securAcath®

Subcutaneous Catheter Securement System

Instructions for Use

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

Indications
The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

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 in place
- Do not twist or rotate the device after securement

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

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.

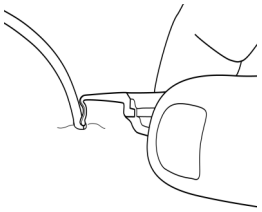
During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.
MR image quality may be compromised if the area of interest is in the exact same area or relatively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

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
   NOTE: A dermatotomy of approximately 3mm made parallel to the shaft of the catheter is recommended

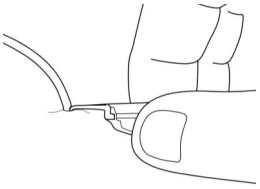
2. Select the appropriate size SecurAcath device to match the catheter diameter. If catheter is labeled with half French size, use the closest smaller size SecurAcath (i.e. with 8.5F catheter use 8F SecurAcath)



3. Fold the anchor base downward until anchor tips come together

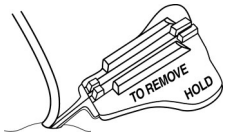
4. Lift the catheter until it is perpendicular to the skin surface to visualize the insertion site on under side of catheter

5. Hold the folded anchor base sideways and insert anchor tips into the insertion site until curved segment is no longer visible
   NOTE: If the insertion site is not large enough to insert the anchor, use one hand to stretch the skin or use the tip of a dialator to widen the insertion site



6. Align anchor base with catheter shaft

7. Release the anchor base to allow it to open



8. Unfold the anchor base until it is flat

9. Gently pull the anchor base to be sure the anchors are fully open under the skin

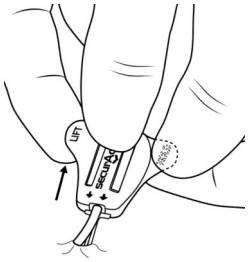
10. If anchors appear to be overlapping slightly, gently move the anchor base back and forth to allow them to open fully

11. Align the catheter with the groove in the anchor base.
    - Be sure the catheter shaft and anchor base are clean and dry
12. Place the cover on the anchor 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 centimeter markings on the catheter where it enters the skin. Frequent visual reassessment should be made to ensure the catheter has not moved
15. Dress catheter site per hospital protocol
    NOTE: Be sure to stabilize catheter hub to prevent pulling or kinking of catheter outside the SecurAcath device. Do not turn or twist the SecurAcath from its original position. Do not apply dressing too tightly or it may pull on SecurAcath device which may cause patient discomfort
13. Attach the included product information tag to the catheter extension tube

Removal Procedure

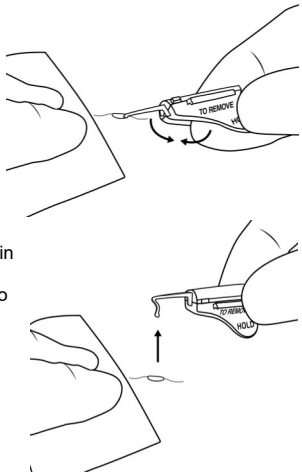
- Remove dressing
- Grip the HOLD tab on SecurAcath device with thumb and finger of one hand to stabilize device
- Pry upward at edge of LIFT tab with the other hand to release the cover from the anchor base
- Remove the cover completely from the base.
  WARNING: Do not attempt to remove the catheter when cover is attached and anchor is deployed
- Remove the catheter. Do not use excessive force
- Hold pressure at the insertion site until hemostasis is achieved and while removing SecurAcath anchor base



Note: If site is scabbed or has adhesions/tissue growth, apply saline soaked sterile gauze to the site for a few minutes to ease anchor removal

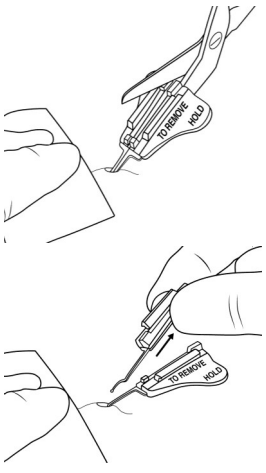
Option 1—Fold Base

- Hold pressure at insertion site with one hand
- Use other hand to fold the edges of the anchor base downward. Place a third finger under device to help begin folding motion
- Hold folded anchor base horizontal to the skin and lift the anchor out of the skin insertion site
- A swift, deliberate tug may be needed to remove the anchor



Option 2—Cut Base

- Use a blunt-tip scissors (Metzenbaum, Mayo or similar) to cut the anchor base completely in half lengthwise along the groove
- The flexible anchors 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 finger right above the anchor foot
- Use a swift, deliberate tug to remove each half of the anchor base separately
- Pressure right at the site with a finger above the anchor foot keeps the tissue still and causes the anchor to flex as it is pulled out without causing tearing or trauma to the tissue



Cleaning the Insertion Site

- Follow Infusion Nursing Society 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 cleaning agent. Ensure the cleaning agent 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 cleaning agent
- Allow area to air dry. Do not blot or wipe away
- Dress catheter site per hospital protocol
  NOTE: Be sure to stabilize catheter hub to prevent pulling or kinking of catheter outside the SecurAcath device. Do not apply dressing too tightly or it may pull on SecurAcath device which may cause patient discomfort

If catheter or anchor dislodges

If the catheter or anchor dislodges, do not reinsert the catheter. Secure the catheter and assess if catheter can be re-secured, repositioned or must be removed and replaced with a new catheter.

24 Hour Clinical Information Line
1-800-225-0000

MR	MR Conditional
	Use by date
	Single use only
STERILE EO	Sterilized by Ethylene Oxide
	Refer to IFU for more information
	Do not re-sterilize
Rx ONLY	Prescription Use Only
EC REP	Authorized Representative in the EEA
	Manufacturer
	Refer to IFU
USA	USA Clinical Support Line
LATEX	Not made with Natural Rubber Latex
	Do not use if package is damaged

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