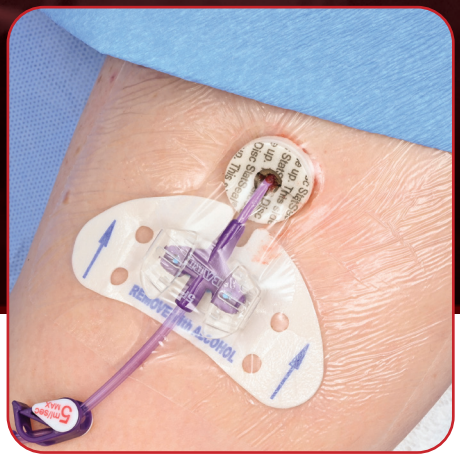
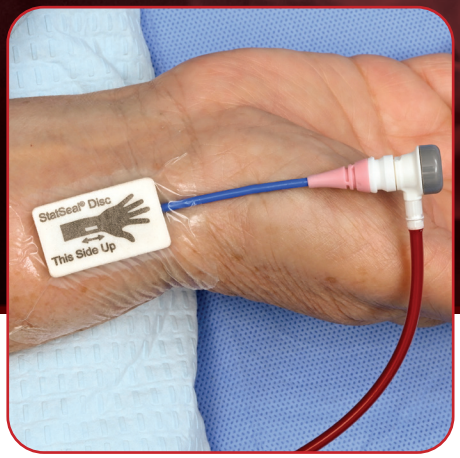
StatSeal® *for* INTERVENTIONAL CARDIOLOGY, INTERVENTIONAL RADIOLOGY & CRITICAL CARE

MERIT MEDICAL®

COMPENDIUM

Clinical evidence to support the safety and efficacy of StatSeal® powder and disc products





StatSeal® removes the variability in hemostasis, so you can move confidently to your next case.

STATSEAL®
Built for every bleed.

StatSeal Venous Closure Device Facilitates Early Ambulation Following Cryoablation of Atrial Fibrillation[1]

Zhang et al.

SUMMARY: From the Essex Cardiothoracic Centre, this study compared the StatSeal venous closure device to the modified figure-of-8 (mFO8) suture technique in patients undergoing atrial fibrillation cryoablation. The primary outcome was time-to-ambulation (TTA). Of the 66 patients, 36 received the StatSeal disc, and 30 received the mFO8 suture. There was a significant 28.7% reduction in mean TTA in the StatSeal group (3.63 ± 1.20 hr vs. 5.09 ± 0.89 hr, $p<0.01$), with no major bleeding complications in either group. Findings indicate that StatSeal is effective in reducing time to ambulation after atrial fibrillation cryoablation, potentially facilitating same-day discharge and supporting improved patient and healthcare system outcomes while maintaining a low incidence of access-site complications.

TYPE: Prospective cohort study **NO. PATIENTS:** 66 **PUBLICATION:** *EP Europace* **YEAR:** 2025

A Randomised Control Trial to Compare Conventional and Haemostatic Dressings in Radial Arterial Access: Assessment of Radial Artery Complications Whilst Achieving Rapid Haemostasis (ARCH Trial)[2]

Proscia et al.

SUMMARY: Dr. Rodney Stables of Liverpool Heart and Chest Hospital was the senior investigator of this randomized trial targeting 3,000 patients across three protocols: C2 used the Terumo TR Band® alone with a 2-hr deflation; C1 used the TR Band alone with a 1-hr deflation; and H1 combined the TR Band with StatSeal and a 1-hr deflation. Hemostasis success was significantly higher in the H1 StatSeal group, with only 5.2% of patients failing to achieve hemostasis at the planned time, compared to 50% in C2 and 62% in C1. StatSeal also accelerated hemostasis, with a median time of 72 min versus 166 min in C2 and 136 min in C1. Additionally, StatSeal reduced radial-related discharge delays by 87% compared to both C1 and C2. Due to safety concerns over high rebleed rates in the non-StatSeal groups, the Data and Safety Monitoring Committee halted the trial early after enrolling 2,114 patients.

TYPE: Randomized controlled trial **NO. PATIENTS:** 2,114 **PUBLICATION:** *Int J Cardiol* **YEAR:** 2025

Radial Hemostasis Is Facilitated With a Potassium Ferrate Hemostatic Patch: The STAT2 Trial[3]

Safirstein et al.

SUMMARY: Drs. Arnold Seto, Jeffrey Schussler, and David Tehrani are contributing authors in this trial, evaluating hemostasis after transradial access in 443 patients using a TR Band, with and without StatSeal Advanced RAD Disc. The study found that adding StatSeal enabled safe, early TR Band deflation at 60 min with minimal complications, whereas early deflation without StatSeal led to increased rebleeding and longer compression times. StatSeal use significantly shortened hemostasis time, averaging 66 min versus 113 min in the control group, representing a 41.6% reduction. The study concluded that use of StatSeal Advanced RAD Disc resulted in shorter hemostasis times and helped reduce vascular complications.

TYPE: Multicenter randomized controlled trial **NO. PATIENTS:** 443 **PUBLICATION:** *JACC: Cardiovasc Interv* **YEAR:** 2022

CONTINUED

Postprocedural Radial Artery Compression Time in Chronic AnticoaguLated Patients Using StatSeal: The PRACTICAL-SEAL Study[4]

Bagur et al.

SUMMARY: This study evaluated the safety and efficacy of the StatSeal disc for adjunct hemostasis in patients undergoing transradial coronary angiography while continuing oral anticoagulation therapy, either warfarin (47.2%) or NOACs (52.8%), with 94% also receiving intravenous unfractionated heparin. The use of StatSeal resulted in rapid hemostasis, with a mean complete hemostasis time of 71.1 ± 13.0 min, and low rates of localized bleeding at the puncture site. No cases of radial artery occlusion were observed among patients assessed by Doppler ultrasound. The findings support StatSeal as a safe, effective adjunct for hemostasis in this high-risk population.

TYPE: Prospective observational study **NO. PATIENTS:** 180 **PUBLICATION:** *Int J Cardiol* **YEAR:** 2022

Accessing the Wrist[5]

Pitta and Prasad

SUMMARY: Radial artery access has increasingly become the standard approach for coronary angiography and intervention, and it is associated with better hemostasis compared to femoral artery access. Transradial access has increased patient preference, facilitates early ambulation, and is cost effective. Following proximal or distal transradial access, use of StatSeal Advanced RAD Disc in conjunction with a compression band can help shorten time to hemostasis following both diagnostic and PCI procedures. Transradial access limitations can be reduced with ultrasonography guidance and increased familiarity with alternative access sites in the wrist.

TYPE: Systematic review **NO. PATIENTS:** N/A **PUBLICATION:** *Interv Cardiol Clin* **YEAR:** 2020

Accelerated Patent Hemostasis Using a Procoagulant Disk; A Protocol Designed to Minimize the Risk of Radial Artery Occlusion Following Cardiac Catheterization[6]

Ayyaz Ul Haq et al.

SUMMARY: Drs. James Nolan and Mamas Mamas are contributing authors in this single center, prospective study where patients were randomized to two hemostasis protocols: use of a Helix compression band alone versus use of a Helix band with StatSeal Advanced Disc and an accelerated protocol. The addition of StatSeal significantly reduced compression time by 51.9% (79.7 min vs. 165.8 min, $p < 0.001$) without increasing the risk of access-site bleeding or radial artery occlusion. The study concluded that a reduction in radial artery compression time can be achieved by using StatSeal in association with an accelerated hemostasis protocol without increasing the risk of access-site bleeding and radial occlusion after transradial catheterization. Use of StatSeal with compression devices may enable earlier mobilization and reduced nursing resources following TRA procedures.

TYPE: Randomized controlled trial **NO. PATIENTS:** 389 **PUBLICATION:** *Cardiovasc Revasc Med* **YEAR:** 2019

CONTINUED

Radial Haemostasis Is Facilitated with a Potassium Ferrate Haemostatic Patch: The StatSeal with TR Band Assessment Trial (STAT)[7]

Seto et al.

SUMMARY: Drs. William Suh, William Rollefson, and Mauricio Cohen are contributing authors in this multicenter study comparing use of a TR Band alone versus use of a TR Band with StatSeal Advanced Disc, in patients who had a minimum of 5,000 units of heparin prior to diagnostic or PCI transradial access procedures. The addition of StatSeal reduced time to hemostasis by 73% (mean 43 min vs. 160 min) and enabled earlier patient discharge (mean 51 min sooner) without a statistically significant increase in complication rates, including minor hematomas and radial artery occlusion. These findings support StatSeal as an effective adjunct to a TR Band for accelerating hemostasis and facilitating earlier patient discharge after transradial procedures.

TYPE: Randomized controlled trial **NO. PATIENTS:** 180 **PUBLICATION:** *EuroIntervention* **YEAR:** 2018

Time to Discharge Following Diagnostic Coronary Procedures via Transradial Artery Approach: A Comparison of Terumo Band and StatSeal Hemostasis[8]

Van Meter et al.

SUMMARY: Dr. Jeffrey Schussler is a contributing author in this study. Held at Baylor Jack and Jane Hamilton Heart and Vascular Hospital, the study looked at patients who underwent diagnostic coronary angiography via transradial access to determine whether using a combination of a TR Band with StatSeal Disc safely decreases time to discharge compared to using the TR Band alone. The use of StatSeal with the a TR Band resulted in a statistically significant 28.3% reduction in median time to discharge compared to a TR Band alone, with no significant difference in safety outcomes, indicating that a StatSeal-band combination safely accelerates patient throughput after transradial procedures.

TYPE: Randomized controlled trial **NO. PATIENTS:** 445 **PUBLICATION:** *Cardiovasc Revasc Med* **YEAR:** 2018

Use of StatSeal Advanced Disc to Decrease Time to Hemostasis in Transradial Cardiac Procedures/A Quality Improvement Project[9]

Condry and Jara

SUMMARY: This project evaluated patients undergoing transradial cardiac catheterization, comparing the standard TR Band protocol to a combination of a TR Band and StatSeal Advanced Disc for hemostasis. The use of StatSeal significantly reduced mean time to hemostasis from 205 min ± 52 min to 77 min ± 20 min ($p < 0.01$), achieving the goal of 1-hr hemostasis without a statistically significant increase in bleeding complications or radial artery occlusion. These findings support StatSeal as a safe and effective adjunct for expediting hemostasis and reducing nursing hours in transradial procedures.

TYPE: Prospective quality improvement project **NO. PATIENTS:** 48 **PUBLICATION:** *Int J Nurs Sci* **YEAR:** 2016

CONTINUED

Distal Transradial Artery Access for Neuroangiography and Neurointerventions[10]

Rodriguez Caamaño et al.

SUMMARY: A total of 100 dTRA procedures were carried out using an optimized protocol for puncture and post-puncture compression: 53 diagnostic angiograms (53%) and 47 interventional procedures (47%). Of the patients, 3 (3%) presented with puncture-site hematomas with no intervention required, and 61 (61%) underwent the ultrarapid hemostasis protocol using StatSeal disc to achieve hemostasis. The analysis concluded that dTRA using a rapid deflation protocol in conjunction with StatSeal disc is a safe and feasible access route for angiography and neurointerventions and does not significantly increase hematoma rates.

TYPE: Retrospective observational study **NO. PATIENTS:** 100 **PUBLICATION:** *Clin Neuroradiol* **YEAR:** 2021

Safety and Efficacy of a Truncated Deflation Algorithm for Distal Transradial Access[11]

Hadjivassiliou et al.

SUMMARY: Dr. Darren Klass is a contributing author in this study, which investigated a 25-min protocol for compression of the distal radial arteriotomy using specific hemostatic bands in combination with StatSeal disc for patients undergoing percutaneous image-guided procedures. In 593 procedures, the mean nursing time for access-site care was 25.1 min. No radial artery occlusions were observed; 1.2% of patients experienced clinically insignificant minor hematomas. The authors conclude that the accelerated 25-min deflation algorithm is safe and effective for hemostasis with no increased risk of complications and that it significantly reduced nursing intensity.

TYPE: Retrospective observational study **NO. PATIENTS:** 434 **PUBLICATION:** *J Vasc Interv Radiol* **YEAR:** 2020

Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis in Percutaneous Arterial, Venous, and Arteriovenous Dialysis Access Procedures[12]

Wang et al.

SUMMARY: This study compared the efficacy of StatSeal Advanced Powder (formerly QR Powder) and D-Stat® in achieving hemostasis across various percutaneous vascular procedures. StatSeal significantly reduced mean time to hemostasis by approximately 50% compared to D-Stat, with covariate-adjusted mean times of 3.05 min for StatSeal versus 6.20 min for D-Stat, without increasing complication rates. The hematoma rate with StatSeal was very low (2.8%), and all hematomas were minor (less than 5 cm). Importantly, the effectiveness of StatSeal was not diminished by the use of anticoagulants, antiplatelet agents, or thrombolytics, indicating robust performance even in patients on blood thinners. Overall, StatSeal provided rapid, safe, and reliable hemostasis in a broad range of vascular access settings.

TYPE: Retrospective observational study **NO. PATIENTS:** 138 **PUBLICATION:** *J Vasc Interv Radiol* **YEAR:** 2008

CONTINUED

Rapid Haemostasis to Achieve Dressing Longevity: Evaluation Trial Results Using StatSeal Catheter Exit Site Protection[13]

Hastings and Barton

SUMMARY: This study took place at Frimley Health NHS Foundation Trust and evaluated the efficacy of StatSeal in managing PICC exit-site bleeding. The trial was conducted on adult inpatients requiring a PICC or outpatients requiring a PICC for chemotherapy or home IV antibiotics. The primary endpoint was dressings that lasted 7 days. Of the 177 patients with StatSeal dressings, 99% lasted 7 days. The study concluded using StatSeal improved patient outcomes by reducing exit-site bleeding and associated complications, while reducing the number of required dressing changes in a 7-day period, which saves nursing time and costs.

TYPE: Retrospective observational study **NO. PATIENTS:** 207 **PUBLICATION:** *Br J Nurs* **YEAR:** 2024

Experience with Implementation of a Nurse Practitioner-Led Newborn Circumcision Clinic[14]

Williams et al.

SUMMARY: This study assessed the implementation of a nurse practitioner-led newborn circumcision clinic, where clamp-style circumcisions were performed on infants without general anesthesia. Minor bleeding events occurred in 4.3% of patients during recovery and were effectively managed with topical StatSeal powder, whereas two additional cases (0.9%) required emergency department evaluation and pressure dressings with StatSeal after discharge. In all cases, bleeding was successfully controlled with StatSeal, and no serious complications were reported. The use of StatSeal contributed to the clinic's strong safety profile, high family satisfaction, and substantial cost savings compared to operating room circumcision.

TYPE: Retrospective analysis **NO. PATIENTS:** 234 **PUBLICATION:** *J Pediatr Urol* **YEAR:** 2020

CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative Integrating Line-Rounding Principles and a Team Approach[15]

Wilder et al.

SUMMARY: The implementation of a systematic, team-based central line maintenance program in a level IV NICU at Dallas Children's Health led to a dramatic reduction in central line associated bloodstream infection (CLABSI) rates. Specifically, the CLABSI rate decreased from 3.9 per 1,000 line days in 2011 to 0.3 per 1,000 line days in 2014, representing a 92% improvement. Over 3 years, this equated to a reduction of seven CLABSI infections, substantial cost savings of $394,162, and a decrease in patient length of stay by approximately 17.6 days. The initiative included standardized protocols, which included the prophylactic use of StatSeal in the dressing-change protocol, daily line rounds, a dedicated maintenance team, and enhanced education for staff and families. The results demonstrate that a multidisciplinary, standardized approach to central line care can significantly improve patient safety and reduce healthcare costs in the NICU setting.

TYPE: Quality improvement study **NO. PATIENTS:** N/A **PUBLICATION:** *Adv Neonatal Care* **YEAR:** 2016

CONTINUED

The Science of a 'Seal' for PICC Line Management: BioSeal CVC Powder: An Alternative Hemostatic Agent That Keeps Sites Dry and Intact[16]

Blough, Hinson, and Hen

SUMMARY: Held at Florida Hospital, this study evaluated StatSeal powder (formerly BioSeal CVC) as a replacement for gauze in managing bleeding at PICC line access sites. StatSeal was highly effective, controlling bleeding or oozing in 94% of applications within 2 min, and was preferred by nursing staff over traditional gauze. Extended use of StatSeal eliminated the need for the 48-hr dressing change protocol, resulting in fewer site manipulations and improved patient comfort. Importantly, post-trial data showed a significant 40% reduction in catheter-related bloodstream infections (CRBSIs), with no site infections or other complications reported.

TYPE: Retrospective observational study **NO. PATIENTS:** 418 **PUBLICATION:** *JAVA* **YEAR:** 2010

REFERENCES
1. Zhang et al. "StatSeal Venous Closure Device Facilitates Early Ambulation Following Cryoablation of Atrial Fibrillation." Supplement, *EP Europace* 27, no. S1. (2025): euaf085.412. doi: 10.1093/europace/euaf085.412.
2. Proscia et al. 2025. "A Randomised Control Trial to Compare Conventional and Haemostatic Dressings in Radial Arterial Access: Assessment of Radial Artery Complications Whilst Achieving Rapid Haemostasis (ARCH Trial)." *Int J Cardiol* 420 (Feb): 132740. doi: 10.1016/j.ijcard.2024.132740.
3. Safirstein et al. 2022. "Radial Hemostasis Is Facilitated with a Potassium Ferrate Hemostatic Patch." *JACC: Cardiovasc Interv* 15, no. 8 (Apr): 810–19. doi: 10.1016/j.jcin.2021.12.030.
4. Bagur et al. 2022. "Postprocedural Radial Artery Compression Time in Chronic AnticoaguLated Patients Using StatSeal: The PRACTICAL-SEAL Study." *Int J Cardiol* 346 (Jan): 14–17. doi: 10.1016/j.ijcard.2021.11.011.
5. Pitta and Prasad. 2020. "Accessing the Wrist." *Interv Cardiol Clin* 9, no. 1: 1–19. doi: 10.1016/j.iccl.2019.08.009.
6. Ayyaz Ul Haq et al. 2019. "Accelerated Patent Hemostasis Using a Procoagulant Disk; A Protocol Designed to Minimize the Risk of Radial Artery Occlusion Following Cardiac Catheterization." *Cardiovasc Revasc Med* 20, no. 2 (Feb): 137–42. doi: 10.1016/j.carrev.2018.03.026.
7. Seto et al. 2018. "Radial Haemostasis Is Facilitated with a Potassium Ferrate Haemostatic Patch: The Statseal with TR Band Assessment Trial (STAT)." *EuroIntervention* 14, no. 11 (Dec): e1236–42. doi: 10.4244/eij-d-18-00101.
8. Van Meter et al. 2018. "Time to Discharge Following Diagnostic Coronary Procedures via Transradial Artery Approach: A Comparison of Terumo Band and StatSeal Hemostasis." *Cardiovasc Revasc Med* 19, no. 7 (Oct): 759–61. doi: 10.1016/j.carrev.2018.03.009.
9. Condry and Jara. 2016. "Use of StatSeal Advanced Disc to Decrease Time to Hemostasis in Transradial Cardiac Procedures/A Quality Improvement Project." *Int J Nurs Sci* 6, no. 4: 103–7. doi: 10.5923/j.nursing.20160604.03.
10. Rodriguez Caamaño et al. 2021. "Distal Transradial Artery Access for Neuroangiography and Neurointerventions." *Clin Neuroradiol* 32, no. 2 (Jun): 427–34. doi: 10.1007/s00062-021-01039-9.\
11. Hadjivassiliou et al. 2020. "Safety and Efficacy of a Truncated Deflation Algorithm for Distal Transradial Access." *J Vasc Interv Radiol* 31, no. 8 (Aug): 1328–33. doi: 10.1016/j.jvir.2020.02.027.
12. Wang et al. 2008. "Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis in Percutaneous Arterial, Venous, and Arteriovenous Dialysis Access Procedures." *J Vasc Interv Radiol* 19, no. 1 (Jan) : 72–9. doi: 10.1016/j.jvir.2007.08.028.
13. Hastings and Barton. 2024. "Rapid Haemostasis to Achieve Dressing Longevity: Evaluation Trial Results Using StatSeal Catheter Exit Site Protection." *Br J Nurs* 33, no. 14 (Jul): S8–S14. doi: 10.12968/bjon.2024.0164.
14. Williams et al. 2020. "Experience with Implementation of a Nurse Practitioner-Led Newborn Circumcision Clinic." *J Pediatr Urol* 16, no. 5 (Oct): 651.e1–7. doi: 10.1016/j.jpurol.2020.08.008.
15. Wilder et al. 2016. "CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative Integrating Line-Rounding Principles and a Team Approach." *Adv Neonatal Care* 16, no. 3 (Jun): 170–77. doi: 10.1097/anc.0000000000000259.
16. Blough, Hinson, and Hen. 2010. "The Science of a 'Seal' for PICC Line Management: BioSeal CVC Powder: An Alternative Hemostatic Agent That Keeps Sites Dry and Intact." *JAVA* 15, no. 2: 66–73. doi: 10.2309/java.15-2-4.

MERIT MEDICAL®
Understand. Innovate. Deliver.™
merit.com

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
1.801.253.1600
1.800.35.MERIT

Merit Medical Europe, Middle East & Africa (EMEA)
Amerikalaan 42, 6199 AE
Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733

408739001_001 ID 072326