Instructions for Use

Product Description
The SecurAcath is a subcutaneous catheter securement system. The device utilizes a small anchor (securement feet) placed just beneath the skin at the catheter insertion site and attached to the catheter shaft. The SecurAcath is designed for round-shaft catheters.

Indications
The SecurAcath device is indicated for catheter securement to the access site by means of subcutaneous anchors in:
- Short or long-term securement of percutaneous indwelling catheters for intravenous use
- Short or long-term securement of percutaneous indwelling catheters for abscess/general drainage

Contraindications, Warnings and Precautions

Contraindications
The device is contraindicated whenever:
- Skin integrity deemed unfavorable by the operator, e.g. friable skin due to chronic steroid use, presence of cellulitis or rashes at the desired site of catheter insertion
- Local tissue factors will prevent proper device stabilization and/or access
- The presence of device-related infection, bacteremia, or septicemia is known or suspected
- The patient’s body size is insufficient to accommodate the size of the implanted device
- The patient is known or is suspected to be allergic to materials contained in the device
- Past irradiation of prospective insertion site

Warnings
Intended for Single Patient Use. DO NOT REUSE. Reuse may lead to SAE and device malfunction
- This product contains nitinol. Do not use in patients with known nickel allergy
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations

Precautions
- Carefully read and follow all instructions prior to use
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
- Only qualified health care practitioners should insert, manipulate and remove these devices
- Follow universal precautions when inserting and maintaining the catheter
- Do not attempt to remove the catheter when the SecurAcath device is securing the catheter
- Do not twist or rotate the device after securement
- SecurAcath device should be removed when the catheter is removed

Possible Complications
The potential exists for serious complications including the following:
- Bleeding
- Brachial Plexus Injury
- Catheter Erosion Through the Skin
- Catheter Related Sepsis
- Insertion Site Infection or necrosis
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration or Perforation of Vessels or Viscus

Preparation for Use
Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened, or the expiration date has passed.
CAUTION: Product cannot be resterilized.

Placement Instructions
1. Place catheter following standard procedure
   NOTE: The SecurAcath requires a minimum of 3cm of catheter shaft exposed above the skin surface. The back end of the SecurAcath device should not be placed beyond the zero mark on the catheter or closer than 1cm from the catheter hub.
   NOTE: A dermatotomy is not required, however, if performed it should be less than 3mm.
2. Select the appropriate size SecurAcath device to match the catheter diameter. If catheter is not a whole French size, use the closest smaller size SecurAcath (i.e. with 8.5F catheter use 8F SecurAcath)
3. Fold the base downward until the feet come together
4. Lift the catheter off the skin surface to visualize the insertion site on under side of catheter
5. Hold the folded base at an angle, aiming the tips of the feet at the insertion site. Insert and advance a few millimeters into the subcutaneous tissue
   NOTE: If the insertion site is not large enough to insert the feet, use one hand to stretch the skin or use the tip of a dialator to widen the insertion site
6. Orient the base in the direction you want the catheter to lie. A maximum angle of 45 degrees in either direction from center is recommended. The base should lie on stable tissue and away from areas of flexion such as joints.
7. Release the base to allow it to open
8. Unfold the base until it is flat
9. Gently pull the base to be sure the feet are fully open under the skin
10. If the feet appear to be overlapping slightly, gently move the base back and forth to allow them to open fully

MRI Information
Non-clinical testing demonstrated that the SecurAcath Device with Nitinol Securement is MR Conditional*. A patient with this device can be scanned safely immediately after placement under the following conditions:
- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

*MR Conditional as defined in ASTM F 2503-05
11. Align the catheter with the groove in the base.
   - Be sure the catheter shaft and base are clean and dry

12. Place the cover on the base by pressing down on cover while holding base to affix the device to the catheter shaft. Visually inspect the edges of the SecurAcath to make sure the cover is fully engaged with the base. There should be no gap along the edge of device.
   - Note: Flush the catheter lumens to assure patency

13. Adjust catheter length (optional) Remove the cover, adjust catheter position, replace the cover.

14. Record on the patient’s chart the indwelling catheter length as to

15. Dress catheter site per hospital protocol
   - NOTE: Be sure to stabilize catheter hub under the dressing to prevent pulling or kinking of catheter outside the SecurAcath device.
   - Do not turn or twist the SecurAcath from its original position while cleaning the insertion site.

Cleaning the Insertion Site
- Follow Infusion Therapy Standards of Practice and hospital protocol for catheter site maintenance.
- Use 3ml or larger 2% chlorhexidine gluconate (CHG)/70% isopropyl alcohol applicator or povidone iodine swabs as an antiseptic solution.
- Follow antiseptic solution manufacturer’s labeled directions for application.
- Gently lift the catheter and SecurAcath device to clean around the catheter insertion site.
- Do not twist or rotate the SecurAcath device from its original position while cleaning the insertion site.
- Flood insertion site area and SecurAcath device with antiseptic solution.
- Ensure the antiseptic solution is applied to all exterior surfaces of the device.
- Scrub skin around entry site. Use repeated back and forth strokes of the applicator for a minimum of 30 seconds. Completely wet the area with antiseptic solution.
- Allow area to air dry. Do not blot or wipe away.
- Dress catheter site per hospital protocol
   - NOTE: Be sure to stabilize catheter hub under the dressing to prevent pulling or kinking of catheter outside the SecurAcath device.
   - Do not apply dressing too tightly or it may create pressure on SecurAcath device which may cause patient discomfort.

If catheter or securement feet dislodge
- If the catheter or securement feet dislodge, do not reinsert the catheter.
- Temporarily secure the catheter and assess if catheter must be removed and replaced.

Removal Procedure
- Remove dressing.
- Grip the HOLD tab on SecurAcath device with thumb and finger of one hand to stabilize device.
- Pry upward at edge of LIFT tab with the other hand to release the cover from the base.
- Remove the cover completely from the base.
   - WARNING: Do not attempt to remove the catheter when cover is attached and feet are deployed.
- Remove the catheter. Do not use excessive force.
- Hold pressure at the insertion site until hemostasis is achieved and while removing SecurAcath feet.
   - Note: If site is scabbed or has adhesions/tissue growth, apply saline soaked sterile gauze to the site for a few minutes to ease removal.

Option 1—Fold Base
- Apply firm pressure at insertion site with one hand.
- Use other hand to fold wings downward to bring feet together under the skin.
- Place a third finger under device to help begin folding motion.
- Hold folded base horizontal to the skin.
- Use a swift, deliberate upward motion to remove following the shape of the feet.

Option 2—Split Base
- Use a blunt-tip scissors to cut the base completely in half lengthwise along the groove
- The flexible feet are shaped like an “L” with the feet extending 5mm to each side of the insertion site.
- Apply firm pressure at the insertion site with one hand.
- Turn blue edge upward and use a swift, deliberate upward motion to remove each foot separately following the shape of the foot.