



Securement Without Sacrifice

3M™ PICC/ CVC Securement System - Frequently Asked Questions

What is the 3M PICC/CVC Securement System made of?

The 3M Tegaderm™ I.V. Advanced Securement Dressing features a pattern-coated adhesive on a highly breathable film. The waterproof film covers the dressing and stabilization securement tape strips. The securement device is formed from polycarbonate resin material. The silicone adhesive of the securement device provides strong yet gentle adhesion to the skin.

Do I have to use the dressing provided with the 3M Securement Device or can I use it with another dressing?

Yes, the Tegaderm™ I.V. Advanced Securement Dressing included in the system was specifically designed to enhance securement of the device, ensuring the best possible experience and outcomes.

What kind of intravascular catheters will this securement system secure and fit properly?

The 3M PICC/CVC Securement System will secure single, double and triple lumen PICCs and short-term CVCs up to and including 12 French. The securement device does not fit well on catheters without a “winged” hub, like most arterial catheters or those with a luer-lock type connection.

What do the CDC guidelines recommend for PICC or short-term CVC securement?

Catheter stabilization is recognized as an intervention to decrease the risk for phlebitis and catheter migration and dislodgement, and may be advantageous in preventing CRBSIs. Pathogenesis of CRBSI occurs via migration of skin flora through the percutaneous entry site. Sutureless securement devices avoid disruption around the catheter entry site and may decrease the degree of bacterial colonization (Yamamoto, et al, 2002). Using a sutureless securement device also mitigates the risk of sharps injury to the health care provider from inadvertent needle stick injury.

What is the definition of a short-term CVC?

A short-term CVC is classified by the FDA in 21 CFR, Section 880.5200 Intravascular catheter:

“An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings that is inserted into the patient’s vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously...The device may be constructed of metal, rubber, plastic, or a combination of these materials.”

What is the definition of a peripherally inserted central catheter (PICC)?

A CVC with placement access via a peripheral vein.

When should the dressing or device be changed?

The Securement System should be changed at least every seven days and may need to be changed more frequently with highly exudative sites or if integrity of the dressing is compromised. The securement device should be changed with each dressing change. Change the dressing when it becomes damp, loosened, or visibly soiled (CDC, 2011).

How is this securement system classified by the FDA?

The non-CHG dressing is classified by FDA in 21 CFR, Section 878.4020 Occlusive wound dressing as a Class I device which is exempt from Premarket Notification (510k). The securement device is classified by FDA in 21 CFR, Section 880.5210 Intravascular catheter securement device as a Class I device which is exempt from Premarket Notification (510k).

Is the silicone adhesive the same used in 3M Kind Removal Silicone Tape?

This silicone adhesive provides stronger adhesion for securing critical tubing than the silicone adhesive found in 3M Kind Removal Silicone Tape, while still removing gently.

Will this system be available with Tegaderm™ CHG I.V. Securement Dressing?

The 3M PICC/CVC Securement Device + Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing is currently undergoing premarket review (pending 510k) by the FDA to be used to secure PICCs and short-term CVCs to the skin and cover and protect catheter insertion sites. The proposed intended use of the device is to accommodate the majority of single, double and triple lumen CVC catheters up to and including 12 French.

Is this system compatible with other antimicrobial dressings or sponges? Yes.

Can this system be used in combination with sutures?

The 3M PICC/CVC Securement System was designed to replace sutures. The 2011 CDC Guidelines recommends the use of a sutureless securement device to reduce the risk of infection for intravascular catheters (Yamamoto, et al, 2002).

Can the dressing be used if the site is bleeding or oozing?

If the site is bleeding or oozing, use a gauze dressing until this has resolved (CDC, 2011). Refer to facility protocol.

Does the 3M PICC/CVC Securement System fit with an Arrow™ Box Clamp?

Yes, the securement system will fit with a catheter that has an Arrow™ Box Clamp. Secure any additional catheter length per facility protocol.

Can the Securement System be used with a variety of antimicrobial skin preps and skin protectants?

Yes, however, antimicrobial ointments containing polyethylene glycols may compromise the film strength of the Tegaderm™ I.V. Advanced Dressing. Testing indicates the 3M Securement System is safe to use with antiseptic preps: 70% Isopropyl Alcohol, Povidone Iodine, and Chloraprep-2% CHG (3M data on file). Testing indicates the Securement System is safe to use with 3M™ Cavilon No Sting Barrier Film, a skin protectant that is chemically compatible with CHG and provides superior skin protection to adhesive trauma compared to other skin protectants.

What clinical information and studies have been performed on this product?

Pre-market evaluation has been conducted; included over 20 hospitals and 130 evaluators. Additional evidence is available on the 3M Securement System website (3M.com/Securement) and in the product brochure, which includes 3M internal clinical studies, such as a 2.5 pound drop test and peak axial pull force testing.

Please explain the repositionable attributes of the securement device.

Based on 3M internal clinical studies, the securement device may be repositioned at the time of initial application without a reduction in securement.

Is the 3M PICC/CVC Securement System MRI-compatible? Yes, the Securement System is compatible with MRI. This product does not contain metal or conductive materials, which have been found unsafe for use in MRI.

References

1. Centers for Disease Control and Prevention (CDC). Guidelines for the prevention of intravascular catheter-related infections. 2011.
2. Yamamoto A., Soloman J., Soulen M., et al. Sutureless securement devices reduces complication of peripherally inserted central venous catheters. J Vascular Interventional Radiology. 2002; 13 (1): 77-81.
3. O'Grady, N. et al. (2011). Guidelines for the preventions of intravascular catheter-related infections. Retrieved from http://www.cdc.gov/hicpac/BSI/BSF_guidelines-2011.htm.
4. Reuter H. et al. (2009). Comparative study of the Skin Protectant performance barrier films.

Critical & Chronic Care Solutions Division

3M Health Care

3M Center, Building 275-4W-02

St. Paul, MN 55144-1000

1-800-228-3957

www.3M.com/healthcare

3M and Tegaderm are trademarks of 3M

Please recycle. Printed in USA

© 3M 2013. All rights Reserved

70-2010-9374-0

