The application of high viscosity DERMABOND® Adhesive requires thorough wound cleansing. Follow standard surgical
preparation. Patients should be instructed that until the polymerized film of high viscosity DERMABOND® Adhesive has sloughed
naturally and the wound has healed closed. Patients should be instructed not to pick at the polymerized film of high viscosity
DERMABOND® Adhesive. Picking at the polymerized film can disrupt the wound edges, leading to dehiscence (skin edge
separation). The film can be disrupted from the skin when the dressing is removed, and dehiscence (skin edge separation) can occur.

If a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the
polymerized film. The film can be disrupted from the skin when the dressing is removed, and dehiscence (skin edge separation) can occur.

If removal of high viscosity DERMABOND® Adhesive is necessary for any reason, carefully apply petroleum jelly or acetone
(depending on the manufacturer) to the portion of the wound to be debrided. Allow the adhesive to soften for approximately
10 seconds before attempting to remove it to prevent any unintentional placement of the liquid high viscosity
DERMABOND® Adhesive into the wound or on the patient.

Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound
edges apart and allowing high viscosity DERMABOND® Adhesive into the wound. High viscosity DERMABOND® Adhesive
polymerizes through an exothermic reaction. If the liquid high viscosity DERMABOND® Adhesive contacts the skin, cool the
applicator tip by applying high viscosity DERMABOND® Adhesive to moisten the applicator tip.

While holding the applicator, and with applicator tip pointed upward, apply pressure at the midpoint of the ampule to
create a tear. Remove glass ampule from the plastic pouch. If using the pen applicator, refer to the instructions on the
pouch for crushing the glass ampule and expressing the liquid adhesive. After crushing the glass ampule, the liquid adhesive
is placed in the pen applicator. If a needle is used, refer to the instructions for crushing the glass ampule, placing the
liquid adhesive in the needle, and using the needle to express the liquid adhesive.

For an optimal result, the liquid adhesive should be expressed in multiple thin layers (at least two). The use of more than
one layer of adhesive in a continuous motion. Wait approximately 30 seconds between applications or layers. Maintain manual
approximation of the wound edges with a clean, dry, sterile gauze dressing during this time. If the primary method of closure
was insufficient for closure, an additional securing device was placed. The time to perform the additional device was included in
the time required later to remove the closure device when applicable. The time to remove the closure device included the
primary method of closure and any additional securing devices placed.

Immediately: Additional securing device approached >50% epidermal apposition @ 3 months:

<table>
<thead>
<tr>
<th>Treatment (Minutes)</th>
<th>N (%): 1.5</th>
<th>6.0</th>
<th>1.3</th>
<th>2.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSS</td>
<td>205 (91.1%)</td>
<td>214 (95.5%)</td>
<td>163 (98.2%)</td>
<td>165 (99.4%)</td>
</tr>
<tr>
<td>DERMABOND®</td>
<td>169 (75.1%)</td>
<td>199 (88.8%)</td>
<td>140 (84.3%)</td>
<td>160 (96.4%)</td>
</tr>
<tr>
<td>WSS</td>
<td>160 (96.4%)</td>
<td>166 (96.8%)</td>
<td>160 (96.4%)</td>
<td>166 (96.8%)</td>
</tr>
</tbody>
</table>

NOTE: The study population included patients at least one year of age, in good general health, who signed informed consent and agreed
to follow-up visits. Patients were excluded if presenting with: significant multiple trauma, peripheral vascular disease, insulin
dependent diabetes mellitus, obesity (body mass index >40). All patients were treated with high viscosity DERMABOND® Adhesive. The
treatment included the time required later to remove the closure device when applicable.

Patients treated with high viscosity DERMABOND® Adhesive should be provided the printed instruction sheet entitled, “How
to use the DERMABOND® Adhesive Pouch” and “How to use the DERMABOND® Adhesive Pen” upon discharge. The
adhesive was used on a variety of wounds with differing closure techniques. Wound characteristics, wound closure
techniques, and surgical environment may affect the time required to achieve adequate epidermal apposition. The
comparative closure times were performed with the expectation of a controlled study and not as a pre- or post-marketing
clinical investigation. The wound tissue types included in this study were: dermal, epidermal, subcutaneous, subcutaneous/epidermal,
and subcutaneous/dermal. The wound areas included in this study were: <1 cm², 1-10 cm², 11-50 cm², >50 cm². The types of wounds
treated in the study were 46.1% lacerations and 53.9% incisions. The incisions were comprised of 47.8% skin incisions, 20.4%
deep wounds (down to subcutaneous fat) and 31.8% deep wounds (down to muscle). The wounds treated in this study included:
minor lacerations, major lacerations, simple lacerations, multiple lacerations, surgical incisions, and surgery-related wounds.

The primary outcome measure was the time required to achieve >50% epidermal apposition at the 3-month visit. The
measured time was the time required to achieve >50% epidermal apposition regardless of the primary method of closure or
additional securing device placed. The primary method of closure was evaluated as surgical methods (sutures/strips/staples/
epidermal apposition), DERMABOND® Adhesive, or a combination of these methods. The additional securing device placed
was evaluated as surgical methods (sutures/strips/staples/) or DERMABOND® Adhesive. The measured outcomes at the 3-month
visit were: >50% epidermal apposition approached, >50% epidermal apposition achieved. The treated wound areas, types of
wounds, and wound closure techniques are summarized in Table 1. The study was double-blinded and conducted at 29
North American sites.

Power analysis: A sample of 239 patients was estimated to yield a 90% chance of detecting a 30% difference in mean time to
>50% epidermal apposition. A total of 242 patients were treated with high viscosity DERMABOND® Adhesive for wounds closed
with subcuticular stitches, mean wound length was 3.2 cm, mean wound width was 2.5 mm, and mean wound depth was
5.8 mm. For wounds closed without subcuticular stitches, mean wound length was 1.5 cm, mean wound width was 2.5 mm, and mean
wound depth was 4.8 mm. A total of 46.1% lacerations and 53.9% incisions were treated in the study. The incisions were
comprised of 47.8% skin incisions, 25.8% deep wounds (down to subcutaneous fat), and 26.4% deep wounds (down to muscle).

Clinical Study

<table>
<thead>
<tr>
<th>N, patients treated</th>
<th>239</th>
<th>242</th>
<th>167</th>
<th>166</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSS</td>
<td>169</td>
<td>199</td>
<td>140</td>
<td>160</td>
</tr>
<tr>
<td>DERMABOND®</td>
<td>160</td>
<td>166</td>
<td>160</td>
<td>166</td>
</tr>
</tbody>
</table>

The clinical characteristics, wound closure techniques, and surgical environment may affect the time required to achieve
adequate epidermal apposition. The study population included patients at least one year of age, in good general health, who
signed informed consent and agreed to follow-up visits. Patients were excluded if presenting with: significant multiple trauma,
peripheral vascular disease, insulin dependent diabetes mellitus, obesity (body mass index >40). All patients were treated with
high viscosity DERMABOND® Adhesive. The treatment included the time required later to remove the closure device when
applicable.
### Adverse Reactions

Suspected Infection* (1) is listed below:

- Skin blistering
- Excessive itching
- Infection (redness more than 3-5 mm from the wound margin, swelling, purulent discharge, pain, increased skin temperature, fever, or other systemic signs of infection. Confirmatory culture is recommended.)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Low Viscosity (n=243)</th>
<th>High Viscosity (n=242)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected Infection*</td>
<td>0 (0.0%)</td>
<td>17 (4.5%)</td>
</tr>
</tbody>
</table>

*Antibiotics, Hibiclens* (chlorhexidine gluconate), or soap, are not recommended to wash DERMABOND® Adhesive wounds with suspected infections were associated with sub-optimal cosmetic outcome.

### Procedure

- Cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/foreign materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that may come into contact with the wound or skin should be avoided. Do not place high viscosity DERMABOND® Adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of high viscosity DERMABOND® Adhesive near the eye has inadvertently caused some patients’ eyelids to be sealed shut. In some of these cases, patients required surgical intervention to remove the adhesive from the wound site.

- Place the applicator in a horizontal position, with high viscosity DERMABOND® Adhesive at the applicator tip, and the patient’s eye closed. Do not allow the applicator to touch the patient’s skin. Do not apply high viscosity DERMABOND® Adhesive to the eye, eyelid, or surrounding skin.

- Do not re-use the applicator. If the applicator tip becomes clogged with high viscosity DERMABOND® Adhesive, after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide gas sterilization). Do not place high viscosity DERMABOND® Adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of high viscosity DERMABOND® Adhesive near the eye has inadvertently caused some patients’ eyelids to be sealed shut. In some of these cases, patients required surgical intervention to remove the adhesive from the wound site.

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### IFU PRINTING SPECIFICATION SHEET

**PAGE LAYOUT**

<table>
<thead>
<tr>
<th>Flat Size</th>
<th>Folded Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.16&quot; (512 mm)</td>
<td>4.03&quot; (102.36 mm)</td>
</tr>
</tbody>
</table>

**STOCK**

- 50 lb. Finch Opaque

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**TITLE**

DERMABOND® Mini

**DESCRIPTION**

Domestic IFU

**LAB NUMBER**

LAB0018680v5

**SPECIAL INSTRUCTIONS/COMMENTS**

n/a

**BINDING**

n/a

**COLORS**

Black, PMS266, PMS3115

**REMARKS**

20.16" x 5"  
512 mm x 127 mm

4.03" x 5"  
102.36 mm x 127 mm

**LANGUAGES**

EN

**SELF-COVER**

☐

**PLUS-COVER**

☐

**SEALING METHOD**

☐

**INNER SEAL**

n/a

**BLEED SIZE**

- ALL SIDES
- BLEED TOP
- BLEED LEFT
- BLEED BOTTOM

- NONE

**BLEED SIZE**

- 5" (127 mm)
- 125' (317.5 mm)

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