



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 5F or 7F 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.**
- 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 anchor is deployed.
- Do not twist or rotate the catheter hub 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

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 and insert anchor tips in the insertion site until curved segment is no longer visible

NOTE: If the insertion site is not large enough to allow the anchor to fit, use the tip of a dilator to widen the insertion site

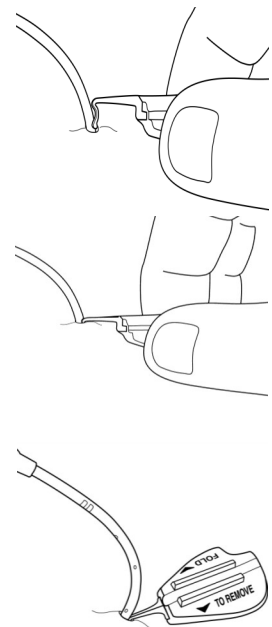
6. Align anchor base with catheter shaft

7. Release the anchor base to allow it to open

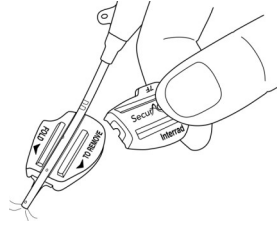
8. Unfold the anchor base until it is flat

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

10. Verify anchors are not stacked or crossed over one another

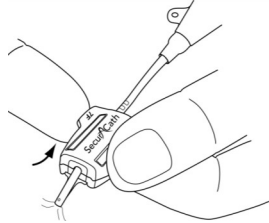


11. Align the catheter with the groove in the anchor base.
 - Be sure the catheter shaft and anchor base are clean and dry
12. Place the cover on the anchor base by pressing down on cover while holding base to affix the device to the catheter shaft. Be sure the cover is fully engaged with the base. There should be no gap along the edge of device.
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. Attach the included product information tag to the catheter extension tube.

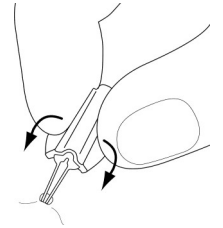


Removal Procedure

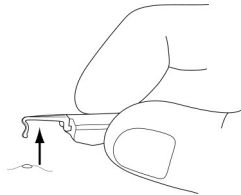
- Remove dressing.
 - Grasp edge of the SecurAcath device with one hand to stabilize device.
 - Lift the tab on the opposite edge of the cover with the other hand to release the cover from the anchor base.
- WARNING:** Do not attempt to remove the catheter when cover is attached and anchor is deployed
- Remove the catheter slowly. Do not use excessive force.



- After the catheter is removed, fold the edges of the anchor base downward



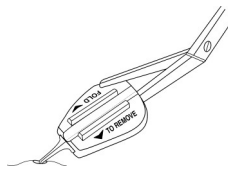
- Hold folded anchor base horizontal to the skin and lift the folded anchor base out of the skin insertion site



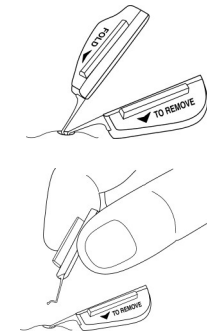
Alternative Removal Procedure

If the anchor cannot be easily removed using the method described above, the following alternative method may be used:

After the catheter is removed, use a scissors to cut the anchor base in half lengthwise along the groove



Remove each half of the anchor base separately



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 hub to clean around the catheter site.
- Do not twist or rotate the hub of the catheter 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.

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.

Symbols

	MR Conditional
	Use by date
	Single use only
	Sterilized by Ethylene Oxide
	Refer to IFU for more information
	Do not re-sterilize
	Prescription Use Only
	Authorized Representative in the EEA
	Manufacturer

Interrad and SecurAcath are trademarks of Interrad Medical, Inc. U.S. Patents 6,695,861, 7,931,658, 7,935,127, 7,753,889, 8,016,794, 8,016,813. European patents EP1539002, EP2002857. Additional patents pending.

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