The SurgiSeal® Topical Skin Adhesive Portfolio offers:

• Rapid set time
• An effective microbial barrier
• 3-step product preparation and application
• 3 distinct applicators

*Mechanical Performance Testing is not necessarily indicative of clinical outcomes and performance.

†Clinical studies were not conducted to demonstrate microbial barrier properties. A correlation between microbial barrier properties and a reduction in infection has not been established.

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 accompanying Instructions for Use.
The SurgiSeal® Topical Skin Adhesive Portfolio: proven adhesion strength and flexibility\(^{1-7}\)

Substantially equivalent to Dermabond\(^{1,2,12}\)

- Adhesion strength and flexibility of the topical skin adhesive within the SurgiSeal Portfolio were shown to be comparable to Dermabond\(^{®}\) in the standardized tests below\(^{1-7}\).

<table>
<thead>
<tr>
<th>Mechanical Performance Testing: SurgiSeal Topical Skin Adhesive vs Dermabond(^{®1-7})</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Values</strong></td>
</tr>
<tr>
<td>Lap-Shear Tensile Loading(^{†})</td>
</tr>
<tr>
<td>Adhesive &amp; Sealant Wound Strength Under Tension(^{‡})</td>
</tr>
<tr>
<td>Adhesive &amp; Sealant Wound Strength Under Tension(^{‡})</td>
</tr>
<tr>
<td>Adhesive &amp; Sealant Wound Strength Under Tension(^{‡})</td>
</tr>
<tr>
<td>T-Peel Tension Loading(^{§})</td>
</tr>
<tr>
<td>Strength Under Tension Loading(^{</td>
</tr>
<tr>
<td>Mandrel Bend Flexibility Testing(^{¶})</td>
</tr>
<tr>
<td>Mandrel Bend Flexibility Testing(^{¶})</td>
</tr>
<tr>
<td>Mandrel Bend Flexibility Testing(^{¶})</td>
</tr>
</tbody>
</table>

*Mechanical Performance Testing is not necessarily indicative of clinical outcomes and performance.

1. Test adhered to protocol ASTM F 2255-05, Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading.\(^{2}\)
2. Test adhered to protocol ASTM F 2458-05, Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants.\(^{4}\)
3. Test adhered to protocol ASTM F 2256-05, Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading.\(^{5}\)
4. Test adhered to protocol ASTM F 2258-05, Standard Test Method for Strength Properties of Tissue Adhesives in Tension.\(^{6}\)
5. Test adhered to protocol ASTM D 4338-97, Standard Test Method for Flexibility Determination of Supported Adhesive Films by Mandrel Bend.\(^{7}\)

Flexibility without a plasticizer\(^{1,2}\)

- Formulation of the topical skin adhesive within SurgiSeal products is 99% 2-octyl cyanoacrylate combined with a preservative (BHA) and a purple colorant.

99%
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 Important Safety Information throughout.
Please see accompanying Instructions for Use.

The average surface coverage for SurgiSeal (0.35 mL) was 26.0 in sq vs Dermabond® (2-octyl cyanoacrylate) (0.5 mL), which covered 11.5 in sq on pigskin, per applicator1,2
The SurgiSeal Portfolio products provide an effective microbial barrier\textsuperscript{8-11}

Microbial barrier

- In vitro studies have shown that the topical skin adhesive within the SurgiSeal products acts as a physical barrier to microbial penetration as long as the adhesive film remains intact\textsuperscript{8-10}
- Does not allow penetration of \textit{Staphylococcus epidermidis}, according to in vitro studies\textsuperscript{11}
- Clinical studies were not conducted to demonstrate microbial barrier properties. A correlation between microbial barrier properties and a reduction in infection has not been established\textsuperscript{8-10}

**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.

\textit{Please see Important Safety Information throughout. Please see accompanying Instructions for Use.}
When incisional wounds were closed topically with a 2-octyl cyanoacrylate adhesive, they showed:

**Stronger adhesion strength**\(^{13,14}\)

- 2-octyl cyanoacrylate skin adhesive
- Butyl cyanoacrylate skin adhesive

**Increased wound-bursting strength**\(^{13,14}\)

- 2-octyl cyanoacrylate skin adhesive
- Butyl cyanoacrylate skin adhesive

**Better adhesive flexibility**\(^{14,15}\)

- 2-octyl cyanoacrylate skin adhesive
- Butyl cyanoacrylate skin adhesive

- 2-octyl cyanoacrylates have long chains, which help them form flexible and strong bonds\(^{13,15}\)

The 2-octyl cyanoacrylate used in these studies was Dermabond\(^{\circledR}\)\(^{13-15}\)

*The testing results of adhesion strength, wound-bursting strength, or adhesive flexibility are not indicative of clinical outcomes or performance.*
SurgiSeal Stylus®

Designed for ease of handling and targeted application\textsuperscript{2,8,16}

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

- Glass-free reservoir containing 0.5 mL of SurgiSeal Topical Skin Adhesive\textsuperscript{8}
- Rigid sleeve helps prevent bending of applicator during adhesive application\textsuperscript{16}
- Applicator design helps avoid dripping or oversaturation of the adhesive during application\textsuperscript{16}
- Color-changing tip in the presence of adhesive
- Angled applicator tip
- Perforation in the middle, allowing ease of adhesive flow\textsuperscript{2}

A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days\textsuperscript{8,13}
Only 3 simple steps needed for product preparation and adhesive application.

To use SurgiSeal Stylus:

1. Point the tip toward the ceiling and away from the patient. Press the bottom of the applicator upward.

2. Invert the applicator and allow the adhesive to flow through the tip. No squeezing is necessary in normal application.
   - It usually takes 2 to 5 seconds for the applicator tip surface to be completely saturated with adhesive.
   - If greater flow is required, the ridged portion of the applicator may be very gently squeezed.
   - The applicator tip changes color in the presence of adhesive.

3. Slowly apply in either 1 thick continuous layer or 2 thin layers.
   - If 2 thin layers are applied, allow 30 seconds of dry time in between layers.

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.

Please see Important Safety Information throughout. Please see accompanying Instructions for Use.
SurgiSeal Twist®

Designed for larger grip and pen-like application

SurgiSeal Twist Topical Skin Adhesive (2-octyl cyanoacrylate) applicator has distinct features for activation, grip, and application.

- Initiates product flow with a twist
- Contains 0.5 mL of SurgiSeal Topical Skin Adhesive
- Ridged plastic sleeve with pen-like grip
- Color-changing tip in the presence of adhesive
- Angled applicator tip

A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days.
3 simple steps for product preparation and adhesive application

To use SurgiSeal Twist:

1. 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 ampule of the applicator to the right until flush with the applicator base.

2. Invert the applicator and allow the adhesive to flow down through the tip. No squeezing is necessary in normal application.
   - If greater flow is required, gently squeeze the ridged portion of the applicator.
   - The applicator tip changes color in the presence of adhesive.

3. Hold the wound together and slowly apply in either 1 thick layer or 2 thin layers.
   - If 2 thin layers are applied, allow 30 seconds of dry time between layers.

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

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

- Teardrop-shaped design
- Foam tip
- Snap to open
- Brodest applicator in the SurgiSeal portfolio (0.8125 inches)
- Purple-colored adhesive
- Contains 0.35 mL of SurgiSeal Topical Skin Adhesive

A single, thick, continuous layer may be sufficient to hold approximated wound edges closed for 5 to 10 days.
3 simple steps for product preparation and adhesive application

To use SurgiSeal:

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 greater flow is required, gently squeeze the adhesive reservoir.
   - The applicator changes color in the presence of adhesive.

3. Hold the wound together and slowly apply either 1 thick continuous layer or 2 thin layers.
   - If 2 thin layers are applied, allow 30 seconds of dry time between layers.

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.
Pfizer is committed to quality, reliability, and customer-focused support.

References:
1. US Food and Drug Administration. SURGISEAL Topical Skin Adhesive 510(k); May 30, 2008.
2. Adhezion Biomedical. SURGISEAL Stylus and Stylus Twist Topical Skin Adhesive abbreviated 510(k); May 2013.
8. SURGISEAL Stylus Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; July 2015.
9. SURGISEAL Twist Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; March 2016.
10. SURGISEAL Topical Skin Adhesive (2-octyl cyanoacrylate) [instructions for use]. Adhezion Biomedical, LLC; March 2016.

Proven adhesion strength and flexibility\(^*\)\(^7\)*

- Substantially equivalent to Dermabond\(^*\)\(^0\)-12
- Formulation of SurgiSeal\(^*\) Topical Skin Adhesive (2-octyl cyanoacrylate) is 99% 2-octyl cyanoacrylate combined with a purple colorant\(^*\)\(^1\)-\(^2\)
- Rapid set time–full apposition strength is expected to be achieved about 60 seconds after final layer is applied\(^*\)\(^8\)-\(^10\)
- Only 3 simple steps required for product preparation and adhesive application\(^*\)\(^8\)-\(^10\)
- In vitro studies have shown that SurgiSeal Topical Skin Adhesive acts as a physical barrier to microbial penetration as long as the adhesive film remains intact\(^*\)\(^8\)-\(^10\)
- SurgiSeal Topical Skin Adhesive offers flexibility without a plasticizer\(^*\)\(^1\)-\(^2\)
- SurgiSeal Topical Skin Adhesive comes in 3 distinct applicators

*Mechanical Performance Testing is not necessarily indicative of clinical outcomes and performance.

Visit PfizerPro.com for more information about the SurgiSeal Portfolio and to order trial products.

Pfizer is committed to quality, reliability, and customer-focused support.

SurgiSeal\(^*\), SurgiSeal Stylus\(^*\), and SurgiSeal Twist\(^*\) are registered trademarks of Adhezion Biomedical, LLC.
Dermabond\(^*\) is a registered trademark of Ethicon US, LLC.

PP-SST-USA-0087-02 ©2016 Pfizer Inc. All rights reserved. September 2016

Please see Important Safety Information on the previous pages.
Please see accompanying Instructions for Use.
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 "STERILE SINGLE USE ONLY" label. Do not remove the applicator from the box until immediately prior to use.

**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 remove all excess 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 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 onto the wound or on the patient.
6. While holding the applicator, and with the applicator sponge facing upward, snap tip along the perforated line and fold over.
7. Gently squeeze the liquid SURGISEAL adhesive from the applicator bubble while maintaining force.
8. Approximate the wound edges using either gloved fingers or sterile forceps.
9. Steady the liquid SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers. If thin layers are applied, allow 10 seconds dry time in between layers.
10. Maintain maximal approximation of the wound edges together for approximately 60 seconds since the final coat of SURGISEAL is applied.

**NOTE.** Excessive pressure of the applicator 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 outcomes.

**NOTE.** Full-penetration 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 is completely solidified and not tacky to the touch (complete polymerization). Arrange 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 skin can be disrupted from the skin when the dressing is removed, and wound dehiscence can result.

12. Patients should be instructed to not pick at the polymerized film of SURGISEAL topical skin adhesive. Picking at the film can disrupt its adherence to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by 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 in 5-10 days, there should be only minimal restraint of the treatment site. Patients may shave and bathe the site gently. The site should not be scumbled, soaped, or exposed to prolonged wetness until after the film has sloughed. Monitoring of the site and the wound has healed must be done. Patients should be cautioned to avoid excessive rubdowns and running water on the wound.

15. 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 and separate the bond from the skin. Do not pull the skin apart.

16. Once the surface is tack-free, full-polymerization has generally occurred.

**HOW SUPPLIED**

SURGISEAL is sterile, easy to use. One single-dose applicator, packaged in a thermal formed blister pack. The applicators are packaged in a box that fits precisely on the skin. The applicators have a perfusion in the middle allowing ease of one application. The applicator contains a topical skin adhesive. Supplied: 3 boxes of 12 applicators/35 ml 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.**

**STABILITY**

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

**CATEGORIES**

Federal (513) law restricts this device to sale by or on the order of a physician.

**PROHIBITED WRITING**

Adhezion Biomedical, LLC Data on file.

**REFERENCES**


1. Mientras sostiene el aplicador de la punta del mismo modo, haga obra corta alrededor, y luego a la larga, a la larga, de la punta perforada y debido.
2. Intervé el aplicador. No es necesario apretar durante la aplicación normal.
3. Aproveche el adhesivo de la otra forma y aplíquelo en una capa gruesa continua, y dos capas finas. Si se aplican dos capas, las distancias de tiempo de secado entre capas.

MODO DE EMPLEO
1. Antes de usar, aclare las instrucciones para aplicar el adhesivo tópico para la piel SURGISEAL y asegúrese de leer las instrucciones sobre superficies rojo bermellón.
2. Use un cepillo de suavidad, intermitente para la propulsión de la herida de la piel para SURGISEAL, y asegúrese de leer las instrucciones sobre superficies rojo bermellón.
3. Si SURGISEAL se aplica en soporte inmediato, debe cortar la piel de la herida con cuchara, y el apósito debe informar que no pueden nadar durante este período.
4. Los apósitos se deben aplicar después de la fecha de caducidad.

ADVERTENCIAS
- No utilice en heridas que presenten pruebas de infección de microbios, bacterias u hongos, o en caso de gangrena.
- Los apósitos de tendido para la piel SURGISEAL se usan en ojos, como suavizar la piel de la esquina de ojo.
- Las reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehido.
- Se pueden producir reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehido.
- Aplique lentamente el líquido adhesivo tópico para la piel SURGISEAL en una capa gruesa continua, o dos capas finas, dejando 30 segundos de tiempo de secado entre capas.
- En cuanto a los extremos de los ojos, la piel debe mantenerse en la piel para evitar la adherencia.
- El adhesivo tópico para la piel SURGISEAL se debe prensar completamente antes de ponerla sobre la piel. Si un apósito, vendaje, cinta o refuerzo adhesivo se aplica después de la polimerización completa, el apósito puede adherirse a la piel.
- La piel puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- La piel puede separarse de la piel por la piel para SURGISEAL. Si no hace, la punta puede perder adherencia.
- El adhesivo tópico para la piel SURGISEAL se puede aplicar a la piel para la piel SURGISEAL, después de la polimerización completa, un apósito, vendaje, cinta o refuerzo adhesivo se aplica después de la polimerización completa.
- Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tópico para la piel SURGISEAL esté completamente seca.
- La película puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- El adhesivo tópico para la piel SURGISEAL se debe aplicar de forma uniforme en una capa gruesa continua.
- La piel puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- Se pueden producir reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehido.
- Se pueden producir reacciones adversas en pacientes que tengan hipersensibilidad a los cianoacrilatos o al formaldehido.
- Aplique lentamente el líquido adhesivo tópico para la piel SURGISEAL en una capa gruesa continua, o dos capas finas, dejando 30 segundos de tiempo de secado entre capas.
- Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tópico para la piel SURGISEAL esté completamente seca.
- La película puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- El adhesivo tópico para la piel SURGISEAL se puede aplicar a la piel para la piel SURGISEAL, después de la polimerización completa, un apósito, vendaje, cinta o refuerzo adhesivo se aplica después de la polimerización completa.
- Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tópico para la piel SURGISEAL esté completamente seca.
- La película puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- El adhesivo tópico para la piel SURGISEAL se debe aplicar de forma uniforme en una capa gruesa continua.
- La piel puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
- El adhesivo tópico para la piel SURGISEAL se puede aplicar a la piel para la piel SURGISEAL, después de la polimerización completa, un apósito, vendaje, cinta o refuerzo adhesivo se aplica después de la polimerización completa.
- Los apósitos secos protectores como la gasa solo se pueden aplicar cuando la película de adhesivo tópico para la piel SURGISEAL esté completamente seca.
- La película puede separarse de la piel por la piel para SURGISEAL, y si hacer, la punta puede perder adherencia.
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 of the tissue adhesive at the tip of the applicator. The SURGISEAL® Twist® applicator is available in 1.5ml or 2.0 ml cartridges. The SURGISEAL® Twist® applicator is designed to deliver a light coating of adhesive to the skin, but not enough to cover the entire wound area.

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 of the tissue adhesive at the tip of the applicator. The SURGISEAL® Twist® applicator is available in 1.5ml or 2.0 ml cartridges. The SURGISEAL® Twist® applicator is designed to deliver a light coating of adhesive to the skin, but not enough to cover the entire wound area.

ADVERSE REACTIONS
- Adverse reactions may occur if adhesive makes contact with the eye.
- Adverse reactions may occur in patients that have a hypersensitivity to cyanoacrylate or formaldehyde.

REFERENCES
- 1. Hold the SURGISEAL® Twist® applicator firmly at the base with the thumb and forefinger and with the tip towards the center of the wound and away from the patient. Twist the ampoule of the applicator to the right until flush with the applicator base.

1. Hold the SURGISEAL® Twist® applicator firmly at the base with the thumb and forefinger and with the tip towards the center of the wound and away from the patient. Twist the ampoule of the applicator to the right until flush with the applicator base.

2. Invert the applicator and allow the adhesive to flow through the tip. No squeezing is necessary in normal application. If greater flow is required, you may gently squeeze the edges of the applicator to increase the flow of adhesive.

3. Hold the wound together and apply in either one thin layer or two film layers. The thickness of the adhesive layers applied will determine the final amount of adhesive in the treated wound.

DIRECTIONS FOR USE
1. Before the use of SURGISEAL® the wound must be thoroughly cleaned.
2. Do not perform surgical preparation for wound preparation before treatment of SURGISEAL® topical skin adhesive and be certain to use deep submucosal layers.
3. Dry the contaminated area with sterile gauze; removing all moisture for proper tissue bonding of SURGISEAL® to the skin.
4. It is important to remove all saline, Betadine® Antibiotics, Chlorhexidine gluconate (CHG), or soap, are not expected to immediately loosen the bond.
5. 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, thick, continuous layer or two thin layers rather than in a few large droplets. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
6. 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 may help loosen the bond. Other agents such as water, thick, continuous layer or two thin layers rather than in a few large droplets. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
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 gently squeeze the edges of the applicator to increase the flow of adhesive.
8. Approximate the wound edges together using either gloved fingers or sterile forceps.
9. SURGISEAL® topical skin adhesive is a clear, colorless, odorless, water-resistant, 2% octyl cyanoacrylate skin adhesive.
10. 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 may render the product unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
11. Application and/or migration (leak) of either version of the product beyond the surface of the skin will impair the healing process by forming a barrier between tissue surfaces. If leakage occurs, the wound should be closed with sutures.
12. DO NOT use on warts, bruises, warts, or open, draining wounds or on any skin area where SURGISEAL® adhesive is intended to adhere.
13. 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 it is unpackaged, to steam or ethylene oxide sterilization processes may cause the adhesive to become tacky, and the product may become unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
14. 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 it is unpackaged, to steam or ethylene oxide sterilization processes may cause the adhesive to become tacky, and the product may become unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
15. 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 it is unpackaged, to steam or ethylene oxide sterilization processes may cause the adhesive to become tacky, and the product may become unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
**SILOXAN®**: adhesivo tópico para la piel. Se utiliza para unir los bordes de una herida, manteniendo cerrado de forma eficaz ese espacio.

**SUGI SEAL Twist®**: adhesivos líquidos estériles y profesionales, con base en monómero (2-octil cianoacrilato) y el 2-octil cianoacrilato.

**DESCRIPCIÓN**

Si el adhesivo tópico para la piel SURGISEAL se aplica correctamente, se puede usar como una forma de sellado temporal de heridas.

1. **Eficaz e inmediato**
   - Acelera el proceso de curación de la herida.
   - Proporciona un sellado eficaz.

2. **Seguro y fácil de usar**
   - No requiere perforación de la piel.
   - Fácil de aplicar.

3. **Resistente a la hidratación**
   - Mantiene el sellado de la herida durante períodos prolongados.

4. **No produce dolor**
   - La aplicación del adhesivo no causa dolor.

5. **No produce adherencia**
   - No se produce adherencia a la piel.

**USOS**

1. **Adhesivo tópico para la piel**
   - Para el sellado de heridas y úlceras.
   - Para el sellado de heridas quirúrgicas.

2. **Adhesivo tópico para la piel con la pasta**
   - Para el sellado de heridas con pasta.

3. **Adhesivo tópico para la piel con la pasta y el índice**
   - Para el sellado de heridas con pasta y el índice.

4. **Adhesivo tópico para la piel con la pasta y el nudo**
   - Para el sellado de heridas con pasta y el nudo.

**INDICACIONES**

1. **Heridas mínimas**
   - Pequeñas heridas no infectadas.

2. **Heridas grandes**
   - Heridas más grandes que requieren un sellado eficaz.

3. **Heridas progresivas**
   - Heridas que pueden progresar con el tiempo.

4. **Heridas que requieren un sellado a largo plazo**
   - Heridas que necesitan un sellado a largo plazo.

**REACCIONES ADVERSAS**

1. **Reacciones adversas**
   - Se producen reacciones adversas en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

2. **Reacciones adversas graves**
   - Se producen reacciones adversas graves en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

**CONTRAINDICACIONES**

1. **Contraindicaciones**
   - Se contraindican en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

2. **Contraindicaciones graves**
   - Se contraindican en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

**USOS RESTRINGIDOS**

1. **Usos restringidos**
   - Se utilizan en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

2. **Usos restringidos graves**
   - Se utilizan en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

**EQUIPO Y MATERIALES**

1. **Equipo y materiales**
   - Equipo y materiales para el sellado de heridas.

2. **Materiales**
   - Materiales para el sellado de heridas.

**MÉTODOS DE ADMINISTRACIÓN**

1. **Métodos de administración**
   - Métodos de administración para el sellado de heridas.

2. **Métodos de administración graves**
   - Métodos de administración para el sellado de heridas.

**ACCIDENTES Y LESIONES**

1. **Accidentes y lesiones**
   - Accidentes y lesiones en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

2. **Lesiones graves**
   - Lesiones graves en pacientes que tienen hipersensibilidad a los adhesivos estéticos.

**REALIZACIÓN DE LA MANIPULACIÓN**

1. **Realización de la manipulación**
   - Realización de la manipulación para el sellado de heridas.

2. **Realización de la manipulación graves**
   - Realización de la manipulación para el sellado de heridas.

**EVALUACIÓN DE LA MANIPULACIÓN**

1. **Evaluación de la manipulación**
   - Evaluación de la manipulación para el sellado de heridas.

2. **Evaluación de la manipulación graves**
   - Evaluación de la manipulación para el sellado de heridas.

**APLICACIÓN DE LA MANIPULACIÓN**

1. **Aplicación de la manipulación**
   - Aplicación de la manipulación para el sellado de heridas.

2. **Aplicación de la manipulación graves**
   - Aplicación de la manipulación para el sellado de heridas.

**APORTACIÓN DE LA MANIPULACIÓN**

1. **Aportación de la manipulación**
   - Aportación de la manipulación para el sellado de heridas.

2. **Aportación de la manipulación graves**
   - Aportación de la manipulación para el sellado de heridas.

**ACTUALIZACIÓN DEL PROTOCOLO**

1. **Actualización del protocolo**
   - Actualización del protocolo para el sellado de heridas.

2. **Actualización del protocolo graves**
   - Actualización del protocolo para el sellado de heridas.

**CONCLUSIÓN**

1. **Conclusión**
   - Conclusión para el sellado de heridas.

2. **Conclusión graves**
   - Conclusión para el sellado de heridas.
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 bottle containing a plastic valve with an applicator tip. This Singh Stylus has an integrated dispenser, allowing easier dose control and simplified application.

INDICATIONS
SURGISEAL is intended for topical application only to hold closed, closely approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and without tension to prevent drainage, devitalization, or sloughing of the edges. SURGISEAL may be used in conjunction with, but not as an in lieu of, deep thermal sutures.

CONTRAINDICATIONS
• DO NOT use on any wounds with evidence of microbial, bacterial or fungal infection or gangrene.
• DO NOT use on or near mucous membranes.
• DO NOT use on infected wounds, wounds that have been treated with topical chlorhexidine gluconate or chlorhexidine acetate, or any other topical medicament that may inhibit the polymerization of SURGISEAL. The product should be used only in noninfected or minimally infected wounds.
• DO NOT use the product if it appears cloudy or discolored.
• DO NOT use the product if it is past its expiration date.
• DO NOT use the product after it has been exposed to heat, freezing, or sun.

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 equipment that is 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 heat or by contact with macromolecules, such as proteins or carbohydrates, resulting in a reduction in the heat set time. Therefore, the application of this adhesive to areas subject to macromolecular macromolecules, such as proteins or carbohydrates, should be avoided.
• SURGISEAL topical skin adhesive should not be applied to a wet surface. If the contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply gentle topical epinephrine solution to help loosen the bond and contact an ophthalmologist.
• Do not resterilize SURGISEAL topical skin adhesive after it has been resterilized. This product is intended for sterile use only. If the applicator is contaminated, the entire device should be discarded and a new one should be provided.
• SURGISEAL topical skin adhesive should not be used as a wound dressing. SURGISEAL topical skin adhesive is not absorbable and therefore should not be used as a wound dressing. SURGISEAL topical skin adhesive is not a substitute for surgical sutures.
• SURGISEAL topical skin adhesive should be applied to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any area where SURGISEAL is intended to adhere.
• SURGISEAL topical skin adhesive should not be applied underneath the skin to repair subcutaneous wounds or to repair skin or fascia defects in the subcutaneous layer. SURGISEAL will only adhere to the skin surface and will not adhere to the subcutaneous layer. The use of this product in the repair of subcutaneous wounds is not supported.
• SURGISEAL topical skin adhesive should not be used on wounds that have been treated with topical chlorhexidine gluconate or chlorhexidine acetate or any other topical medicament that may inhibit the polymerization of SURGISEAL or may alter the color of the adhesive. The product should be used only in noninfected or minimally infected wounds.

PRECAUTIONS
Tissue adhesives for the topical approximation of skin should not be used on wounds that are, dirty, deep, not approximated, subject to drainage (e.g. lacerations or abrasions), or exposed to bodily fluids or excreta. TOPICAL SKIN ADHESIVE SURGISEAL should not be used in the presence of infection, nursing, bleaching, and disinfectant solutions on mucous membranes which may interfere with polymerization.

ADVERSE REACTIONS
• Adverse reactions may occur if adhesive makes contact with the eye.
• Adverse reactions may occur in patients that have a hypersensitivity to cyanoacrylate 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.

APPLICATION
1. Point the tip of the applicator toward the patient. Press the bottom of the applicator upward.
2. Invert the applicator and allow the adhesive to flow through the tip. No squeezing is necessary in normal application.
3. Hold the wound edges in approximate positioning in either one thick layer or two thin layers.

REFERENCES
**TOPICAL SKIN ADHESIVE**

**2-Octyl Cyanoacrylate**

**Stylus**

**Manufactured by:** Adhezion Biomedical, LLC

**Hudson, NC 28638 USA**

**SSS-IFU02-15IR**

**EN**

**Español**

**RELACIONES ADVERSAS**

- Se ha observado que el adhesivo surgen causa reacciones adversas, como irritación local, en pacientes con dermatitis atópica.

**CONTRAPUNTOS**

- Se ha observado que el adhesivo surgen causa reacciones adversas, como irritación local, en pacientes con dermatitis atópica.

**MODOS DE EMPLEO**

**INSTRUCCIONES**

1. **Mantenga el adhesivo libre de la piel**. 2. Aplique la película de la piel. 3. **Aplicar el adhesivo sobre la piel en una capa gruesa continua**. 4. **Utilizar el botón del aplicador**. 5. **Eliminar la película de la piel**. 6. **Eliminar la película de la piel**.

**COMO USAR**

1. **Mantenga el adhesivo libre de la piel**. 2. Aplique la película de la piel. 3. **Aplicar el adhesivo sobre la piel en una capa gruesa continua**. 4. **Utilizar el botón del aplicador**. 5. **Eliminar la película de la piel**. 6. **Eliminar la película de la piel**.

**PRECAUCIONES**

- **No aplique medicamentos tópicos**. 2. **No aplique medicamentos tópicos**. 3. **No aplique medicamentos tópicos**.

**ALMACENAMIENTO**

- **No se recomienda almacenarlo en condiciones únicas**. 2. **No se recomienda almacenarlo en condiciones únicas**. 3. **No se recomienda almacenarlo en condiciones únicas**.