securAcath®

Subcutaneous Catheter Securement System

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 then attached to the catheter shaft. The SecurAcath is designed for round-shaft catheters and will secure a round shaft catheter right at the insertion site while remaining in place for the entire catheter dwell.

Expected Clinical Benefits
- Reduced catheter-related infections
- Decreased catheter movement and dislodgements
- Improved efficiency
- 360-degree catheter site cleaning while secured
- Eliminates suture needlesticks

Indications
The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters 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 with appropriate training 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

MRI Information
Non-clinical testing demonstrated that the SecurAcath Device is MR Conditional*. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the SecurAcath is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the SecurAcath extends approximately 4-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

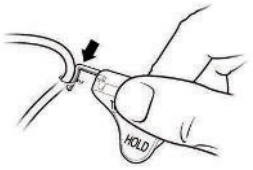
* MR Conditional as defined in ASTM F2503-20

Preparation for Use
Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is sterilized via Ethylene Oxide, 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

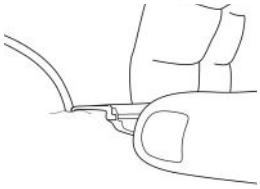
1. Place catheter following standard procedure
   NOTE: The SecurAcath requires a minimum of 3cm of catheter shaft exposed above the skin surface. The back end of the SecurAcath device should not be placed beyond the zero mark on the catheter or closer than 1cm from the catheter hub.
   NOTE: A dermatotomy is not required, however, if performed it should be less than 3mm.
   NOTE: Catheters made of soft materials (i.e. silicone) can stretch and elongate at low tension forces which reduces the catheter's outer diameter and decreases the SecurAcath holding force.

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)

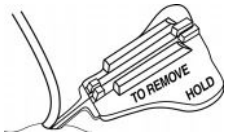


3. Fold the base downward until feet come together

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 feet 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.

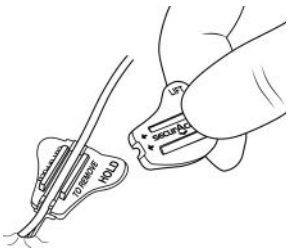
7. Release the base to allow it to open

8. Unfold the base until it is flat

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

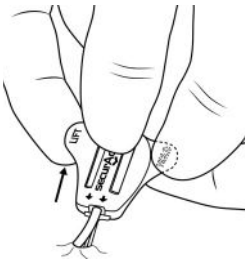
10. If the feet appear to be overlapping slightly, gently move the base back and forth to allow them to open fully

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



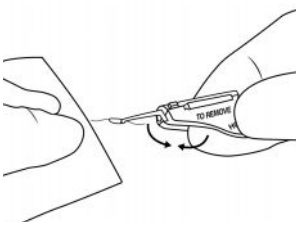
13. Adjust catheter length (optional) Remove the cover, adjust catheter position, replace the cover
14. Record on the patient's chart the indwelling catheter length as to centimeter markings on the catheter where it enters the skin. Frequent visual reassessment should be made to ensure the catheter has not moved
15. Dress catheter site per hospital protocol
    NOTE: Be sure to stabilize catheter hub under the dressing to prevent pulling or kinking of catheter outside the SecurAcath device. Catheter slippage within the SecurAcath device can be mitigated by stabilizing the catheter and suture wings under the dressing to minimize tension forces on the catheter. Do not turn or twist the SecurAcath from its original position. Do not apply dressing too tightly or it may create pressure on SecurAcath device which may cause patient discomfort.

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

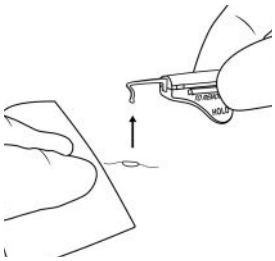
NOTE: If site is scabbed or has adhesions/tissue growth, apply saline soaked sterile gauze to the site for a few minutes to ease removal



Option 1—Fold Base

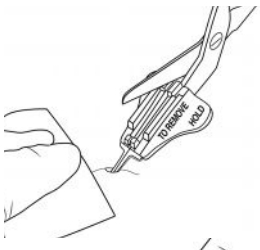
- Apply firm pressure at insertion site with one hand
- Use other hand to fold wings downward to bring feet together under the skin. Place a third finger under device to help begin folding motion
- Hold folded base horizontal to the skin
- Use a swift, deliberate upward motion to remove following the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

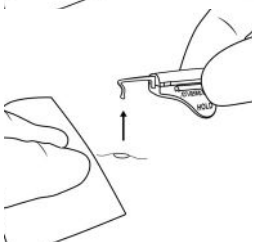
NOTE: If difficulty in removal is experienced, use Option 2 (below).



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





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 until perpendicular to the skin 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. Catheter slippage within the SecurAcath device can be mitigated by stabilizing the catheter and suture wings under the dressing to minimize tension forces on the catheter. Do not turn or twist the SecurAcath from its original position. 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. Any serious incident relating to SecurAcath should be reported to Interrad Medical and the competent authority of the Member State.

MR	MR Conditional
	Use by date
	Single use only
	Non-pyrogenic
STERILE EO	Sterilized by Ethylene Oxide
MD	Medical Device
	Do not re-sterilize
Rx Only	Prescription Use Only
EC REP	Authorized Representative in the EEA
	Manufacturer
	Date of manufacture

	Refer to IFU
	eIFU Indicator
USA	USA Clinical Support Line
LATEX	Not made with Natural Rubber Latex
	Do not use if package is damaged and refer to Instruction for Use
LOT	Batch code
REF	Catalogue number
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Consult instructions for use
	Model number

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