



What is the SecurAcath made of?

The securement feet are Nitinol which is a flexible, shape-memory nickel/titanium alloy. Nitinol is used in a number of medical devices including self-expanding stents and IVC filters. The plastic is polypropylene and elastomer. The SecurAcath is latex-free.

How long can the SecurAcath remain in place?

The SecurAcath can remain in place for the life of the catheter. It is approved for long-term catheter dwell. So far, the longest SecurAcath dwell has been on a PICC secured for over two years with no issues.

Do the securement feet beneath the skin hurt?

No, it is placed in the subcutaneous tissue beneath the skin. Pain receptor nerves are located in the dermis, not in the subcutaneous tissue. Patients in the 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 1.5. The data supports that the device is comfortable for patients.

Can the securement feet damage the catheter?

No, the securement feet are blunt and flexible. Bench testing has been performed to show the feet do not damage the catheter.

What happens if the catheter is accidentally pulled out?

The flexible securement feet flex out as they are pulled out without causing trauma to the skin.

How well does the SecurAcath hold?

The securement feet hold to a pull force of 5-7 pounds. Bench testing shows the SecurAcath holds better than the Statlock device. Sutures can have a higher pull force, however, sutures can be highly variable because the hold force is dependent on the suture type, suturing technique, knot tying, and skin integrity. Sutures have known issues with suture site infections, redness, irritation, and erosion.

Can the SecurAcath be used on patients with frail skin?

Yes, the SecurAcath has been used on a variety of skin conditions including the very elderly, burn patients and chronic steroid patients and has performed very well. The SecurAcath may be a good option for patients with compromised skin.

Can the SecurAcath be removed before the catheter is removed?

It is possible to remove the device while the catheter is still in place. It may not be as comfortable for the patient. It is easier to remove the device after the catheter is removed.

Is the SecurAcath MRI compatible?

It is ok to send patient to MRI. Current MRI terminology for medical devices are: safe, conditional or unsafe. The old term "compatible" is the same as "conditional". The SecurAcath device is MRI conditional. An MRI conditional device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. 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. 5-10% of the population is estimated to be allergic to nickel. The allergic response usually presents as contact dermatitis caused by exposed nickel contained in the metal of costume jewelry. If a patient believes 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 that acts as a barrier against ion exchange, protecting against nickel release, this is 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 hypersensitivity is observed during dwell time.

Can I use the Biopatch with the SecurAcath?

Yes, the SecurAcath is designed to allow space for the Biopatch to fit.

Can I use Tegaderm CHG with the SecurAcath?

Yes, Tegaderm CHG can be used with the SecurAcath.

Does the SecurAcath increase risk for air embolism during removal?

The SecurAcath does not increase the chance for an air embolism when removing the catheter and 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 using either the fold base or cut base removal methods.

Do the securement feet being in the same opening with the catheter cause any infection risk?

The feet being placed alongside the catheter in the same insertion site does not appear to be an issue and actually provides a couple of major benefits. One benefit is improved stability. The feet secure the catheter right at the insertion site and does not allow the catheter to "piston" or move in and out of the tissue. This reduction in movement helps to keep bacteria from getting below the skin on the catheter shaft. The stability also allows the skin to heal very well at the insertion site and act as a natural barrier to infection.

The second benefit is improved site cleaning. The subcutaneous feet allow the SecurAcath device to be lifted up and cleaned underneath. Improved site cleaning minimizes bacteria present on the skin near the insertion site. We believe improved stability and site cleaning may lead to a reduction in catheter-related infections.

Do you have data on infection rates?

A clinical study was run to evaluate the clinical performance of the SecurAcath device. The study enrolled 142 patients. The SecurAcath clinical study was not a comparative, randomized study and was not powered to be able to provide comparative data for any complications such as infection rates.

We believe the data suggests that the SecurAcath device does not create an infection risk. There was only one CRBSI reported in the SecurAcath clinical study. It is not known if the SecurAcath was related to the infection or not, but because the device was on the catheter it was reported. We have not received any information from sites using the SecurAcath that they have had any increase in CRBSI.

What if blood gets into the SecurAcath device?

The SecurAcath has been designed to minimize the ability for blood to get into the device. There is a seal around the edge of the device. If blood is visible on top of the cover, use sterile saline soaked gauze to clean the blood off the device. Saline dissolves blood better than alcohol based solution. We have performed bench testing demonstrating that even if blood gets inside the device, the CHG or cleaning agent, being less viscous than blood, will go wherever the blood goes to effectively clean the device.

Teleflex/Arrow has supplied a catheter clamp with their CVCs for many years. The clamp is usually sutured down near the catheter insertion site. The clamp has also had blood present on and inside it, but has not been shown to cause an increase in catheter infections.



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