NOTE: DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. The width of the layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive is to be applied in one continuous layer. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer on a dry wound will result in the cessation of bleeding. If a second layer of DERMABOND ADVANCED™ Adhesive is applied or if large drops of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Avoid excessive pressure of the applicator tip against the wound edges or surrounding skin to avoid forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound. Full apposition strength is expected to be achieved within minutes after the application. Full apposition is expected at the midpoint of the bulb during application. To ensure optimal apposition, gently squeeze the applicator sufficiently to ensure the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator. DERMABOND ADVANCED™ Adhesive is available in boxes of 6 or 12 single-use applicators. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged. DERMABOND ADVANCED™ Adhesive is supplied sterile, in a pre-filled, single-use applicator. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged.

HOW SUPPLIED

The width of the layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive is to be applied in one continuous layer. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer on a dry wound will result in the cessation of bleeding. If a second layer of DERMABOND ADVANCED™ Adhesive is applied or if large drops of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Avoid excessive pressure of the applicator tip against the wound edges or surrounding skin to avoid forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound. Full apposition strength is expected to be achieved within minutes after the application. Full apposition is expected at the midpoint of the bulb during application. To ensure optimal apposition, gently squeeze the applicator sufficiently to ensure the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator. DERMABOND ADVANCED™ Adhesive is available in boxes of 6 or 12 single-use applicators. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged. DERMABOND ADVANCED™ Adhesive is supplied sterile, in a pre-filled, single-use applicator. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged.

NOTE: DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule. If a second layer of DERMABOND ADVANCED™ Adhesive is applied or if large drops of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Avoid excessive pressure of the applicator tip against the wound edges or surrounding skin to avoid forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound. Full apposition strength is expected to be achieved within minutes after the application. Full apposition is expected at the midpoint of the bulb during application. To ensure optimal apposition, gently squeeze the applicator sufficiently to ensure the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator. DERMABOND ADVANCED™ Adhesive is available in boxes of 6 or 12 single-use applicators. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged. DERMABOND ADVANCED™ Adhesive is supplied sterile, in a pre-filled, single-use applicator. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain sterility of the device until opened or damaged.
DERMABOND ADVANCED™ Adhesive may be used in conjunction with, from surgical incisions, including incisions from minimally invasive procedures. DERMABOND ADVANCED™ Adhesive is intended for topical application to facilitate healing of incisions and incision lines. Studies have shown that following application, the polymerized material will remain in place, facilitating wound healing and minimizing pain and discomfort. Applied to the skin, the liquid is syrup-like in viscosity and polymerizes rapidly within minutes. The exothermic reaction in which a small amount of heat is released may be experienced following contact with the eye. Applying a second layer is not required or recommended. If large droplets of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound will maximize the resistance of the wound to shearing forces. For wounds that are not to be closed primarily, if a second layer of DERMABOND ADVANCED™ Adhesive is applied in a second frame of liquid topical adhesive, the patient may experience an increased sensation of heat or discomfort. Adverse reactions may be experienced following contact with the eye. Reactions may occur in patients who are hypersensitive to 2-Octyl Cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.

APPLICATION

DERMABOND ADVANCED™ Adhesive is a first setting adhesive capable of adhering to most body tissue and many other materials, such as surgical glove and stainless steel instruments. The adhesive’s polymerized form is composed of a crushable ampoule contained within a plastic applicator. As it is applied to the skin, the liquid is syrup-like in viscosity and polymerizes rapidly within minutes. DERMABOND ADVANCED™ Adhesive acts as a barrier to prevent microbial penetration as well as the adhesive resists drying. See DIRECTIONS FOR USE. INSTRUCTIONS

INDICATIONS

DERMABOND ADVANCED™ Adhesive is intended for topical application only to closed, cleanly excised skin edges of wounds. It is contraindicated for use on surgical incisions, including incisions from minimally invasive procedures. DERMABOND ADVANCED™ Adhesive is not intended for use in conjunction with, but is not limited to, deep dermal injuries.

CONTRAINDICATIONS

• Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.
• Do not use on mucosal surfaces or across mucocutaneous junctions.
• Do not use on wounds that may be exposed to repetitive moisture or friction (e.g., oral cavity, lips), or on skin which may be regularly exposed to perspiration or if large droplets of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort.

WARRANTINGS

• Use only as directed. Do not use the medication in any manner that is not consistent with the directions for use in the label of the container of the drug product. See DIRECTIONS FOR USE.
• Adverse reactions may be experienced following contact with the eye. Reactions may occur in patients who are hypersensitive to 2-Octyl Cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.

ADMINISTRATION

• DERMABOND ADVANCED™ Adhesive should be used only after wounds have been thoroughly and adequately cleaned and debrided. The application site should be well irrigated, and all foreign material, debris, and necrotic tissue should be removed. The wound should be maintained in a horizontal position, with the patient’s head tilted away from the wound. DERMABOND ADVANCED™ Adhesive should be applied to unintended areas, the patient will experience an increased sensation of heat or discomfort. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound will maximize the resistance of the wound to shearing forces. For wounds that are not to be closed primarily, if a second layer of DERMABOND ADVANCED™ Adhesive is applied in a second frame of liquid topical adhesive, the patient may experience an increased sensation of heat or discomfort.

DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule because the adhesive will polymerize in air. Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND ADVANCED™ Adhesive. The use of topical medications (e.g., anesthetize, irrigate, debride, assure hemostasis, and prophylactic antibiotics) or radiation treatment (e.g., gamma or electron beam) will increase its viscosity and may render DERMABOND ADVANCED™ Adhesive within the wound or on the skin surface non-adhesive. Other agents such as petroleum jelly, alcohol, or soap are not expected to immediately loosen the bond.

PRECAUTIONS

• Use only as directed. Do not use the medication in any manner that is not consistent with the directions for use in the label of the container of the drug product. See DIRECTIONS FOR USE.
• Do not place DERMABOND ADVANCED™ Adhesive in a procedure area where it is not intended to be used. Before exposure to DERMABOND ADVANCED™ Adhesive, to prevent excessive reaction, all foreign material, debris, and necrotic tissue should be removed. The wound should be maintained in a horizontal position, with the patient’s head tilted away from the wound. DERMABOND ADVANCED™ Adhesive should be applied to unintended areas, the patient may experience an increased sensation of heat or discomfort. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound will maximize the resistance of the wound to shearing forces. For wounds that are not to be closed primarily, if a second layer of DERMABOND ADVANCED™ Adhesive is applied in a second frame of liquid topical adhesive, the patient may experience an increased sensation of heat or discomfort.

NOTE: Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound will maximize the resistance of the wound to shearing forces. For wounds that are not to be closed primarily, if a second layer of DERMABOND ADVANCED™ Adhesive is applied in a second frame of liquid topical adhesive, the patient may experience an increased sensation of heat or discomfort. Note: Gentle pressure of the applicator tip against the wound or surrounding skin can cause irritation and redness. The wound should be maintained in a horizontal position, with the patient's head tilted away from the wound. DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule because the adhesive will polymerize in air. Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND ADVANCED™ Adhesive. The use of topical medications (e.g., anesthetize, irrigate, debride, assure hemostasis, and prophylactic antibiotics) or radiation treatment (e.g., gamma or electron beam) will increase its viscosity and may render DERMABOND ADVANCED™ Adhesive within the wound or on the skin surface non-adhesive. Other agents such as petroleum jelly, alcohol, or soap are not expected to immediately loosen the bond.
**TITLE**
Dermabond Advanced™

**DESCRIPTION**
Domestic IFU

**LAB NUMBER**
LAB0012189v3

**STOCK**
40 lb. Finch Opaque

**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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