FOR THE LIFE OF THE LINE™

SecurAcath®

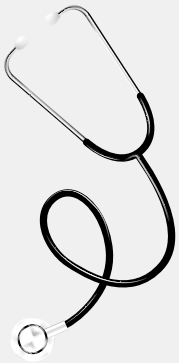
PRODUCT GUIDE

VYGON
Value Life

WHY CHOOSE VYGON?

OVER 60 YEARS EXPERIENCE

PATIENT CARE LIES AT THE HEART OF WHAT WE DO



CLINICAL EXPERTISE

WE ARE A **CARBON NEUTRAL** COMPANY

MORE THAN **100 MILLION** PRODUCTS IN **110 COUNTRIES**

CONTENTS

OUR SERVICE OFFERING

Customer Service & Technical Support

Talk through your enquiry with our dedicated Teams.

Education & Training

We offer our customers a variety of valuable and comprehensive training options to help you and your teams meet your training requirements.

BECAUSE PATIENTS DESERVE BETTER™

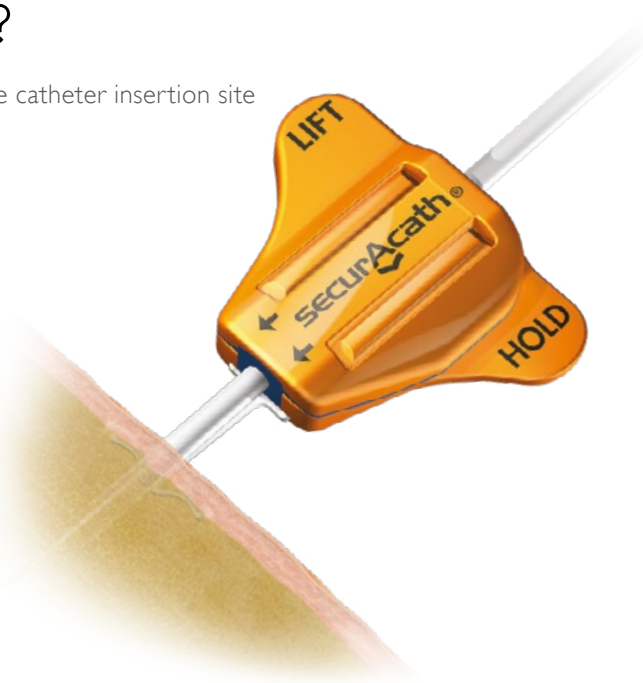
HOW DOES THE SECURACATH® WORK?

- Small, blunt, nitinol securement feet are placed just beneath skin right at the catheter insertion site
- The cover is snapped onto base to affix to catheter shaft
- No sutures or additional skin punctures are needed
- No adhesives needed for securement
- Remains in place for life of the catheter
- Works with venous access and general/abscess drainage catheters

Fold

Insert

Snap



IMPROVING THE QUALITY OF CARE

The current standard practices around venous access device securement include the use of sutures or adhesives, both of which can be challenged with complications. Sutures are designed and indicated for wound closure and not device securement. The orientation of sutured lines leads to compromised dressings, and displaced catheters because of the tensions and weight of the lumens, patients' hair, skin folds and moisture. The impetus for infection is obvious. Adhesive securement can be challenged by many of the variables coupled by the weight and tensions exposing dislodgement and migration risk with every dressing change.

SecurAcath offers a single application solution that stabilises the catheter beneath the insertion site, throughout the entire catheter dwell time. This offers clinician confidence, ease and success for the needed care for your venous access catheters. With a suite of clinical support resources, to support your every step of the way.

Scan or Visit to Learn How SecurAcath® Improves Patient Care

SECURACATH® PROVIDES IMPROVED CATHETER SECUREMENT FOR THE LIFE OF THE LINE™

Significantly Reduces Risk of CLABSI

- University of Arkansas for Medical Sciences (UAMS) analysed 7,779 patients over four years of Central Line Associated Bloodstream Infection (CLABSI) data[1]
- Analysis compared outcomes of patients whose PICCs were secured with a SecurAcath to those secured with an adhesive device
- Study found a substantial difference in relative risk among securement devices
- Adhesive device had a 288% increase in risk of CLABSI compared

  to SecurAcath.

Dramatically Decreases Catheter Dislodgement

- Catheter dislodgement is defined as accidental removal or movement that resulted in loss of function
- SecurAcath clinical data publications show very low dislodgement rates of 0–1.6%[2-7]
- Adhesive securement devices have published dislodgement rates of 7-12%[8-11]
- Many accidental dislodgements occur during dressing changes when catheter is not secured
- Catheter replacement cost is approximately £300 for beside and £500 for IR; these are decreased with SecurAcath.

Prevents Catheter Movement

- Catheter movement at the insertion site can introduce bacteria beneath the skin[13]
- Improved stability may promote healing at insertion site which acts as a natural barrier to infection
- May reduce phlebitis, thrombosis and infection.

Improves Efficiency

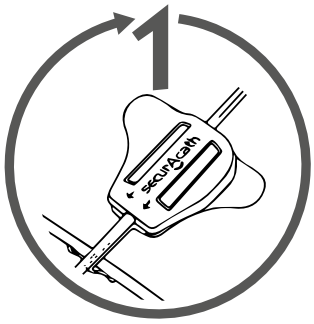
- One SecurAcath secures for the life of the line
- Catheter remains secure during dressing changes
- Dressing change can be done 41% faster[14]
- Allows for easy catheter repositioning if catheter tip must be pulled back.

Allows 360 Degree Site Cleaning While Secured

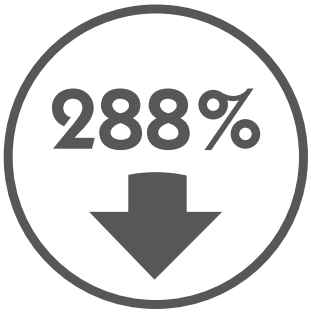
- Excellent cleaning access around the entire insertion site
- Catheter remains stable and secure during cleaning
- Improved stability and cleaning may help reduce infections.

Eliminates Costly Suture Needle Stick Risk

- The NHS received 2,600 claims for needle stick injuries for incidents occurring in the period 2012-2022. Of these, 1,947 were successful claims with 167 claims still open[15]
- These resulted in a cost of £10.8 million to the NHS[15].

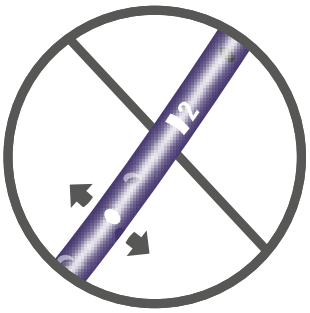


Just one device for the Life of the Line™



Decreased risk of CLABSI with SecurAcath compared to adhesive devices

Peer-reviewed publications on subcutaneous securement



0-1.6% SecurAcath dislodgement VS 7-12% with adhesive devices

Suitable for your youngest patients to eldest

Lowers total cost of patient care

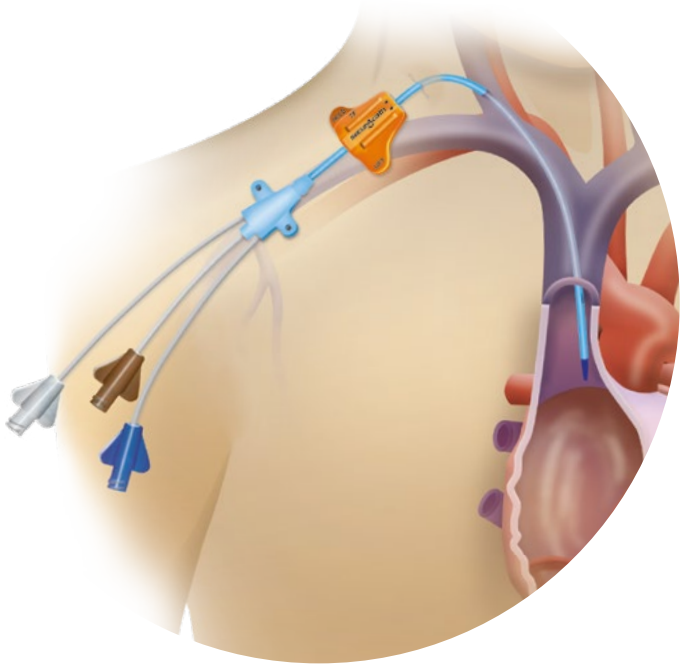
SECURACATH® IS SUITABLE FOR USE WITH PICCS AND CVC LINES

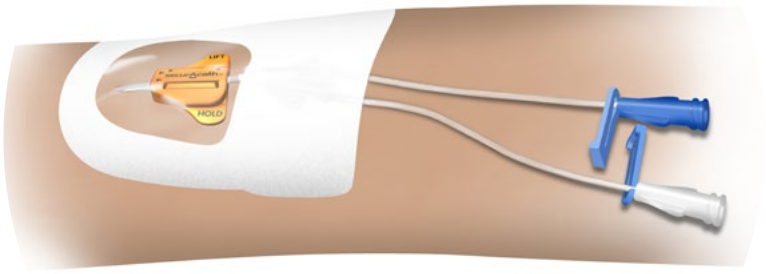
Securement

- SecurAcath secures the line at the catheter skin junction
- Ensure the dressing covers the suture hub to increase stability
- Consider adding an additional fixation dressing to the suture hub to maximise stability.

SecurAcath® vs. Sutures

- Stability increases dressing wear time
- No unnecessary skin punctures
- Improved ability to clean insertion site may reduce infections
- Maximises patient comfort
- Eliminates suture needle stick risk
- Standardises practice.





CVC Optimal Placement

- Adopt a lower IJV or subclavian approach
- Utilise the shoulder as a splint to stabilise the hub and dressing.

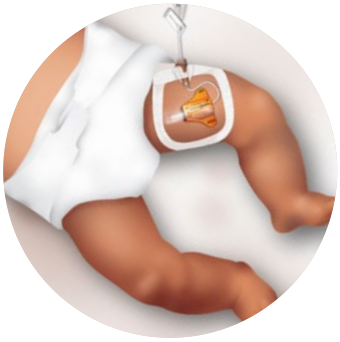
NICE Recommended for PICCs

- SecurAcath is associated with a low incidence of catheter-related complications
- SecurAcath should be considered for any PICC with an anticipated dwell of 15 days or more
- Cost modelling shows savings of £9 – £95 per patient compared to Statlock
- Annual cost savings to NHS in England estimated to be a minimum of £4.2 million.

EFFECTIVE IN A WIDE RANGE OF PAEDIATRIC APPLICATIONS

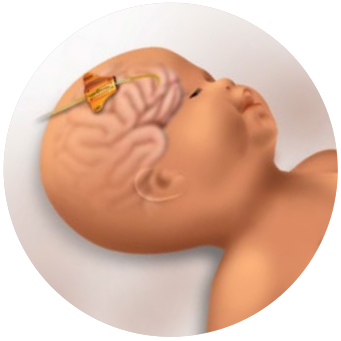
SecurAcath has demonstrated its effectiveness at securing catheters in a variety of applications, including tunnelled and non-tunnelled venous catheters, external ventricular or spinal CSF drains, chest and other general drains in neonates as young as 32 weeks.[16-24]

Protecting your youngest patients from premature line replacements, adhesive or suture related skin tears, and infections is key to achieving the desired outcomes from these percutaneous catheters.

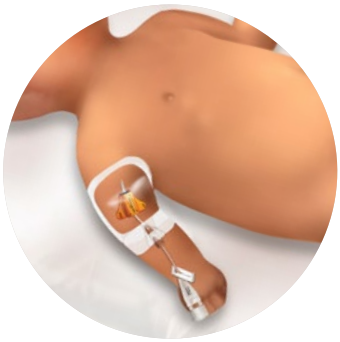


Femoral CVC

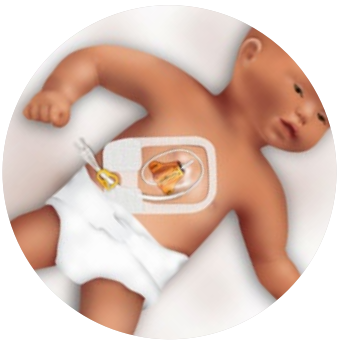
Drainage



CSF ventricular drains



PICC



Tunneled CVC

Percutaneous CVC

Before the introduction of the subcutaneously sutureless stabilisation system as a mean to anchor the thoracic catheter in neonates, these patients were forced to position various devices as they were easily dislodged, compromising their conditions, causing pain and stress, increasing risk of complications and prolonging their hospitalization time.

– Dr Carmen Rodriguez - Consultant Neonatal & Paediatrics, Maria Grazia Romitti - Neonatal Intensive Care Nurse
Dr Elena Pezotti, Neonatologist - NICU, Childrens' Hospital
ASST Spedali Civili Brescia, Italy

Scan or Visit to Learn How SecurAcath® Improves Patient Care

FAQs

What is SecurAcath made of?

- The flexible securement feet are made of Nitinol which is a shape-memory alloy of nickel and titanium. Nitinol is used in several medical devices including self-expanding stents and IVC filters. The plastic is polypropylene and elastomer. The SecurAcath is not made with natural rubber latex.

What catheters can SecurAcath be used on?

- SecurAcath has successfully been utilised on a variety of percutaneous catheters. Indications for use vary by geography. Refer to the IFU for your area. SecurAcath is available in eight sizes from 3-12 Fr.

How long can SecurAcath remain in place?

- The SecurAcath can remain in place for the entire catheter dwell time. The longest known SecurAcath dwell has been on a tunnelled catheter secured for over four years.

Do the securement feet beneath the skin hurt or cause discomfort to the patient?

- No. When properly inserted in the subcutaneous tissue beneath the skin, the patient should not experience any discomfort. Pain receptor nerves are mainly located in the dermis, not in the subcutaneous tissue. Patients in a SecurAcath clinical study were asked to rate their pain on a scale of 0-10 (zero being no pain). The average score while device is indwelling was 0.8, and on removal was 1.5[25]. The data supports that the device is comfortable for patients. Proper positioning of the device on the skin and dressing application is key to avoid pain or discomfort. The SecurAcath should not be twisted, rotated, or repositioned from the original placement position. The dressing should not be stretched tightly over the device and insertion site.

Can the securement feet damage the catheter?

- No. The securement feet are blunt, rounded, polished and flexible. There are no sharp edges on the SecurAcath device. Extensive testing has been performed to demonstrate the securement feet do not cause damage to the catheter.

What happens if the catheter and SecurAcath are accidentally pulled out?

- The SecurAcath feet will pull out of the skin without causing damage to the tissue. The securement feet are rigid enough to hold the device in place but also flexible enough to not cause skin damage if extreme tension or pulling on the device occurs. The feet will come out through the existing skin puncture and will not create trauma even when the skin is frail. If there is extreme tension on the catheter, the catheter outer diameter may change due to stretching and may lead to slipping in the device. This can be prevented with proper dressing application and dressing management and ensuring the catheter suture wings are under the dressing. Proper dressing management and appropriate positioning of SecurAcath have demonstrated it is possible to reduce dislodgements to 0%[26].

Can SecurAcath be used on patients with frail skin?

- Yes. The SecurAcath has been used on a variety of skin conditions including the elderly, neonates, burn patients and chronic steroid patients and has performed very well. As indicated in the 2021 INS Standards of Practice, SecurAcath may be a good option for patients with compromised skin integrity[27].

Can SecurAcath be removed before the catheter is removed?

- Yes. It is possible to remove the device while the catheter is still in place. However, it is easier to remove the device after the catheter is removed. Please see our website for removal videos.

Does SecurAcath increase risk for air embolism during removal?

- No. The SecurAcath does not increase the chance for an air embolism when removing the device. Standard practice should be followed when removing the catheter. Hold pressure at the insertion site as catheter is removed and then maintain pressure until hemostasis is achieved.
  Once hemostasis is achieved, the SecurAcath can be removed. Please see our website for removal videos.

Can a patient have an MRI with the SecurAcath?

- Yes. SecurAcath is compatible with MRI up to 3 Tesla (3T). Current MRI terminology for medical devices are: safe, conditional or unsafe. The SecurAcath has been tested and poses no hazards in typical MRI conditions. Additional details can be found in the IFU.

Can I use the antimicrobial or hemostatic protective disc with SecurAcath?

- Yes, the design of SecurAcath allows space for the disk products to fit 360 degrees around the insertion site.

Can I use SecurAcath on a patient with nickel sensitivity?

- The SecurAcath IFU include a warning not to use the device in patients with a known nickel allergy. An estimated 5-10% of the population is said to be allergic to nickel[28]. The allergic response usually presents as contact dermatitis caused by exposed nickel contained in the metal of some jewellery. If a patient reports they have a nickel allergy, it is important to understand the difference between Nitinol and other nickel containing alloys. The Nitinol in the SecurAcath undergoes a process called electropolishing during manufacturing. When electropolished, Nitinol forms a stable protective layer known as passivated nitinol. Electropolished nitinol has excellent biocompatibility, similar to that of stainless steel, which also contains nickel. Unpassivated metal alloys, like those used in inexpensive jewellery, have free nickel ions exposed on the surface, which can cause a hypersensitivity response on the skin. Consider the risks and consequences of skin adhesive reactions, device migration, catheter tip malposition, and dislodgement versus a potential reaction to nickel. Be aware the SecurAcath device can be removed if skin sensitivity or reaction is observed during dwell time.

Can I use Tegaderm CHG with the SecurAcath?

- Yes, Tegaderm CHG can be used with the SecurAcath. SecurAcath is compatible with all types of adhesive dressings used for vascular access devices and catheters.

Can I use tissue adhesive (cyanoacrylate, glue) with SecurAcath?

- Yes, we recommend applying the glue while holding the device in the upright position with slight tension, apply the glue per IFU, let dry, then lay it down.

How do I disinfect the site?

- The SecurAcath allows for 360-degree cleaning of the skin and we recommend you use your institution's preferred skin antiseptic, including but not limited to CHG/Isopropyl Alcohol, Betadine, etc.

Does SecurAcath affect the risk of catheter-related infection?

- A recently published study out of the University of Arkansas for Medical Sciences showed the SecurAcath reduces the risk of CLABSI compared to an adhesive securement device. The study examined 7,776 PICC cases over a 4-year period. The analysis showed the adhesive securement device had a 288% increase in risk of CLABSI compared to SecurAcath.[29] The author postulates that improved catheter stability and site cleaning attributed to the significant improvement in CLABSI risk.

What if blood gets into the SecurAcath device?

- The SecurAcath has been designed to minimize the ability for blood to get into the device with a seal around the edge of the device. If blood is visible on the SecurAcath, use sterile saline soaked gauze to clean the blood off the device. Saline dissolves blood better than an alcohol-based cleaning solution. Once the visible blood is removed, disinfect using standard skin antiseptic solutions such as 2% CHG/70% IPA. We have performed bench testing demonstrating that even if blood gets inside the device, the skin antiseptic agent, being less viscous than blood, will go wherever the blood goes to effectively disinfect the device.

Does SecurAcath cause bleeding at the insertion site?

- SecurAcath is atraumatic and does not puncture or breach the skin or vessels to cause bleeding. It rests in the same puncture site as the catheter and the feet deploy in the subcutaneous tissue just beneath the dermis. Exit site bleeding that is observed in certain patient populations can be easily managed with pressure and several tools already in your hospitals like cyanoacrylate tissue adhesive or hemostatic dressings.

Can you use SecurAcath in neonates and paediatric patients?

- Yes. Several studies have demonstrated that SecurAcath performs very well for securing percutaneous devices in these populations. [30, 31, 32, 33, 34]

Can you place SecurAcath in a patient with shallow veins (<1cm) or cachectic patients?

- Yes, the SecurAcath has been used successfully in a wide variety of patients, including those with shallow veins and very low body fat. The securement feet are small and blunt and will deploy in the subcutaneous space between the dermis and the vein even when there is less subcutaneous tissue than normal.

Do we need to adjust the size of SecurAcath we use to accommodate the taper on some catheters?

- SecurAcath is designed to work on both tapered and non-tapered catheters. There is no need to adjust the SecurAcath size to accommodate the larger diameter on the taper. Select the appropriate size SecurAcath device to match the labelled catheter diameter. If the catheter is labelled with a half French size, use the closest smaller size SecurAcath, e.g. with 8.5F catheter, use 8F SecurAcath.

REFERENCES

Please refer to instructions for use for indications, contraindications, hazards, warnings, cautions and directions for use.

1. Rowe, et al, "Catheter Securement Impact on PICC-related CLABSI: A University Hospital Perspective" American Journal of Infection Control, Open Access, June 17, 2020
2. Brescia, et al, "Subcutaneously anchored securement for peripherally inserted central catheters: Immediate, early, and late complications." Journal of Vascular Access (2021) June
3. McParlan et al, "Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement." Journal of Vascular Access (2020) Jan;21(1):33-38.
4. Pittiruti, et al. "Clinical experience of a subcutaneously anchored sutureless system for securing central venous catheters." British Journal of Nursing (2019) Jan 24;28(2):S4-14.
5. Zerla et al. "Evaluating Safety, Efficacy, and Cost-Effectiveness of PICC Securement by Subcutaneously Anchored Stabilization Device." Journal of Vascular Access 18.3 (2017):238-242.
6. Dolcino et al. "Potential Role of a Subcutaneously Anchored Securement Device in Preventing Dislodgement of Tunneled-Cuffed Central Venous Devices in Pediatric Patients." Journal of Vascular Access 18.6 (2017):540-545.
7. Hughes, Meinir Elen. "Reducing PICC migrations and improving patient outcomes." British Journal of Nursing 23:Sup1, (2014): S12-S18.
8. Paquet, F. et al. "Impact of arm selection on the incidence of PICC complications: results of a randomized controlled trial," JVA (2017) 18(5),408-414.
9. Gibson, C. et al. "Peripherally Inserted Central Catheters: Use at a Tertiary Care pediatric Center," JVIR (2013) 24, 1323-133.
10. Le Royer, C. et al. "Prospective follow-up of complications related to peripherally inserted central catheters", Médecine et Maladies Infectieuses (2013) 43, 350-355.
11. Yamamoto, Alvin J., et al. "Sutureless securement device reduces complications of peripherally inserted central venous catheters." Journal of Vascular and Interventional Radiology 13.1 (2002): 77-81.
12. Cardella et al., Cumulative experience with 1,273 peripherally inserted central catheters at a single institution. JVIR 1996; 7:5-13.
13. Abebe, A., Catheter-Related Bloodstream Infection Review. Hosp Med Clin, Jan. 2014, (3) e32-e49.
14. Gossens, et. al., SecurAstaP trial: securement with SecurAcath versus StatLock for PICCs, a randomised open trial. BJM 2018
15. 24. NHS Resolution. Launch of resources on preventing needlestick injuries 30th March 2023. https://resolution.nhs.uk/2023/03/30/launch-of-resources-on-preventing-needle-stick-injuries/
16. Crocoli, et al., Vascular Access in Pediatric Oncology and Hematology: State of the Art, Children (2022), 9, 70
17. Crocoli, et al, Safety and effectiveness of subcutaneously anchored securement for tunneled central catheters in oncological pediatric patients: A retrospective study, Journal of Vascular Access (2021) June
18. D'Andrea, et al, Securement of central venous catheters by subcutaneously anchored suturless devices in neonates, Journal of Maternal-Fetal & Neonatal Medicine (2021) April
19. Cellini, et al. Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with onco-hematological disease, Journal of Vascular Access (2020) Nov
20. Barone, et al, Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein, Journal of Vascular Access, (2020) June
21. Dolcino, A., et al, Potential Role of a Subcutaneously Anchored Securement Device in Preventing Dislodgement of Tunneled-Cuffed Central Venous Devices in Pediatric Patients, Journal of Vascular Access (2017) Oct
22. Frassanito, et al, Securing CSF catheters to the skin: from sutures and bolt system to subcutaneous anchoring device towards zero complications, Child's Nervous System, (2020) June
23. Fitzsimmons, et al, 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, Journal of Vascular Access, (2020) May
24. Rodriguez Perez, et al, Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonate with Pleural Effusion: Three Case Reports, Case Reports in Paediatrics, (2020) March
25. Egan GM, Siskin GP, Weinmann R, et al. A prospective postmarket study to evaluate the safety and efficacy of a new peripherally inserted central catheter stabilization system. J Infus Nurs 2013;36:181–8. DOI: 10.1097/NAN.0b013e3182893690
26. McParlan D, Edgar L, Gault M, Gillespie S, Menelly R, Reid M. Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement. The Journal of Vascular Access. 2020;21(1):33-38. doi:10.1177/1129729819851059
27. Gorski LA, Hadaway L, Hagle ME, et al. Infusion therapy standards of practice. J Infus Nurs. 2021;44(suppl 1):S1-S224. doi:10.1097/NAN.0000000000000396
28. http://www.nature.com/news/2010/100815/full/news.2010.407.html
29. https://doi.org/10.1016/j.ajic.2020.06.178
30. Rodriguez Perez C, Romitti MG, Pezzotti E, D'Andrea V, Pezza L, Pittiruti M. Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonates with Pleural Effusion: Three Case Reports. Case Rep Pediatr. 2020 Mar 10;2020:7480483. doi: 10.1155/2020/7480483. PMID: 32231838; PMCID: PMC7086429.
31. Cellini, et al. Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with onco-hematological disease, The Journal of Vascular Access, Nov 2020
32. Barone, et al, Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein, Journal of Vascular Access, June 2020
33. Frassanito, et al, Securing CSF catheters to the skin: from sutures and bolt system to subcutaneous anchoring device towards zero complications, Child's Nervous System, June 2020
34. Fitzsimmons, et al, 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, Journal of Vascular Access, May 2020

OUR COMMITMENT TO THE ENVIRONMENT

Vygon UK has been working towards creating a sustainable future for many years and we are a Carbon Neutral Company. We believe that sustainability isn't just about meeting current needs, but more importantly, it is about ensuring we are here for the long term and are paving the way for a bright tomorrow. We strive to deliver enhanced Corporate Social Responsibility (CSR), ensuring we manage the social, economic, and environmental effects of Vygon UK's operations responsibly in line with public expectations.

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No.	Size	Quantity
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VIA400140	4F	Box (10 each)
VIA400110	5F	Box (10 each)
VIA400150	6F	Box (10 each)
VIA400120	7F	Box (10 each)
VIA400160	8F	Box (10 each)
VIA400170	9F	Box (10 each)
VIA400180	10F	Box (10 each)
VIA400200	12F	Box (10 each)

Additional SecurAcath® product information

- Not made with natural latex rubber
- MRI Conditional
- Pyrogen Free

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Please refer to instructions for use for indications, contraindications, hazards, warnings, cautions and directions for use.

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