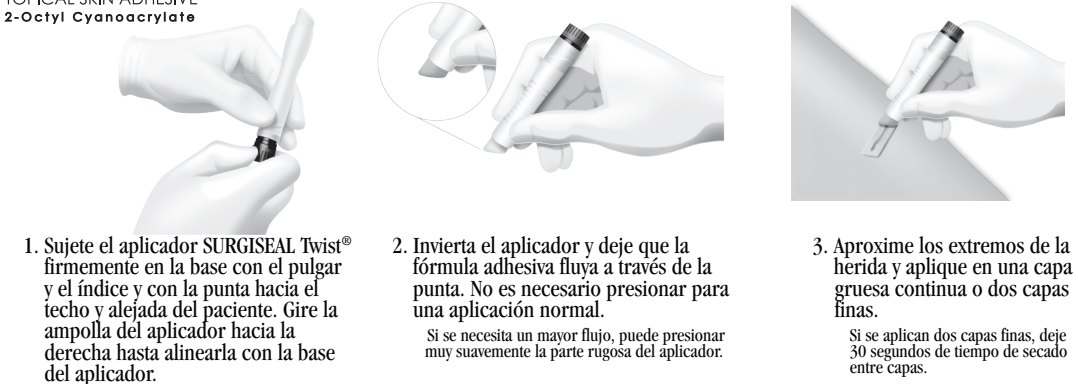
US Patent Nos. 6,667,031; 8,729,121;
8,980,947; 9,018,254; 9,066,711 and
D663,836

REACCIONES ADVERSAS

- Se pueden producir reacciones adversas si el adhesivo entra en contacto con el ojo.
- Se pueden producir reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehído.
- El adhesivo tóxico para la piel SURGISEAL siempre se debe aplicar en una capa gruesa continua, o dos capas finas para que no se acumulen grandes cantidades de líquido, lo que provocaría malestar térmico al paciente.

SurgiSeal *Twist*®

TOPICAL SKIN ADHESIVE
2-Octyl Cyanoacrylate



MODO DE EMPLEO

- Antes de utilizar SURGISEAL, la herida debe limpiarse completamente.
 - Lleve a cabo el protocolo quirúrgico habitual para la preparación de la herida antes del tratamiento con el adhesivo tóxico para la piel SURGISEAL y asegúrese de suturar las capas subcutáneas profundas.
 - Seque la zona herida con gasa esterilizada, eliminando toda la humedad para permitir la adherencia apropiada del tejido a la piel mediante SURGISEAL.
 - Para evitar el derrame involuntario del adhesivo tóxico para la piel SURGISEAL en zonas no deseadas del cuerpo, se debe mantener la herida en posición horizontal y SURGISEAL se debe aplicar desde por encima de la herida.
 - Saque el aplicador Twist de la bolsa alveolada. Mantenga el aplicador con el dedo pulgar y el índice alejado del paciente para evitar cualquier aplicación involuntaria del adhesivo líquido tóxico para la piel SURGISEAL dentro de la herida o sobre el paciente.
 - Sujete el aplicador SURGISEAL Twist® firmemente en la base con el pulgar y el índice y con la punta hacia el techo y alejada del paciente. Gire la ampolla del aplicador hacia la derecha hasta alinearla con la base del aplicador.
- NOTA: Para disminuir la tensión en la funda del aplicador, NO gire la funda, sino solo la ampolla que contiene la fórmula adhesiva.
- Invierta el aplicador y deje que la fórmula adhesiva fluya a través de la punta. No es necesario presionar para una aplicación normal. Si se necesita un mayor flujo, puede presionar muy suavemente la parte rugosa del aplicador.
 - Aproxime los extremos de la herida utilizando guantes o un fórceps estéril.
 - Aplique lentamente el líquido adhesivo tóxico para la piel SURGISEAL en una capa gruesa continua o dos capas finas. Si se aplican dos capas finas, deje 30 segundos de tiempo de secado entre capas.
 - Mantenga la aproximación de los extremos opuestos de la herida de manera manual durante unos 60 segundos una vez que haya aplicado la capa final de SURGISEAL.
- NOTA: una presión excesiva de la punta del aplicador contra los extremos de la herida o de la piel circundante puede forzar la separación de los extremos de la herida y permitir que el adhesivo tóxico para la piel SURGISEAL penetre en la herida. La penetración en la herida del adhesivo tóxico para la piel SURGISEAL puede retrasar la curación de la herida y/o provocar un resultado cosmético adverso.
- NOTA: la fuerza total de aposición se obtiene aproximadamente 1 minuto después de haber aplicado la capa final. La polimerización completa se produce cuando la capa superior del adhesivo tóxico para la piel SURGISEAL ya no está pegajosa.
- Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tóxico para la piel SURGISEAL esté completamente sólida/polimerizada: que no esté pegajosa al tocarla (aproximadamente cinco minutos después de la aplicación). Deje que la capa superior se polimerice completamente antes de poner una venda. Si un apósito, vendaje, cinta o refuerzo adhesivo se aplica antes de la polimerización completa, el apósito puede adherirse a la película. La película puede separarse de la piel al retirar el apósito, provocando su dehiscencia.
 - Se les debe indicar a los pacientes que no toquen la película polimerizada del adhesivo tóxico para la piel SURGISEAL. Si lo hacen, la película puede perder adhesión a la piel, provocándose la dehiscencia de la herida. Puede prevenirse que se toque la película cubriéndola con un apósito.
 - Aplique un apósito seco de protección para niños u otros pacientes que no sean capaces de seguir las recomendaciones para el cuidado apropiado de la herida.
 - A los pacientes se les debe indicar que solo se podrá humedecer ligeramente el lugar del tratamiento, hasta que la película polimerizada del adhesivo tóxico para la piel SURGISEAL se haya asentado con naturalidad (generalmente entre 5 y 10 días). Los pacientes pueden duchar y bañar la zona con suavidad. La zona no debe restregarse, mojarse o exponerse a humedad prolongada hasta que la película se haya asentado con naturalidad y la herida esté cerrada y curada. A los pacientes se les debe informar que no pueden nadar durante este período.
 - Si por algún motivo es necesario retirar el adhesivo tóxico para la piel SURGISEAL, aplique suavemente vaselina o acetona en la película de adhesivo tóxico para la piel SURGISEAL para reducir la adherencia. Despegue la película, pero no separe la piel.
 - Generalmente, una vez que la superficie esté completamente libre del adhesivo, ya se ha producido la polimerización completa.

CÓMO SE SUMINISTRA

SURGISEAL Twist® es un aplicador monodosis, estéril y fácil de usar, que se presenta en un envase alveolado termoformado. El aplicador SURGISEAL Twist® tiene una ampolla que se gira para facilitar la aplicación. El aplicador contiene un adhesivo tóxico para la piel. Suministrada: 1 caja de 12 aplicadores/0,50 ml de adhesivo.

ALMACENAMIENTO

Se recomienda almacenarlo en unas condiciones igual o inferior de 30 °C (86 °F) alejado de la humedad y del calor y la luz directos. NO utilice después de la fecha de caducidad.

ESTERILIDAD

El adhesivo tóxico para la piel SURGISEAL está esterilizado en forma terminal con óxido de etileno. SURGISEAL Twist® componente ampolla llena se esteriliza por irradiación terminal.

SOLO PARA UN USO ÚNICO, ESTÉRIL.

PRECAUCIONES

Las leyes federales de EE. UU. restringen la venta de este dispositivo por parte de un médico o por orden facultativa.

¹ Adhezion Biomedical, LLC Data on File.

REFERENCIAS:

- Bernard, L., et al., A prospective comparison of octyl cyanoacrylate tissue adhesive and suture for the closure of excisional wounds in children and adolescents. Arch Dermatol, 2001. 137 (9):p 1177-80.
- Penoff, J., Skin closures using cyanoacrylate tissue adhesives. Plastic Surgery Educational Foundation DATA Committee. Device and Technique Assessment, Plast Reconstr Surg, 1999. 103(2): p. 730-1
- Singer, A.J. y H.C. Thode, Jr., A review of the literature on octylcyanoacrylate tissue adhesive. Am J Surg, 2004. 187(2):p. 238-48
- Narang, U., et al., In-vitro analysis for microbial barrier properties of 2-octyl cyanoacrylate-derived wound tretment films. J Cutan Med Surg, 2003. 7 (1): p 13-9.