SecurePortIV®

Catheter Securement Adhesive

Highly Purified Medical Cyanoacrylate

EN English

INDICATION FOR USE

SECUREPORTIV® Catheter Securement Adhesive is to be applied as a film forming securement and sealant at the point of vascular access catheter skin entry. The film holds the catheter to the skin to reduce catheter movement, migration, and/or dislodgment. It is used to protect the catheter skin entry site by creating a sealant that immobilizes surface bacteria, preventing them from entering into the catheter skin entry site while also providing a moisture barrier. SECUREPORTIV® is intended to be used with a transparent film dressing for the securement of short-term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.

ACTIONS

SECUREPORTIV® adhesive has been shown to immobilize bacteria in in vitro studies with gram+ and gram- bacteria and fungi including MRSA, Staphylococcus epidermidis, Pseudomonas aeruginosa, Candida albicans, and Corynebacterium pseudodiptheriticum, to prevent those inadvertently introduced from migrating into the catheter insertion site. SECUREPORTIV® also effectively seals the catheter insertion site.

WARNINGS

- SECUREPORTIV® Catheter Securement Adhesive use after application of skin preparations containing chlorhexidine gluconate (CHG) may occur only after the surface is completely dry. Inadequate surface drying may result in the film cracking or flaking.
- SECUREPORTIV® Catheter Securement 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 body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- SECUREPORTIV® Catheter Securement Adhesive is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent post-operative infections.
- SECUREPORTIV® Catheter Securement Adhesive polymerizes through an exothermic reaction in which a small amount of heat may be released. With the proper technique of applying SECUREPORTIV® Catheter Securement Adhesive, heat may be released slowly.

PRECAUTIONS

- For external use only.
- Sterile unless package is open and damaged. Do not use if the package is damaged or if the package sterility is breached.
- Recommended storage conditions are at or below 30ºC, 86 ºF, away from moisture, direct heat and direct light.
- Single use only. Do not reuse.
- Do not use if the adhesive is activated in the package, as demonstrated by a film in the package or on the applicator.
- Special care should be used when securing and removing catheters with SECUREPORTIV® Catheter Securement Adhesive in geriatric and pediatric patients with fragile skin.

CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of microbial, bacterial or fungal infections or gangrene.
- DO NOT use on mucosal surfaces or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids or with dense natural hair.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

ADVERSE REACTIONS

- Adverse reactions may occur if Catheter Securement Adhesive makes contact with the eye.
- Adverse reactions may occur to patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

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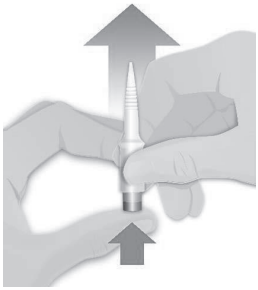
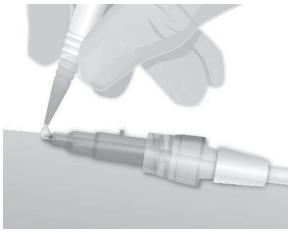
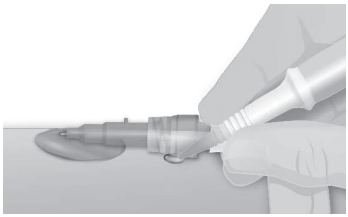


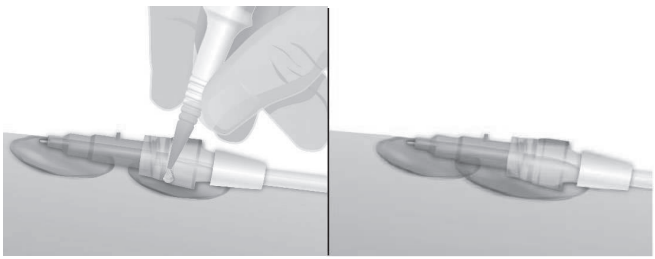
A. Point the tip towards the ceiling and away from the patient. Press the bottom of the applicator upward.



B. Invert the applicator and gently squeeze the ridges to initiate adhesive flow. Place 1-2 drops of adhesive at the catheter-skin junction.



C. Place 1-2 drops of adhesive under the catheter hub and wings (if present) if a suture or mechanical securement device will not be used. Apply gentle pressure on the hub/wings for 30 seconds to ensure securement between the catheter and the skin surface.



D. Place one drop on the top of the catheter skin junction and an additional drop on each side of the catheter hub and allow the drops to flow around the catheter. This creates the film sealant that forms the topical protective barrier to the catheter and skin insertion site.

DIRECTIONS FOR APPLICATION

1. Prep the patient at the catheter insertion site per facility protocol.
2. Insert the catheter per facility protocol.
3. Flush catheter, attach extension set, administration set and/or needleless connector per facility protocol.
4. Before application of SECUREPORTIV® adhesive allow all skin prep agents to dry thoroughly. Dry the insertion site with sterile gauze, removing all moisture for proper skin bonding to the catheter.
5. Remove SECUREPORTIV® applicator from packaging. Hold the applicator tip away from patient to prevent any unintentional placement of the liquid SECUREPORTIV® adhesive onto the patient.
6. To apply the SECUREPORTIV® adhesive, hold the SECUREPORTIV® applicator firmly at the base with the thumb and forefinger and with the applicator tip facing the ceiling, away from the patient. Push the SECUREPORTIV® ampoule until flush with the applicator base. (A)
7. Invert the applicator and gently squeeze the ridges located medially along the tapered applicator tip to initiate adhesive flow.

8. Place 1-2 drops of adhesive at the catheter-skin junction. (B)
9. Place 1-2 drops of adhesive under the catheter hub and wings (if present) if a suture or mechanical securement device will not be used. (C)
10. Apply gentle pressure on the hub/wings for 30 seconds to ensure securement between the catheter and the skin surface.
11. Place one drop on the top of the catheter skin junction and an additional drop on each side of the catheter hub and allow the drops to flow around the catheter. This creates the film sealant that forms the topical protective barrier to the catheter and skin insertion site. (D)
12. If desired, the remaining adhesive can be spread out beyond the initial coverage to increase adherence strength by placing an additional one or two drops in 4 equally spaced locations around the catheter insertion site at the outer edge of the initial adhesive coverage and spread evenly to continue even coverage outward without voids. This additional coverage is to approximate the surface area to be covered by the transparent window of the sterile dressing.
13. Apply sterile transparent film dressing per facility protocol.
    a. If additional adhesive was used as indicated in step 12, align the window area of the transparent dressing with the area covered with the SecurePortIV® adhesive.
    b. In applying the sterile window dressing, press down on the window gently (avoiding the area close to the catheter insertion site) creating contact with the adhesive and a bonding seal of the adhesive and the window surface. Next, press down on the peripheral surface of the window dressing to complete the bonding seal to the adhesive, catheter and skin.

AFTER APPLYING
SECUREPORTIV® Catheter Securement Adhesive is intended to be left on the skin and gradually wear away during the skin's natural sloughing process. Typically, this process takes 5 to 7 days. Inspect the catheter insertion site daily and change the dressing if necessary according to facility protocol. Dressing change should occur no later than day 7 after application. Reapplication has not been evaluated for long-term securement.

REMOVAL
Removal of SECUREPORTIV® Catheter Securement Adhesive may be performed quickly with a commercially available medical adhesive remover.

STORAGE
Recommended storage conditions are at or below 30ºC, 86 ºF, away from moisture, direct heat and direct light. DO NOT use after expiration date.

STERILITY
SECUREPORTIV® Catheter Securement Adhesive is terminally sterilized by ethylene oxide. SECUREPORTIV® filled ampoule component is terminally sterilized by irradiation. STERILE SINGLE USE ONLY.

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

U.S. Patent Nos. 8,652,510; 9,309,019 and D801,830

International patents: 003462308-001; ZL201630545915.0; 1580947; 1590626; 2583260; 201710041

Adhezion BIOMEDICAL®

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For most current instructions for use, please consult revision level included within the product packaging.