**DIRECTIONS FOR USE**

1. The application of DERMABOND ADVANCED™ Adhesive requires thorough wound preparation before application of DERMABOND ADVANCED™ Adhesive. Wounds that are unclean, have debris, or close deep layers making sure that the wound edges can be easily approximated.

2. For the wound dry with a sterile gauze to ensure direct contact with DERMABOND ADVANCED™ Adhesive to the skin. Moisten DERMABOND ADVANCED™ Adhesive’s polymerization and may affect wound healing.

3. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive to unintended areas of the body, the wound should be maintained in a horizontal position and the DERMABOND ADVANCED™ Adhesive should be applied from above the wound.

4. After opening the ampoule, gently squeeze the applicator sufficiently to moisten the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator.

5. Approximately the wound edges with gloved fingers or sterile forceps. Apply the liquid DERMABOND ADVANCED™ Adhesive to one continuous layer to the surface of the approximated wound edges using a gentle brushing motion. Maintain manual approximation of the wound edges for approximately 10 seconds after the application. The width of the layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application.

**NOTE:** DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction which is a small amount of heat is released. This increase in temperature is uncomfortable for the patient. The technique used to crush the ampoule contained within a plastic applicator. The applicator contains the sterility of the device until opened or damaged. Discard any unused material following completion of each medical procedure.

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7. Apply pressure at the midpoint of the bulb to crush the ampoule, since the liquid DERMABOND ADVANCED™ Adhesive should be applied from above the wound. DERMABOND ADVANCED™ Adhesive to unintended areas of the body, the wound should be maintained in a horizontal position and the DERMABOND ADVANCED™ Adhesive should be applied from above the wound.

8. If a second layer of DERMABOND ADVANCED™ Adhesive is applied one continuous layer onto a dry wound will minimize the sensation of heat. Applying a second layer is not required or recommended. Full adhesion strength is expected to be obtained within minutes after applying a second layer of DERMABOND ADVANCED™ Adhesive. However, the DERMABOND ADVANCED™ Adhesive layer no longer sticky.

9. Do not apply liquid DERMABOND ADVANCED™ Adhesive to soaked wound surfaces coated with DERMABOND ADVANCED™ Adhesive because these substances can weaken the polymerized film, leading to dehiscence (skin edge separation).

10. If removal of DERMABOND ADVANCED™ Adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the DERMABOND ADVANCED™ Adhesive film to help loosen the bond. Patients should be instructed that until the polymerized film of DERMABOND ADVANCED™ Adhesive has sloughed naturally (usually in 5–10 days), there should be only transient wetting of the treatment site. Patients may immediately shower or bathe the site gently as directed by the physician. The site should not be scrubbed, soaped, or exposed to prolonged wetness until after DERMABOND ADVANCED™ Adhesive has sloughed naturally and the physician has determined that the wound is adequately healed. Patients may immediately shower or bathe the site gently as directed by the physician. The site should not be scrubbed, soaped, or exposed to prolonged wetness until after DERMABOND ADVANCED™ Adhesive has sloughed naturally and the physician has determined that the wound is adequately healed. Patients may immediately shower or bathe the site gently as directed by the physician. The site should not be scrubbed, soaped, or exposed to prolonged wetness until after DERMABOND ADVANCED™ Adhesive has sloughed naturally and the physician has determined that the wound is adequately healed. Patients may immediately shower or bathe the site gently as directed by the physician. The site should not be scrubbed, soaped, or exposed to prolonged wetness until after DERMABOND ADVANCED™ Adhesive has sloughed naturally and the physician has determined that the wound is adequately healed.

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**STERILE SINGLE USE ONLY**

**TOPICAL SKIN ADHESIVE (2-Octyl Cyanoacrylate)**

**PM72434E DERMABOND ADVANCED™ non-CE IFU Codes DNX6 and DNX12**

**Labeling Specification**

**PPE Specification**

**Reorder number**

**5. Refer to the instructions on the package for crushing the ampoule.**
**TOPICAL SKIN ADHESIVE**

**(2-Octyl Cyanoacrylate)**

**DESCRIPTION**

**DERMABOND ADVANCED™ Topical Skin Adhesive** is a single patient use topical skin adhesive containing 2-Octyl Cyanoacrylate (2-Octyl CA) in a liquid form that is autoclavable. The liquid is contained within a crushable ampoule, to be dispensed using a plastic applicator that contains a light sensitive precipitant and an electron donor. When the bottle is crushed, the cyanoacrylate polymerizes to a solid bond.

**INDICATIONS**

**DERMABOND ADVANCED™ Adhesive is intended for topical application from surgical incisions, including incisions from minimally invasive procedures and laparoscopies, to hold closed easily approximated skin edges of wounds resulting from trauma, surgery, or burns.**

**CONTRAINDICATIONS**

- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g. oral cavity, naso or oral oropharynx or nasal passages, conjunctiva).
- Do not use on patients with a known hypersensitivity to 2-Octyl CA or to formaldehyde, or benzalkonium chloride.

**WARNINGS**

- **DERMABOND ADVANCED™ Adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as surgical dressings, clothing, pulls and loose hair.** Do not use on any wounds with evidence of active infection, gangrene, or necrosis.
- **DERMABOND ADVANCED™ Adhesive should not be used on wounds that have a history of delayed healing.** Do not use on any wounds where the polymerized material is not absorbed by tissue and can elude a foreign-body reaction. Avoid excessive pressure of the applicator tip against wound edges or surrounding skin. This can cause the wound edges apart and allow adhesive into the wound or surrounding skin to result in forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound.
- **DERMABOND ADVANCED™ Adhesive is intended to adhere. Use of DERMABOND ADVANCED™ Adhesive near or touching areas other than the wound edges caused some patients’ eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.

**PRECAUTIONS**

- **DERMABOND ADVANCED™ Adhesive should only be used after wounds have been thoroughly and adequately cleansed and dried.** Wounds should be monitored for signs of infection. Wounds with purulent exudate, should be evaluated and treated according to standard practice for infection.
- **DERMABOND ADVANCED™ Adhesive should not be used on wounds that will be subjected to repeated or prolonged moisture or friction.** Wounds have to have levitated and adequately cleansed and dried and should not be subject to repeated or prolonged moisture or friction.

**ADVERSE REACTIONS**

- **Intracutaneous Reactions**
  - **Excessive itching**
  - **Dehiscence (Skin Edge Separation)**
  - **Acute inflammation (erythema, edema, pain, warmth)**

Adhesive reactions related to the wound closure procedure or use of DERMABOND ADVANCED™ Adhesive as a surgical enhancer have been identified as potentially associated with the wounds closed with DERMABOND ADVANCED™ Adhesive. These reactions have been reported in postmarketing surveillance and may include:

- **Infection (more than 2 of the following)**
  - **Redness, increased warmth, swelling, induration (somewhat firm, warm) to fluctuance (a pushable, fluctuant mass) to fluctuance (a pushable, fluctuant mass) to fluctuance (a pushable, fluctuant mass)**
  - **Hyperemia (redness)**
  - **Acute inflammation (erythema, edema, pain, warmth)**

**ADVERSE REACTIONS**

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  - **Dehiscence (Skin Edge Separation)**
  - **Acute inflammation (erythema, edema, pain, warmth)**

**PRECAUTIONS**

- **Do not use on any wounds with evidence of active infection, gangrene, or wounds of delayed healing.**
### IFU PRINTING SPECIFICATION SHEET

**PAGE LAYOUT**

- **Flat Size**: 20.16” (512 mm)
- **Folded Size**: 4.03” (102.36 mm)

<table>
<thead>
<tr>
<th>TITLE</th>
<th>DESCRIPTION</th>
<th>LAB NUMBER</th>
<th>SPECIAL INSTRUCTIONS/COMMENTS</th>
<th>BINDING</th>
<th>COLORS</th>
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</thead>
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<td>Domestic IFU</td>
<td>LAB:0012189v5</td>
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| STOCK | 40 lb. Finch Opaque |

**FLAT SIZE**

- 20.16” x 5” (512 mm x 127 mm)

**BLEED SIZE**

- 5” (127 mm) x 5” (127 mm)

**DRAWING IS NOT TO SCALE:** DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

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