

What is the SecurAcath made of?

The flexible securement feet are made of Nitinol which is a shape-memory alloy of nickel and titanium. Nitinol is used in several medical devices including self-expanding stents and IVC filters. The plastic is polypropylene and elastomer. The SecurAcath is not made with natural rubber latex.

What catheters can SecurAcath be used on?

SecurAcath has successfully been utilized on a variety of percutaneous catheters. Indications for use vary by geography. Refer to the IFU for your area. SecurAcath is available in eight sizes from 3-12 Fr.



How long can the SecurAcath remain in place?

The SecurAcath can remain in place for the entire catheter dwell time. The longest known SecurAcath dwell has been on a tunneled catheter secured for over four years.

Do the securement feet beneath the skin hurt or cause discomfort to the patient?

No. When properly inserted in the subcutaneous tissue beneath the skin, the patient should not experience any discomfort. Pain receptor nerves are mainly located in the dermis, not in the subcutaneous tissue. Patients in a SecurAcath clinical study were asked to rate their pain on a scale of 0-10 (zero being no pain). The average score while device is indwelling was 0.8, and on removal was 1.51. The data supports that the device is comfortable for patients. Proper positioning of the device on the skin and dressing application is key to avoid pain or discomfort. The SecurAcath should not be twisted, rotated, or repositioned from the original placement position. The dressing should not be stretched tightly over the device and insertion site.



Can the securement feet damage the catheter?

No. The securement feet are blunt, rounded, polished and flexible. There are no sharp edges on the SecurAcath device. Extensive testing has been performed to demonstrate the securement feet do not cause damage to the catheter.

What happens if the catheter and SecurAcath are accidentally pulled out?

The SecurAcath feet will pull out of the skin without causing damage to the tissue. The securement feet are rigid enough to hold the device in place but also flexible enough to not cause skin damage if extreme tension or pulling on the device occurs. The feet will come out through the existing skin puncture and will not create trauma even when the skin is frail. If there is extreme tension on the catheter, the catheter outer diameter may change due to stretching and may lead to slipping in the device. This can be prevented with proper dressing application and dressing management and ensuring the catheter suture wings are under the dressing. Proper dressing management and appropriate positioning of SecurAcath have demonstrated it is possible to reduce dislodgments to 0%².



Can the SecurAcath be used on patients with frail skin?

Yes. The SecurAcath has been used on a variety of skin conditions including the elderly, neonates, burn patients and chronic steroid patients and has performed very well. As indicated in the 2021 INS Standards of Practice, SecurAcath may be a good option for patients with compromised skin integrity³.

Can the SecurAcath be removed before the catheter is removed?

Yes. It is possible to remove the device while the catheter is still in place. However, it is easier to remove the device after the catheter is removed. Please see our website for removal videos.



Does the SecurAcath increase risk for air embolism during removal?

No. The SecurAcath does not increase the chance for an air embolism when removing the device. Standard practice should be followed when removing the catheter. Hold pressure at the insertion site as catheter is removed and then maintain pressure until hemostasis is achieved. Once hemostasis is achieved, the SecurAcath can be removed. Please see our website for removal videos.

Can a patient have an MRI with the SecurAcath?

Yes. SecurAcath is compatible with MRI up to 3 Tesla (3T). Current MRI terminology for medical devices are: safe, conditional or unsafe. The SecurAcath has been tested and poses no hazards in typical MRI conditions. Additional details can be found in the Instructions for Use.



Can I use the SecurAcath on a patient with nickel sensitivity?

The SecurAcath Instructions for Use include a warning not to use the device in patients with a known nickel allergy. An estimated 5-10% of the population is said to be allergic to nickel.⁴ The allergic response usually presents as contact dermatitis caused by exposed nickel contained in the metal of some jewelry. If a patient reports they have a nickel allergy, it is important to understand the difference between Nitinol and other nickel containing alloys. The Nitinol in the SecurAcath undergoes a process called electropolishing during manufacturing. When electropolished, Nitinol forms a stable protective layer known as passivated nitinol. Electropolished nitinol has excellent biocompatibility, similar to that of stainless steel, which also contains nickel. Unpassivated metal alloys, like those used in inexpensive jewelry, have free nickel ions exposed on the surface, which can cause a hypersensitivity response on the skin. Consider the risks and consequences of skin adhesive reactions, device migration, catheter tip malposition, and dislodgement versus a potential reaction to nickel. Be aware the SecurAcath device can be removed if skin sensitivity or reaction is observed during dwell time.

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Can I use the antimicrobial or hemostatic protective disc with the SecurAcath?

Yes, the design of SecurAcath allows space for the disk products to fit 360 degrees around the insertion site.

Can I use Tegaderm CHG with the SecurAcath?

Yes, Tegaderm CHG can be used with the SecurAcath. SecurAcath is compatible with all types of adhesive dressings used for vascular access devices and catheters.



Can I use tissue adhesive (cyanoacrylate, glue) with SecurAcath?

Yes, we recommend applying the glue while holding the device in the upright position with slight tension, apply the glue per instructions for use, let dry, then lay it down.

How do I disinfect the site?

The SecurAcath allows for 360-degree cleaning of the skin and we recommend you use your institution's preferred skin antiseptic, including but not limited to CHG/Isopropyl Alcohol, Betadine, etc.



Does the SecurAcath affect the risk of catheter-related infection?

A recently published study out of the University of Arkansas for Medical Sciences showed the SecurAcath reduces the risk of CLABSI compared to an adhesive securement device. The study examined 7,776 PICC cases over a 4-year period. The analysis showed the adhesive securement device had a 288% increase in risk of CLABSI compared to SecurAcath.⁵ The author postulates that improved catheter stability and site cleaning attributed to the significant improvement in CLABSI risk.

What if blood gets into the SecurAcath device?

The SecurAcath has been designed to minimize the ability for blood to get into the device with a seal around the edge of the device. If blood is visible on the SecurAcath, use sterile saline soaked gauze to clean the blood off the device. Saline dissolves blood better than an alcohol-based cleaning solution. Once the visible blood is removed, disinfect using standard skin antiseptic solutions such as 2% CHG/70% IPA. We have performed bench testing demonstrating that even if blood gets inside the device, the skin antiseptic agent, being less viscous than blood, will go wherever the blood goes to effectively disinfect the device.

Does SecurAcath cause bleeding at the insertion site?

SecurAcath is atraumatic and does not puncture or breach the skin or vessels to cause bleeding. It rests in the same puncture site as the catheter and the feet deploy in the subcutaneous tissue just beneath the dermis. Exit site bleeding that is observed in certain patient populations can be easily managed with pressure and several tools already in your hospitals like cyanoacrylate tissue adhesive or hemostatic dressings.



Can you use SecurAcath in neonates and pediatric patients?

Yes. Several studies have demonstrated that SecurAcath performs very well for securing percutaneous devices in these populations.^{6,7,8,9,10}

Can you place SecurAcath in a patient with shallow veins (<1cm) or cachectic patients?

Yes, the SecurAcath has been used successfully in a wide variety of patients, including those with shallow veins and very low body fat. The securement feet are small and blunt and will deploy in the subcutaneous space between the dermis and the vein even when there is less subcutaneous tissue than normal.

Do we need to adjust the size of SecurAcath we use to accommodate the taper on some catheters?

SecurAcath is designed to work on both tapered and non-tapered catheters. There is no need to adjust the SecurAcath size to accommodate the larger diameter on the taper. Select the appropriate size SecurAcath device to match the labelled catheter diameter. If the catheter is labeled with a half French size, use the closest smaller size SecurAcath, e.g. with 8.5F catheter, use 8F SecurAcath.

- 1 Egan GM, Siskin GP, Weinmann R, et al. A prospective postmarket study to evaluate the safety and efficacy of a new peripherally inserted central catheter stabilization system. *J Infus Nurs* 2013;36:181-8. DOI: 10.1097/NAN.0b013e3182893690
- 2 McParlan D, Edgar L, Gault M, Gillespie S, Menelly R, Reid M. Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement. *The Journal of Vascular Access*. 2020;21(1):33-38. doi:10.1177/1129729819851059
- 3 Gorski LA, Hadaway L, Hagle ME, et al. Infusion therapy standards of practice. *J Infus Nurs*. 2021;44(suppl 1):S1-S224. doi:10.1097/NAN.0000000000000396
- 4 <http://www.nature.com/news/2010/100815/full/news.2010.407.html>
- 5 <https://doi.org/10.1016/j.ajic.2020.06.178>
- 6 Rodriguez Perez C, Romitti MG, Pezzotti E, D'Andrea V, Pezza L, Pittiruti M. Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonates with Pleural Effusion: Three Case Reports. *Case Rep Pediatr*. 2020 Mar 10;2020:7480483. doi: 10.1155/2020/7480483. PMID: 32231838; PMCID: PMC7086429.
- 7 Cellini, et al. Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with onco-hematological disease, *The Journal of Vascular Access*, Nov 2020
- 8 Barone, et al. Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein, *Journal of Vascular Access*, June 2020
- 9 Frassanito, et al. Securing CSF catheters to the skin: from sutures and bolt system to subcutaneous anchoring device towards zero complications, *Child's Nervous System*, June 2020
- 10 Fitzsimmons, et al. An observational study of the securement of central venous access devices with a subcutaneous anchor device in a paediatric population at a tertiary level hospital, *Journal of Vascular Access*, May 2020



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