1438-005

REPORT, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Rev 03

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1 PURPOSE

1.1 This Summary of Safety and Clinical Performance (SSCP) report is presented in accordance with EU MDR 2017/745, Article 32 and MDCG 2019-9 and is intended to provide public access to a summary of the main aspects of the safety and clinical performance of the SecurAcath device.

1.2 This SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the SecurAcath nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients

1.3 The following information is intended for users/healthcare professionals. Immediately following this section, there is a section intended for patients.

2 DEVICE IDENTIFICATION AND GENERAL INFORMATION

2.1 Device Trade Name(s):

SecurAcath Universal 1.4 (SecurAcath u1.4), Packaged and Sterilized

2.2 Manufacturer's name and address:

Interrad Medical, Inc.
181 Cheshire Lane
Suite 100
Plym*outh, MN 55441*

2.3 Manufacturer's single registration number (SRN):

US-MF-000009878

2.4 Basic UDI-DI:

Cat. No.	Description	EUDAMED-DI Code
400110	SECURACATH CATHETER SECUREMENT - 5FR	B-00865382000228
400120	SECURACATH CATHETER SECUREMENT - 7FR	B-00865382000242
400130	SECURACATH CATHETER SECUREMENT - 3FR	B-00865382000204
400140	SECURACATH CATHETER SECUREMENT - 4FR	B-00865382000211
400150	SECURACATH CATHETER SECUREMENT - 6FR	B-00865382000235
400160	SECURACATH CATHETER SECUREMENT - 8FR	B-00865382000259
400170	SECURACATH CATHETER SECUREMENT - 9FR	B-00865382000273
400180	SECURACATH CATHETER SECUREMENT - 10FR	B-00865382000297
400200	SECURACATH CATHETER SECUREMENT - 12FR	B-00865382000280

2.5 Medical device nomenclature description/text

The SecurAcath Universal is a standalone subcutaneous anchoring securement system used to secure the catheter to the access site. The securement is achieved by means of a blunt nitinol Anchor deployed into the subcutaneous space at the catheter access site, and the locking of the catheter shaft between the Base Assembly and Cover of the device. The SecurAcath Universal can be used to secure percutaneous catheters at the insertion site. Examples of catheters that may be secured by this device are PICC, CVC, and drainage catheters. The device is available in different sizes, permitting securement of catheters with a 3F to 8F, 10F, 12F outer diameter. The only difference in the device sizes is the size of the catheter shaft lock formed by the Base Assembly and the Cover. All other aspects of the device between sizes are the same.

Trade/Proprietary Name: SecurAcath Universal

Model Number: SCR-1

Common or Usual Name: Subcutaneous catheter securement system

Device Classification: Class IIb

Device Rule: 8

UMDN Code: 13-368

MDN Code: 1203 – Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

MDA Codes:

MDT 2001 – Devices manufactured using metal processing
MDT 2002 – Devices Manufactured using plastic processing
MDT 2008 – Devices Manufactured in clean rooms and associated controlled environments
MDT 2011 – Devices which require packaging, including labelling.

Applicable European Medical Device Nomenclature (EMDN) Codes:

C010180 PERIPHERAL I.V. CATHETERS AND CANNULAS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES

C010299 CENTRAL VENOUS CATHETERS – OTHER

V9099 VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES – OTHER

2.6 **Year when the first certificate (CE) was issued covering the device:** 2010

2.7 Authorized representative if applicable; name and the SRN:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

SRN: DE-AR-000005430

2.8 **Notified Body name (the NB that will validate the SSCP) and the Notified Body SRN**:

Intertek Medical Notified Body (IMNB)

SRN: 2862

3 SSCP SUMMARY FOR CLINICIANS

3.1 Intended Use of the Device

3.1.1 Product Description

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.

3.1.2 Expected Clinical Benefits

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

3.1.3 Intended Users

Physicians, Nurse Practitioners, Registered Nurses, and other trained Health Care Professionals.

3.1.4 Indication

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.

3.1.5 Patient Target Group

The SecurAcath Device is designed for patients who undergo therapies that utilize percutaneous indwelling catheters.

3.1.6 Contraindications and/or limitations

The device is contraindicated whenever:

- Skin integrity is 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.
- Local tissue factors would 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

3.2 Principle of Operation

Principle	Description
Preparation for Use	Examination of the device and sterile packaging to ensure there is no damage to the packaging prior to use.
Application Consistent with Intended Use	The short- or long-term securement of percutaneous indwelling catheters to the access site by means of a subcutaneous anchor.
Technique/ Deployment Method	The SecurAcath Universal is placed using a manual technique that applies pressure to the "wings" on the base of the device to fold the anchor into a perpendicular position. The unit is then inserted into the catheter insertion point and the wings are unfolded. The catheter is then placed in the shaft lock and the cap of the device is affixed on top of the unit.
Mode of Action	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. The external catheter shaft is then secured with a friction-fit clamp between the SecurAcath base and cover. The SecurAcath is designed for round-shaft catheters and when in place, will secure and stabilize the catheter for the entire catheter dwell time.

3.2.1 SecurAcath u1.4 is a unique device. Prior generations included a catheter where the SecurAcath was an integrated part. This product was never commercialized. The current device, SecurAcath Universal without a catheter, was first released in 2010 and is available in the eight (8) sizes:

3F SecurAcath

4F SecurAcath

5F SecurAcath

6F SecurAcath

7F SecurAcath

8F SecurAcath

9F SecurAcath

10F SecurAcath

12F SecurAcath

3.2.2 There are no accessories to be used with SecurAcath u1.4. The device is sold independently of the catheter systems for which its use is intended and is not sold with any accessories.

3.2.3 SecurAcath is intended for securement of percutaneous indwelling catheters including Peripherally Inserted Central Catheters (PICCs), Central Venus Catheters (CVCs) and Drains. The SecurAcath can be used for short or long-term catheter dwell times.

3.3 Risks and Warnings

3.3.1 The potential exists for serious complications, including the following, and have been quantified by actual rate of occurrence in received complaints and or reportable incidents from 2010 through Jun 2022:

	Number Complaints Received (2010 – Jun 2022)	% rate vs. volume of devices sold
Bleeding	5	0.000%
Brachial Plexus Injury	0	0.000%
Catheter Erosion Through the Skin	5	0.000%
Catheter Related Sepsis	0	0.000%
Insertion Site Infection or necrosis	7	0.001%
Hematoma	0	0.000%
Intolerance Reaction to Implanted Device	8	0.001%
Laceration or Perforation of Vessels or Viscus	0	0.000%

3.3.2 The complaint rate % is based on 1,190,690 SecurAath devices sold between 2010 and June 2022.

3.3.3 Warnings and Precautions

3.3.3.1 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.

3.3.3.2 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.

3.4 Field Safety Corrective Actions

At time this SSCP report, there are no known field safety corrective actions for the SecurAcath device.

3.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

3.5.1 Summary of Clinical Data related to equivalent device(s):

Clinical evaluation followed the clinical investigation route and there is no equivalence claim to any other subcutaneous catheter securement systems. It is based on data generated and held by the manufacturer (Interrad), Scientific literature of clinical data from clinical investigations initiated by physicians who

used the Interrad SecurAcath devices and Post-market device experience. The data have been evaluated towards the safety and performance.

3.5.2 Summary of clinical data from investigations conducted of the device:

Pre-Clinical Data - A Design Validation study compared SecurAcath to Statlock and Sutures

3.5.2.1 The SecurAcath catheter was rated by three of the evaluating nurses to be the easiest device to clean around during the cleaning study as well as the most secure. This was due to its ability to provide 360° access to the catheter entry site while still being fully secured when the catheter hub is lifted off the skin. Additionally, SecurAcath had zero movement into and out of the catheter entry site compared to the Statlock device which had an average movement of 6.3 mm. The sutured in device also performed very well as far as catheter movement into and out of the entry site. However, it was more difficult to clean around because the hub could not be lifted off the skin. This resulted in some of the water washable marker used to visually indicate the cleaning effectiveness remaining on the skin around the sutures and skin entry site.

3.5.2.2 The SecurAcath provided a statistically significant higher average pull out force than the Statlock device. Since the Statlock device is an acceptable securement method used for PICCs, the pull-out force for the SecurAcath is acceptable. The pullout forces for the sutured in device on average was higher than the SecurAcath device, however there was a much higher standard deviation indicating that suturing is much more operator dependent vs. simply deploying the Anchors on the SecurAcath catheter.

3.5.2.3 Rapid pull-out tests showed that the SecurAcath device did not cause any damage to the skin entry site when it was rapidly removed. Statlock devices also did not damage the skin at the attachment site when rapidly removed. Sutures did damage the skin. Damage at a rate of 96.7% was seen to the surrounding skin tissue of the sutured in catheters during this test. Sutures tended to either cut through (“cheese cut”) the skin or increase the size of the puncture points where the sutures were initially inserted through the skin.

3.5.2.4 Animal Studies

A GLP animal study was conducted to demonstrate that cleaning of the entry site around SecurAcath is effective and that entry site cleaning testing showed that the SecurAcath is the easiest to clean with no catheter shaft movement in and out of the entry site. The securement force of the

SecurAcath is higher than that of the Statlock (pull out test) without causing damage to the skin as demonstrated by the rapid pull-out test.

3.5.3 Clinical Investigations

Clinical investigations have evaluated the safety and performance of SecurAcath and there have been two Clinical Trials. A SecurAcath I (PICC) Clinical Trial and a SecurAcath (Universal) Clinical Trial. The results of these clinical trials are published at:

https://www.clinicaltrials.gov/search?intr=SecurAcath

The results are summarized as follows:

3.5.3.1 SecurAcath I (PICC) Clinical Trial Summary

3.5.3.1.1 SecurAcath I (PICC) Clinical Trial Summary

- *Study Title: Comparing SecurAcath Versus StatLock to Secure Peripherally Inserted Central Catheters: a Randomized, Open Trial*
- *Date: 2015*
- *Patients: 105*
- *Location: Leuven, Belgium*
- *Patients: Primarily patients with PICC lines*
- *Patient Populations: 18 Years and older (Adult, Older Adult)*
- *Sexes: All*
- *Study Plan: Randomized*
- *Primary End Point: Device Securement Success: 64%*
- *Secondary End Point: Acute Procedural Success: 97.3%.*
- *Secondary End Point: Securement / Deployment Time: 11 ± 01 minutes.*
- *Secondary End Point: In-Dwelling Time: 19.4 ± 36.0 days.*
- *Secondary End Point: Device Complication Rate: 12 incidents*
- *Secondary End Point: Pain Scale: 0.4 ± 1.0.*
- *Secondary End Point: Satisfaction: 91.0%*
- *Secondary End Point: Ease of Maintenance: 65.6% to 71.1%*
- *Adverse Events: 25*
- *Study Limitations: None*
- *Safety or Performance Issues: None*

3.5.3.1.2 SecurAcath I (Universal) Trial

- *Study Title: Prospective SecurAcath Subcutaneous Securement Trial (SecurAcath)*
- *Patients: 142*
- *Location: USA*
- *Patient Populations: 18 Years and older (Adult, Older Adult)*
- *Sexes: All*
- *Type: Cohort Prospective*
- *Primary End Point: Securement success*
- *Secondary End Point: Device Securement Success: 91.2%*
- *Secondary End Point: Acute Procedural Success: 100%*
- *Securement / Deployment time: 31.0±38 to 55.4±77 seconds*
- *Secondary End Point: In-Dwelling Time: 22.6 to 228 days.*
- *Secondary End Point: Device Complication Rate:*
  - *2.9% (2/68) of PICC subjects*
  - *0% (0/74) of CVC subjects*
  - *1.4% (2/42) combined subjects*
- *Secondary End Point: Pain Scale:*
  - *1.5 ± 2.5 for PICC subjects*
  - *1.6 ± 2.1 for CVC subjects*
  - *1.5 ± 2.3 overall*
- *Secondary End Point: Satisfaction*
  - *76.9% PICC subjects,*
  - *93.3% CVC subjects*
  - *82.9% overall*
- *Secondary End Point: Ease of Maintenance: 100%*
- *Adverse Events: 27*
- *Study Limitations: None*
- *Safety or Performance Issues: None*

3.5.3.2 The results of the Clinical Trials show that the SecurAcath Device is over 91% effective in achieving catheter securement and is a safe and effective method. The patients treated experienced little to no pain and were satisfied with the SecurAcath device. Healthcare providers had a better than standard-of-care experiences in majority cases. The device- or procedure-related complications were acceptable and there were no unanticipated adverse device effects reported in the trial.

3.6 Summary of clinical data from other sources:

3.6.1 A comprehensive survey of scientific literature for SecurAcath was performed spanning from initial market inception (2010) through June 2022. The search generated 274 hits. Of the 274 hits, 154 were removed for secondary to non-peer

reviewed scholarly journals, 55 were removed as duplicates and 41 were removed as opinion related articles. A total of 24 unique articles remained:

1. **A Prospective Trial on a New Sutureless Securement Device for Central Venous Catheters** Cordovani, D., Cooper, R., Canadian Journal of Anesthesia (2013) May, Vol. 60, No. 5, pg. 504-505.
   - Prospective, non-randomized study of SecurAcath on CVCs
   - 2 sites, 74 patients
   - 0% dislodgement
   - No infections
2. **A prospective postmarket study to evaluate the safety and efficacy of a new peripheral inserted central catheter stabilization system.** Egan GM, Siskin G, Weinmann R, et al. J Infus Nurs. 2013;36:181-8
   - The primary endpoint of this study, percentage of patients with SecurAcath devices implanted and explanted without (1) securement-related device malfunctions or (2) device-related complications/AEs attributed to the subcutaneous securement system, was 91.2% (62/68).
   - The authors concluded that "SecurAcath, which was readily accepted by both patients and nursing staff, represents a novel, safe, and effective method for catheter securement."
3. **Reducing PICC Migrations and Improving Patient Outcomes** Hughes, M., British Journal of Nursing (2014) Jan Vol. 23, No. 2, pg. 16-21
   - PICCs
   - Prospective, non-randomized
   - Site places 460 PICCs per year, 500 secured with SecurAcath to date
   - Average PICC dwell time = 3 months
   - 0% dislodgment rate, not a single catheter replacement since SecurAcath introduction
   - Previous adhesive device catheter replacement rate was 4.6% (21/460)
   - Annual cost savings (due to reduced dressing change, catheter replacement, x-ray, and nursing time costs) to Velindre Cancer Center = £21,610

4. **A new subcutaneously anchored device for securing external cerebrospinal fluid catheters: our preliminary experience.** Frassanito P, Massimi L, Tamburrini G, et al. World Neurosurg. 2016; 93:1-5
   - This study was a single center, observational study. The study enrolled 29 consecutive patients (age range: 3 weeks to 16 years). The SecurAcath device was used to secure cerebral-spinal fluid (CSF) external drainage. In particular, the device was used for 25 ventricular catheters (a patient received 2 catheters in the same procedure for bilateral brain abscess) and 5 spinal drainages. The device stayed in place for a period ranging from 1 to 4 weeks (median, 22 days).
   - The authors concluded "In our experience, SecurAcath is a safe and effective device to secure CSF external catheters to the skin, with several relevant advantages: its placement and maintenance are easy; it may stay in place for the entire duration of the catheter; it allows a more complete antisepsis of the exit site, thus reducing local skin complications; it eliminates the risk of suture-related needlestick injuries."
5. **Evaluating Safety, Efficacy, and Cost-Effectiveness of PICC Securement by Subcutaneously Anchored Stabilization Device.** Zerla, P. A., et al, Journal of Vascular Access (2017) February
   - 30 patients with SecurAcath on PICCs
   - Long-term oncology patients, average dwell time of 4.8 months
   - 0% catheter replacement rate
   - Cost savings due to not replacing SecurAcath at each dressing change = €3,354
   - Previous catheter replacement rate of 7.9% with adhesive device
   - Potential catheter replacement savings = €18,710
6. **Potential Role of a Subcutaneously Anchored Securement Device in Preventing Dislodgement of Tunneled-Cuffed Central Venous Devices in Pediatric Patients** Dolcino, A., et al, Journal of Vascular Access (2017) Oct
   - 173 pediatric patients receiving cuffed, tunneled catheters
   - 122 secured with adhesive device, 51 secured with SecurAcath
   - Dislodgement rates
   - Adhesive 14.4%
   - SecurAcath 1.1%

- Conclusion: "We strongly suggest this new securement device be adopted for the whole life of every tunneled CVC and for the first 3-4 weeks for all cuffed CVCs."

7. **SecurAstaP trial: Securement with SecurAcath versus Statlock for Peripherally Inserted Central Catheters, a Randomised Open Trial** Goossens, L., et al, BMJ Open (2018); 8:e016058. doi: 10.1136/bmjopen-2017-016058
   - RCT on PICCs
   - N = 52 SecurAcath, n = 51 Statlock
   - Primary end point - time needed to perform dressing change
   - SecurAcath median time = 4.3 minutes
   - Statlock median time = 7.3 minutes
   - 3 minutes saved at each dressing change using SecurAcath
   - No differences seen in migration, dislodgement, or infections
8. **SecurAcath for Securing Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance.** Macmillan T, Pennington M, Summers JA, et al. Applied health economics and health policy. 2018;16(6):779-791
   - The key points for decision making were summarized in the article as: available evidence suggests that SecurAcath is an effective catheter securement device and is easy to insert and maintain, well tolerated, and associated with a low rate of catheter-related complications.
   - SecurAcath should be considered for any peripherally inserted central catheter with an anticipated indwell time of 15 days or longer.
   - SecurAcath is cost saving compared with adhesive securement devices, when the peripherally inserted central catheter is in places for 15 days or longer. Cost savings range from £9 to £95 per patient with a minimum annual saving of an estimated £4.2 million in the National Health Service in England.
9. **Clinical Experience of a Subcutaneously Anchored Sutureless System for Securing Central Venous Catheters** Pittiruti, M. et al, British Journal of Nursing (2019) Vol. 28, No. 2, January
   - Paper presents results of three prospective clinical studies of SecurAcath (SAS device) on PICCs and other central lines in different patient populations, 190 patients total

- Three clinical studies demonstrated a 98.4% efficacy of SAS in preventing catheter dislodgement
- SAS device proved to be safe and well tolerated since SAS-related complications were few and of little or no relevance
- SAS cost-effectiveness was very high in all studies

10. **Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement** McParlan et al, J Vasc Access (2019) June
    - PICC securement study from Belfast, Northern Ireland
    - Compared one full year of Statlock use to one full year of SecurAcath use
    - n = 1,111 patients with Statlock, n = 1,139 patients with SecurAcath
    - Average dwell time 6 months
    - 5.9% catheter replacement rate with Statlock, 0% replacement with SecurAcath
    - Cost savings due to decrease in catheter replacement = £17,952
    - Cost savings due to not changing out SecurAcath = £59,322
    - Total savings = £77,274
11. **Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonates with Pleural Effusion: Three Case Reports** Rodriguez Perez, et al, Case Reports in Pediatrics (2020) March
    - Three neonates, all of them premature, requiring the placement of a chest tube for drainage of a massive pleural effusion
    - In all three patients, the chest tube was secured using a new subcutaneously anchored sutureless system (SecurAcath)
    - In conclusion, we recommend SAS (SecurAcath) as a safe and effective alternative option for securing chest tubes in neonate: it is easy to insert and easy to remove; it is not associated with any undesired effect, not even in premature newborns; most of all, it minimizes and virtually eliminates the risk of accidental dislodgment of the chest tube, an event associated with increased morbidity and increased health cost.

12. **Securing CSF catheters to the skin: from sutures and bolt system to subcutaneous anchoring device towards zero complications**. Frassanito, et al, Child's Nervous System (2020) June
    - SecurAcath® was used in 209 patients (mean age 7 years) to secure 195 external cranial catheters and 16 spinal drainages
    - Indwell time ranged from 5 to 30 days
    - No complication related to the use of the device was observed. In particular, there was no case of dislocation or accidental pullout of the catheter. Rate of infection, or superinfection in case of ventricular catheter implanted for CSF infection, was null.
13. **An observational study of the securement of central venous access devices with a subcutaneous anchor device in a paediatric population at a tertiary level hospital**. Fitzsimons, et al, Journal of Vascular Access (2020) May
    - 52 consecutive paediatric patients, aged less than 18 years old, who required peripherally inserted central catheters and non-cuffed tunnelled centrally inserted central catheters.
    - There was a reduction in securement failure from 2.58 per 1000 catheter days using historical data to 2.01 per 1000 catheter days with the use of SecurAcath
    - We advocate the use of subcutaneous anchor devices (SecurAcath) in pediatric patients who require medium-term venous access
14. **Do subcutaneously engineered stabilization devices reduce PICC migration? A product evaluation report.** Culverwell, et al. The Australian Journal of Cancer Nursing (2020) Vol. 21, No. 2, Nov
    - In 2013, a concerning trend in PICC migration complications and re-insertions related to catheter movement was identified
    - In 2014, 150 (11%) PICCs required reinsertion due to migration
    - Social costs in terms of patient suffering and delays in therapy, as well as financial implications in terms of associated additional costs, calculated to a value of NZ $54,750
    - Furthermore, in one of these cases of PICC migration, a fatality occurred that was linked to inadequate PICC securement
    - Our findings showed that implementation of a SESD (SecurAcath) had benefits for both patients and staff
    - The aim to reduce PICC migration rates and associated complications was achieved.

- The SESD used in this product evaluation proved a successful measure to reduce PICC migration events. An organizational decision was made to embed SESD as the preferred securement method in PICC care bundles for adult patients.

15. **Catheter Securement Impact on PICC-related CLABSI: A University Hospital Perspective**. Rowe, et al, American Journal of Infection Control (2020) Vol. 48, Dec
    - University of Arkansas for Medical Sciences (UAMS) analyzed 7,779 patients over four years of Central Line Associated Bloodstream Infection (CLABSI) data
    - Analysis compared outcomes of patients whose PICCs were secured with a the SecurAcath to those secured with an adhesive device
    - Study found a substantial difference in relative risk of CLABSI among securement devices • Analysis showed those who had an adhesive device had a 288% increase in risk of CLABSI compared to those who had a SecurAcath
16. **Retrospective survey from vascular access team Lombardy net in COVID-19 era**. Gidaro, et al. Journal of Vascular Access (2021) Jan
    - Multicenter, retrospective cohort study collected data from seven hospitals in Lombardy during the pandemic period from February 21st to May 31st 2020
    - A total of 2206 VADs were evaluated, 1107 (50.2%) of which were inserted in COVID-19 patients • A minority of "central tip" VADS were held by a subcutaneous securement device such as SecurAcath® (5 CICC and 40 PICC in COVID-19 and 78 PICC in non COVID-19)
    - CRT, CRBSI, and accidental removal are significantly more frequent in COVID-19 patients. Accidental removals are the principal complication, for this reason, the use of subcutaneously anchored securement is recommended for a shorter period than usual
17. **Ultrasound-guided cannulation of the superficial femoral vein for central venous access.** Annetta MG, Marche B, Dolcetti L, et al. J Vasc Access. 2021 Mar 21
    - This study was a retrospective study on ultrasound-guided cannulation of the superficial femoral vein for central venous access. The vascular access site securement using SecurAcath were mentioned in the report. The device use and study population were per IFU.

- The authors concluded the ultrasound approach to the superficial femoral vein is an absolutely safe technique of central venous access. Also, the exit site of the catheter at mid-thigh may have advantages if compare to the exit site in the inguinal area.

18. **Vascular access device securement for oncology patients and those with chronic diseases.** Hawes ML. Br J Nurs. 2021
    - The author reported 3 PICC cases with different exit securement methods. One of the 3 cases used SecurAcath device as the securement method. The subject was 30-year-old woman with multiple chronic illnesses requiring long-term vascular access. The patient developed an allergy to adhesives, causing skin breakdown (MARSI, medical adhesive related skin injury). During the course of infusate treatment, the patient experienced PICC migration. SecurAcath device was then selected to secure the PICC in place for 6 months with no migration, no infection, no discomfort, and dramatically less skin irritation. The author commented that the choice of securement should be weighed against the patient's activity level, duration of the line placement, infection risks and inevitable skin irritation caused by repeated replacement of adhesive securement.

19. **Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein** Barone, et al, Journal of Vascular Access (2020) June
    - Thirty centrally inserted catheters were placed in 30 neonates
    - Success rate of the procedure was 100%
    - Insertion bundle included use of subcutaneously anchored securement (SecurAcath) to minimize dislocations
    - No complications during the procedure and no late complications (infection, thrombosis, dislocation, or catheter malfunction).

20. **Subcutaneously anchored securement for peripherally inserted central catheters: Immediate, early, and late complications**. Brescia, et al, Journal of Vascular Access, June 2021
    - Retrospective analysis of 639 adult cancer patients who had a PICC inserted and secured with SAS (SecurAcath), over 3 years and 93,078 catheter days.
    - Average number of catheter days was 154 days per patient (range 32–657 days)
    - Dislodgment occurred only in seven cases (1.1%); 4 were due to mismatched SecurAcath/Catheter OD; 3 were non-collaborative

patients.

- Literature reports an incidence of dislodgment between 5% and 15% (when SAS not used)
- Our data confirm that subcutaneously anchored securement of PICCs is associated with very low risk of dislodgment and that this risk is limited to non-collaborative patients
- Overall incidence of CRBSI was 0.17 per 1000 catheter days; Symptomatic catheter related thrombosis was 1.9%; resolved with therapeutic doses of LMWH
- It is possible that an adequate stabilization of the catheter may have reduced the thrombotic risk and that the elimination of "in and out" micro-movement of the catheter at the exit site, as much as an optimal disinfection all around the exit site, might have reduced the risk of infection
- Subcutaneously anchored securement of PICCs was a safe and effective strategy for reducing the risk of dislodgment.

21. **Safety and effectiveness of subcutaneously anchored securement for tunneled central catheters in oncological pediatric patients: A retrospective study.** Crocoli, et al, Journal of Vascular Access (2021) June
    - Data from 311 tunneled catheters, all secured with subcutaneously anchored securement
    - Approximately half of the catheters (51%) were non-cuffed.
    - The range of duration of the central lines was 0.1–113 weeks (median: 24.9 weeks)
    - No significant difference in complications comparing cuffed versus non-cuffed catheters, or CICCs versus PICCs.
    - SAS (SecurAcath) will be probably associated with even less risk of complications if compared to skin adhesive sutureless securement, as suggested by our complication rate (1.35/1000 catheter days), better than any previously reported in pediatric literature.
    - Rate of dislodgment was similar in cuffed and non-cuffed catheters, suggesting that the cuff may play a less important role in securement of tunneled CVADs
    - SAS (SecurAcath) was very effective as securement of tunneled central catheters, since the incidence of dislodgment was very low 2.6% or 0.18/1000 catheter days, less than previously reported in literature, regardless of the presence of a cuff
    - Securement device was very well tolerated by all patients

- This securement was not associated with any increased risk of CRBSI (extremely low in our experience: <1 episode/1000 CVAD days) or of symptomatic Catheter-Related Thrombosis (no case reported in our series)

22. **Securement of central venous catheters by subcutaneously anchored sutureless devices in neonates**. D'Andrea, et al, Journal of Maternal-Fetal & Neonatal Medicine (2021) April
    - Accidental dislodgement of central venous catheters is a frequent complication in NICU and it often requires catheter replacement
    - Study evaluated safety and efficacy of Subcutaneous Anchored Securement (SAS) in neonates
    - 72 central catheters were inserted, all secured with SAS
    - The median duration of the line was 6 weeks
    - SAS was effective in preventing accidental catheter dislodgement in 100% of cases
    - Complications during insertion, maintenance and removal were negligible
23. **Systematic Review of the Safety and Efficacy of CVAD Securement** Bell, et al, Journal of the Association for Vascular Access, Sept 2022
    - Researchers conducted a systematic review of more than 8,000 studies to examine safety and efficacy outcomes related to CVAD securement.
    - In the studies with good comparative data on rates of catheter migration and dislodgement, researchers found clear benefits for the subcutaneous anchor securement system.
    - Subcutaneous anchor securement systems (SASS) are shown to be more effective at keeping central catheters in place, compared to either suture-based or adhesive device-based securement methods.
    - The median incidence of migration and dislodgement for SASS was just 1.76%, compared to 6.77% for suture-based systems, and 9.69% for adhesive securement devices

24. **A GAVeCeLT bundle for central venous catheterization in neonates and children: A prospective clinical study on 729 cases**. Pittiruti, et al, Journal of Vascular Access (2022) May

- Study evaluated the use of a procedure bundle in 729 pediatric central venous catheter placements
- Cases were separated into 3 groups, neonates (n=68), infants (n=173), and children (n=488)
- SecurAcath was used in 100% of the neonates, 81% of infants, and 72% of children, total of 77%, 555 of 729
- No dislodgement occurred with SecurAcath use
- "In our experience, the most effective securement—particularly in children—was subcutaneous anchorage. This method minimizes the risk of dislodgment and may theoretically reduce the risk of infection and venous thrombosis."
- Absence of CRBSI in the first 2 weeks of follow up is secondary to the appropriate use of the currently recommended strategies for infection prevention, including SecurAcath
- Subcutaneous anchorage – by avoiding securement with skin-adhesive sutureless devices - might also have reduced the risk of CLABSI

3.6.2 Summary of Clinical Literature:

Among the 24 presented articles, 21 articles deal with securing a PICC or CVC and 3 articles focus on securing a drainage system, including cerebral-spinal fluid (CSF) external drainage, chest tube, cranial catheters, and spinal drainage. The clinical evidence in literature demonstrates that:

- The Interrad SecurAcath is safe to secure PICC or CVC or drainage catheter.
- SecurAcath can be used for short-term or long-term catheter securement.
- SecurAcath reduces the time dressing.
- In general, both patients and healthcare providers had positive responses to the therapy. SecurAcath can also be safely used in pediatric patients, infants, or neonates.
- The reported incidence of adverse effects is acceptable.

3.7 Overall summary of the clinical performance and safety:

SecurAcath is a safe and effective device for securing percutaneous indwelling catheters and is over 91% effective in catheter securement success.

SecurAcath provides several relevant advantages, including easy placement and maintenance. Moreover, it may stay in place for the whole duration of the catheter without any skin tissue trauma and allows a complete antisepsis of the exit site, thus reducing local skin complications. This factor has a significant impact on the reduction of infection rate of associated with percutaneous catheters.

Clinical evidence demonstrates that SecurAcath device can remain in place for the duration of catheter indwell (i.e., for the life of the line).

3.8 Ongoing or planned post-market clinical follow-up.

Interrad Medical has implemented a comprehensive Post Market Surveillance Plan to collect information to reduce the uncertainty about the safety and performance of SecurAcath u1.4 during its life cycle. The plan includes monitoring of adverse events when they occur, proactive customer feedback surveys, clinical evaluation plans, continuous risk evaluation and Periodic Safety Update Reports.

The information is used to review safety and performance including usability and labelling and any other opportunities for improvement.

3.9 Summary of Benefits:

Clinical safety and performance claims in addition to the intended purpose/indications are summarized in the below. Clinical performance attributes are made in comparison to standard of care catheter securement methods.

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

3.10 Benefits versus Risk:

Overall, the Risk vs Benefit ratio assessment clearly indicates that the effectiveness of the device, benefits the patient by reducing catheter migration and dislodgements and these benefits clearly outweigh any risks associated with the use of the device.

3.11 Possible Diagnostic or Therapeutic Alternatives:

Competitive devices include sutures or adhesive pads. Clinical data suggests that sutures create additional entry points for bacteria whereas both sutures and adhesive securement patches hold the catheter hub to the skin resulting in increased difficulty when cleaning around the catheter entry site. Furthermore, securing a catheter outside the skin, away from the catheter entry point, as with sutures or adhesive securement pads may cause pistoning of the catheter which is also believed to possibly increase infection risks.

3.12 Suggested Profile and Training for Users

Customers who submit a purchase order will receive consultation from an Interrad Medical representative on their training needs to properly use SecurAcath. This consultation will be followed up with an email providing training resources including but not limited to the Instructions for Use, PDFs of Placement, Care and Removal instructions with graphics, videos to procedures and links to smart phone application for access to training resources prior to receipt of the first shipment of product. Once training is scheduled, this will be reported in our customer records and a quarterly log will be retained.

3.13 Reference to Harmonized Standards and Common Standards Applied in full:

BS EN ISO 11135:2014+A1:2019
BS EN ISO 10993-1: 2020
ASTM F2503-20 (MRI Conditional)
ASTM D4169-22
BS EN ISO 15223-1:2021
BS EN ISO 14971:2019
BS EN ISO 11607-1:2020+A11:2022
BS EN ISO 11607-2:2020+A11:2022
BS EN ISO 13485:2016+A1:2021
BS EN ISO 14155: 2020
BS EN ISO 14644-1:2015
BS EN ISO 14644-2:2015
BS EN ISO 14644-5:2004
BS EN ISO 22442-1:2020
ASTM F88/F88M-23
ASTM F2129-19a
ASTM F2096-11

4 REVISION HISTORY

SSCP Revision	Date Issued	Change Description	Revision Validated by the Notified Body
01	22Nov2022	Initial Release	No (only applicable for Class IIa or some IIb implantable devices for which the SSCP is not yet validated by NB)
02	07Jul2023	Update to include Benefit-Risk Statement and to reword Patient section to laymen language requirement.	This revision is written in English, a member language, and will be translated into other member state languages after the NB has validated the English version. This document will be published on EUDAMED (when the SSCP module is available) and at www.securacath.com website.
03	10Oct2023	Update to align indications with clinical documentation and the IFU. Added 9F (Note: 9F was not initially included because it was not yet released to the market for the period covered by this report). Added principle of operations for physicians section. Reworked lay persons section for readability.	This revision is written in English, a member language, and will be translated into other member state languages after the NB has validated the English version. This document will be published on EUDAMED (when the SSCP module is available) and at www.securacath.com website.

5 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR PATIENTS

Document revision: 03
Date issued: XX Oct 2023

This report is for the SecurAcath device. It is intended to give you access to important information about safety and clinical performance.

This information is intended for patients or lay persons. A more extensive report for your doctor is in the first part of this report.

This report is not intended to give you advice on how to treat a medical condition.

Please contact your doctor if you have any questions about your medical condition or about the use of this device in your situation.

5.1 Clinical Background

The device is used to hold a line where it enters your body. The device keeps the line from moving. The device has been on the market since 2010 and has a record of safe and reliable use.

5.2 Device Trade Name(s):

SecurAcath Universal

5.3 Manufacturer's name and address:

Interrad Medical, Inc.
181 Cheshire Lane
Suite 100
Plymouth, Minnesota, USA 55441

5.4 Manufacturer's single registration number (SRN):

US-MF-000009878

5.5 Basic UDI-DI:

Cat. No.	Description	EUDAMED-DI Code
400110	SECURACATH CATHETER SECUREMENT - 5FR	B-00865382000228
400120	SECURACATH CATHETER SECUREMENT - 7FR	B-00865382000242
400130	SECURACATH CATHETER SECUREMENT - 3FR	B-00865382000204
400140	SECURACATH CATHETER SECUREMENT - 4FR	B-00865382000211
400150	SECURACATH CATHETER SECUREMENT - 6FR	B-00865382000235
400160	SECURACATH CATHETER SECUREMENT - 8FR	B-00865382000259
400170	SECURACATH CATHETER SECUREMENT – 9F	B-00865382000273

Cat. No.	Description	EUDAMED-DI Code
400180	SECURACATH CATHETER SECUREMENT - 10FR	B-00865382000297
400200	SECURACATH CATHETER SECUREMENT - 12FR	B-00865382000280

5.6 Year when the device was CE Marked:

2010

5.7 Intended Use of the Device

5.7.1 Intended Purpose

If you have a line, the device will help keep it from moving or falling out.

5.7.2 Intended Users

The device should be placed and cared for by your doctor, nurses or care staff who have been trained to properly use it.

5.7.3 Patients

The device can be used in children and adults that have short- or long-term line placements.

5.7.4 Contraindications and/or limitations

The device is not recommended whenever:

- Your skin is fragile from long term steroid use or, you have a skin infection, or there is a rash where the line is placed.
- You have an infection or suspect that you do.
- Your body size is too small for the device.
- You have a known, or suspected allergy to the materials in the device including nickel (i.e., metallic anchors) or certain plastics.
- You have had past radiation therapy where the line is placed.
-

5.8 Device Description

5.8.1 Description of the device:

The device uses two small metal anchors. The anchors are placed through the skin using the same hole your line enters. The line is laid into the channel of the device and a Cover is snapped on to hold the line in place. The materials in the device have been tested and proven to be safe for use in humans.

5.8.2 Information about medicinal substances:

There are no medicines in the device.

5.8.3 How the device works:

The device uses a Base and a Cap to snap onto and hold your line in place to help keep the line from moving or falling out.

5.8.4 Accessories:

The device is sold independently of the line, it is not sold with any accessories.

5.8.5 Risks, Warnings, and Precautions

Although the device is generally considered safe, and the manufacturer has reduced the risks as far as possible, the potential still exists for serious side effects including the following:

- Bleeding.
- Nerve injury where pain may extend away from the line.
- The device could potentially cut through the skin.
- The device could be involved in a line related infection.
- The device could be involved in an infection where the line is inserted.
- Bruising.
- Allergic Reaction to materials in the device.
- The device could be involved in damage to a blood vessel or other surrounding tissue.

5.8.6 Contact your doctor if you believe that you are experiencing side effects related to the device, or if you are concerned about risks. This document is not intended to replace a consultation with your doctor.

The following Warnings and Precautions are listed in the SecurAcath Instructions for Use (IFU) provided to your health care professional.

Warnings:

- Intended for Single Patient Use. DO NOT REUSE. Reuse may lead to SAE and device malfunction.
- This product contains nitinol. Do not use it in patients with a 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.

5.9 Clinical Evidence for the CE Marking:

5.9.1 The device was carefully tested by the manufacturer. Testing included animal testing to show that the device functions as expected and provides the desired clinical benefits.

5.9.2 Two clinical trials were performed using human subjects and the results show that the device is a safe and effective method for holding lines and helping to prevent movement. The patients treated during the clinical trials experienced little to no pain and were satisfied with the device. The level of side effects was acceptable and there were no unexpected side effects reported during the trials.

5.9.3 There are currently 24 scientific papers written about the device. Overall, the clinical literature shows that the device is safe and effective for holding lines and helping to prevent unwanted movement.

5.9.4 Summary clinical performance and safety:

The device can safely hold lines and it performs as intended.

- The device is safe and effective, and when used as it is supposed to be, the device will not harm the patient.

- The device should only be used by physicians who are experienced and trained.
- Overall, the side effects occur at a very low rate and are found to be acceptable risks when compared to the benefits.
- The device functions like tape or glue pads that attach to the skin and hold a line.
- The Instructions for Use clearly demonstrate steps for safe use of the device.

5.10 Safety

5.10.1 Summary of Benefits:

SecurAcath holds your line to help prevent movement or coming out. At the same time, it makes care and cleaning easier.

5.10.2 Benefits versus Risk:

Overall, the benefits of using SecurAcath clearly outweigh any risks.

5.10.3 Summary of Clinical Evaluation related to equivalent device(s)

SecurAcath is the first and only line holding device to use an anchor that goes under your skin. Other devices like tape or glued pads work above the skin.

5.11 Ongoing or planned post-market clinical follow-up.

Interrad Medical continuously monitors the market and actively works to reduce the risks and improve the performance of the device.

6 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

SecurAcath is the only device on the market that uses an anchor to hold your line at the entry site. Other devices used to hold lines include stiches or glue pads. Stiches create additional entry points in your skin where bacteria can enter your body increasing your risk of infection. Glue pads increase the difficulty for your health care provider to clean the entry site which can also increase your risk of infection.

Additionally, when holding a line using stitches or glue pads, the chance that your line moves is increased, and it may be pushed further into your body leading to an increased risk of infection. Or, if the stiches or glue pads fail to hold your line in place, your line could fall out.

When considering alternative treatments, it is recommended to contact your doctor who can consider your individual situation.

7 SUGGESTED PROFILE AND TRAINING FOR USERS

Before they received their first shipment of product, your care Doctor and care team was provided with training resources including, but not limited to, SecurAcath's Instructions for Use, PDFs detailing Placement, Care and Removal instructions with graphics and videos including smart phone links to additional training resources.

8 REVISION HISTORY

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