

SURGISEAL Topical Skin Adhesives

IMPORTANT SAFETY INFORMATION AND INDICATION 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

Avoid inadvertent contact with any body tissue, surface, or equipment.

SURGISEAL topical skin adhesive is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent post-operative infections.

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.

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.

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.

Sterile single patient use only. Do not re-sterilize. Discard remaining opened material after use.

Potential systemic toxicity is unknown. Application of product below skin surface will impair healing process.

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Do not apply liquid or ointment medication or other substances to the wound after closure with SURGISEAL.

Safety and effectiveness of SURGISEAL in animal or human bites, puncture or stab wounds have not been studied.

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.

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