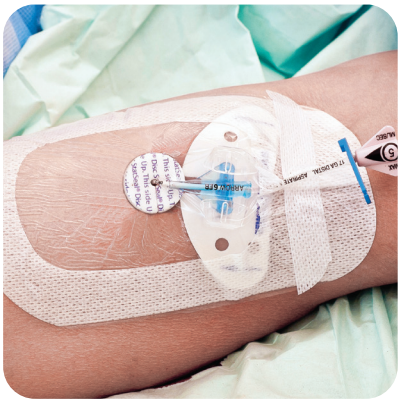
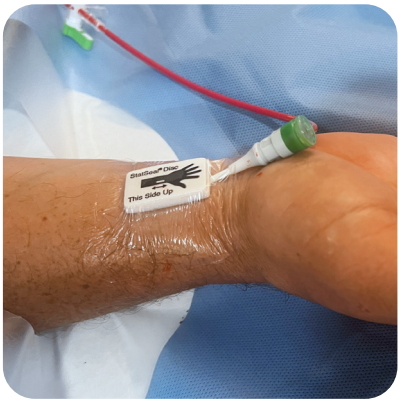
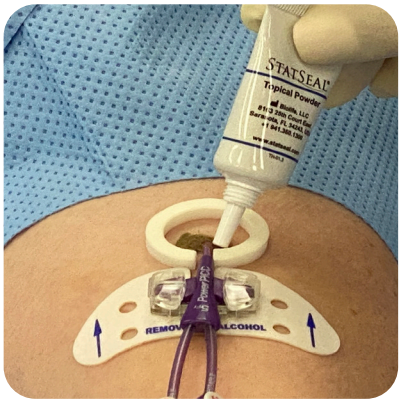
Interventional Cardiology • Vascular Access • Interventional Radiology

StatSeal®







COMPENDIUM

Clinical evidence to support the safety & efficacy of StatSeal® Powder & Disc products

BIOLIFE®

Biolife, LLC, maker of StatSeal® products

MKT-FORM-073.7

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Interventional Cardiology

Title	Author	Source	Year	Summary	Investigator Initiated	Study Type
StatSeal Groin Closure after AF Ablation to Allow Rapid Same Day Discharge	Peralta R, et al.	AF Healthcare Pioneers Report	2023	This study performed at the Essex Cardiothoracic Centre in the UK, evaluated using the StatSeal Advanced Plus Disc for femoral vein groin closure of AF ablation patients who remained on their anticoagulation medications. The previous closure method used was physician-placed sutures. During the study, 50 AF ablations were performed and StatSeal was applied to the closure site. The median recovery time for the StatSeal group was 2 hours, compared to 4 hours with the suture closure method. The median discharge time for the StatSeal group was 2.5 hours, compared to 5 hours with the suture closure method. StatSeal use resulted in a more than 50% decrease in recovery time, with no rise in complications, allowing patients to safely mobilize and get home up to 1 hour earlier compared to the suture closure method. The study concluded that StatSeal use will likely lead to increased same-day discharge and less overnight stays following AF ablations.	X	Retrospective Observational Study
Assessment of Radial Artery Complications Whilst Achieving Rapid Haemostasis – ARCH Trial	Proscia C, et al.	EuroPCR	2022	Dr. Rod Stables of Liverpool Heart and Chest Hospital was the senior investigator of this trial which set out to randomize 3,000 patients to three different protocols: a TR (Terumo) band alone with a 2-hr deflation time, a TR band alone with a 1-hr deflation time, or a TR band with StatSeal and a 1-hr deflation time. Only 5.2% of the patients randomized to StatSeal failed to reach hemostasis within the allotted time, as compared with 50% of those with a TR band alone with the 2-hr deflation, and 62% of those with a TR band alone with the 1-hr deflation. The Data and Safety Monitoring Committee stopped the trial early, after 2,114 patients, over safety concerns of the high rebleed rate without StatSeal use. Time to hemostasis also favored StatSeal with a median of 72 minutes, compared to 166 minutes for the TR band alone with the 2-hr deflation, and 136 minutes for the TR Band alone with the 1-hr deflation. Discharge delays related to radial care were significantly higher in the groups without StatSeal.	X	Randomized Controlled Trial
Radial Hemostasis Is Facilitated With a Potassium Ferrate Hemostatic Patch: The STAT2 Trial	Safirstein JG, et al.	Journal of the American College of Cardiology: Cardiovascular Interventions	2022	Drs. Arnold Seto, Jeffrey Schussler and David Tehrani are contributing authors in this multicenter, prospective, randomized clinical trial which evaluated using a Terumo Band (TR Band), both with and without StatSeal Advanced RAD Disc, to achieve hemostasis following transradial access. Results found that adjunctive use of StatSeal disc facilitates early (60 min)deflation of the TR Band after transradial access with minimal complications. Early TR Band deflation without StatSeal disc resulted in increased rebleeding and longer compression times. The study concluded that use of StatSeal Advanced RAD Disc resulted in shorter hemostasis times and helped reduce vascular complications.	X	Multicenter Randomized Controlled Trial
Postprocedural Radial Artery Compression Time In Chronic AnticoaguLated patients using StatSeal: The PRACTICAL- SEAL study	Bagur R, et al.	International Journal of Cardiology	2022	This study evaluated the safety and efficacy of StatSeal disc for adjunct hemostasis in patients undergoing transradial coronary angiography under uninterrupted OAC therapy. Among 180 included patients, 85 (47.2%) patients were on warfarin and 95 (52.8%) patients were on NOACs. Intravenous unfractioned heparin (UFH) was administered in 94% of all patients. The study found that in patients undergoing transradial coronary angiogram and intervention under contemporary uninterrupted (D)OAC therapy and periprocedural administration of UFH, the use of StatSeal disc for adjunctive hemostasis was associated with short times to complete hemostasis (mean total compression time 71.1 ± 13.0 min.), a low rate of localized bleedings at the puncture site, and no radial artery occlusion (RAO) was observed.	X	Prospective Observational Study
Heparin, compression, and radial artery occlusion: Less is more	Tehrani DM, et al.	Catheterization & Cardiovascular Interventions	2021	Dr. Arnold Seto is a contributing author in this editorial that reviews results from recent studies, including STAT2. Radial artery occlusion is a function of anticoagulation, compression time, compression pressure, and vascular injury from sheath size and puncture attempts. Recent data shows that increased levels of anticoagulation during transradial cases is associated with a higher incidence of occlusive hemostasis, increasing the risk of radial artery occlusion. Reduction in compression time was made possible by adjunctive hemostatic patch (StatSeal) and may obviate the need for high doses of heparin, allowing operators to use as little heparin as necessary.	X	Editorial

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Postprocedural Radial Artery Compression Time in Chronic Anticoagulated Patients Using StatSeal. The Practical-Seal Feasibility Study	Bagur R, et al.	Journal of the American College of Cardiology	2020	A total of 142 patients under chronic anticoagulation (warfarin or novel oral anticoagulant) were included in this feasibility study to assess the safety and efficacy of using StatSeal disc in patients undergoing coronary angiography through transradial approach. After completion of the procedure, the sheath was removed and a StatSeal disc was used in conjunction with a radial compression band. The primary safety outcome was access-site related bleeding complications, and the primary efficacy endpoint was the time to complete hemostasis (compression band removal). The use of StatSeal was safe with short compression times of 73.4±13.1 to achieve complete hemostasis without RAO or other safety issues.	X	Prospective Observational Study
Accessing the Wrist: From Data to Tips and Tricks	Pitta SR, et al.	Interventional Cardiology Clinics	2020	Radial artery access has increasingly become the standard approach for coronary angiography and intervention, and is associated with better hemostasis compared with femoral artery access. Transradial access has increased patient preference, facilitates early ambulation, and is costeffective. 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.	X	Systemic Review
Meta-Analysis of Radial Hemostasis Trials Using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc	Khuddus MA, et al.	Journal of the American College of Cardiology	2019	Investigator initiated clinical trials from both interventional cardiology and interventional radiology used StatSeal to minimize the duration of compression and to minimize related RAO. This more than 2,000-patient meta-analysis combined patent hemostasis and a very short time to hemostasis of 50.7 min (SD 13.70 min) to produce a very low RAO rate of 1.9% (95% CI 0.08%-6.1%). The only other complications were some (5.9%) minor, clinically insignificant, Class 1 and Class 2 hematomas that were remedied by 10-15 minutes of additional compression. Presented at TCT 2019.	X	Multi-disciplinary, Intercontinental Meta-analysis
The Quest for a Radial Lounge: StatSeal Reduces Transradial Coronary Angiography Turn-Around Time and Cost	Galusko V, et al.	Journal of the American College of Cardiology	2019	This study focused on the operational benefits of using StatSeal. The study concluded that StatSeal is an effective aid to achieve quicker and more consistent hemostasis, and helped achieve an operational cost savings of $104.90 per angiogram and $341.69 per PCI. Presented at TCT 2019.	X	Case Series
Accelerated patent hemostasis using a procoagulant disk; a protocol designed to minimize the risk of radial artery occlusion following cardiac catheterization	Ayyaz M, et al.	Cardiovascular Revascularization Medicine	2019	Drs. Jim Nolan and Mamas Mamas are contributing authors in this single center, prospective study where 389 patients were randomized to 2 hemostasis protocols: use of a Helix compression band alone OR use of a Helix band with StatSeal Advanced Disc. Study concluded that a reduction in compression time can be achieved by using StatSeal in association with an accelerated hemostasis protocol without increasing the risk of access site bleeding and RAO. The combination of reduced compression time combined with maintained radial flow via patent hemostasis has the potential to reduce the risk of radial occlusion after transradial catheterization. Presented at AIM Radial 2018.	X	Randomized Controlled Trial
Radial haemostasis is facilitated with a potassium ferrate haemostatic patch: the Statseal with TR Band assessment trial (STAT)	Seto AH, et al.	Euro-Intervention	2018	Drs. William Suh, William Rollefson and Mauricio Cohen are contributing authors in this investigator initiated, multicenter, randomized control study comparing use of TR band alone vs. use of TR band with StatSeal in 180 patients who had a minimum of 5k units of heparin and prior to diagnostic and PCI transradial access procedures. Use of StatSeal in conjunction with the TR band reduced time to hemostasis by 75% and improved patient time to discharge without statistically increasing complication rates. Presented at TCT 2017.	X	Randomized Controlled Trial

Interventional Cardiology

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Time to discharge following diagnostic coronary procedures via transradial artery apporach: A comparison of Terumo band and StatSeal hemostasis	Van Meter C, et al.	Cardiovascular Revascularization Medicine	2018	Dr. Jeffrey Schussler is a contributing author in this Jack & Jane Hamilton Heart & Vascular Hospital at Baylor University retrospective study that looked at 445 patients who underwent diagnostic coronary angiography via transradial access to determine whether using a combination of a Terumo band with StatSeal disc safely decreases time to discharge compared to using the Terumo band alone. The median time to discharge was statistically and significantly reduced by 28.3% for patients who had a combination of a TR band and StatSeal, with no significant alteration in safety.	X	Retrospective Cohort Study
Reduction in Radial Artery Occlusion and Time to Hemostasis: Results from the StatSeal Advanced with Patent Hemostasis by Titration Effectiveness Trial (SAPHTE)	Khuddus MA, et al.	Transcatheter Cardiovascular Therapeutics, Annual Scientific Symposium	2018	This 60-patient, prospective, single arm observational study looked at transradial hemostasis performed using a TR band with StatSeal Advanced Disc. A TR band was applied post procedure and inflated with 8 cc of air just prior to sheath removal. On arrival to recovery, patients were titrated to patency via reverse Barbeau test. Full deflation was performed at 40 minutes. This protocol resulted in minimal occurrence of RAO, rapid time to hemostasis and infrequent hematomas. Use of this protocol has the potential to increase lab efficiency, throughput and staff satisfaction, while also reducing cost and length of stay by shortening time to discharge.	X	Prospective Observational Study
Improving Patient Care and Post Procedure Efficiency Following Transradial Access	Khuddus MA	Cath Lab Digest	2017	Article discusses how using StatSeal Advanced Disc following transradial access has proven effective at decreasing post procedure recovery time with no increase in bleeding, and how a simplified radial hemostasis protocol allows for improved staff efficiency.	X	Opinion
Utilization of a Potassium Ferrate Hemostatic Disc (StatSeal) to Accelerate Time to Hemostasis in Transradial Cardiac Procedures (TRA)	Rollefson W, et al.	Society for Cardiovascular Angiography & Interventions, Scientific Sessions	2016	This 51-patient radial pilot study achieved hemostasis 100% of the time with bands fully deflated in an average of 40 minutes. A single minor hematoma was resolved with 15 minutes additional inflation time. All bands were removed in the cath lab and all patients were discharged per SOP for same day PCI, with no evidence of acute radial artery occlusion. Presented at SCAI 2016.	X	Case Series
Use of StatSeal Advanced Disc to Decrease Time to Hemostasis in Transradial Cardiac Procedures/A Quality Improvement Project	Condry H, et al.	International Journal of Nursing Science	2016	A quality improvement project evaluated the difference in time to hemostasis using the standard Terumo band protocol, both with and without the StatSeal Advanced Disc in 48 patients. Use of StatSeal reduced time to hemostasis to 1 hour with no significant increase in bleeding complications or radial artery occlusion.	X	Retrospective Analysis
Transradial Catheterization: Hemostasis, Patency, and Same-Day Discharge	Dugas CM, et al.	Cardiac Interventions Today	2016	Dr. Jeffery Schussler is a contributing author. Transradial access, compared to the femoral access, can lead to safer, less costly and more satisfactory coronary angiography and interventions. Use of StatSeal when applied to the arteriotomy at the time of band placement dramatically reduced the time to hemostasis. Because reduction of time to hemostasis is associated with a reduction in complications such as radial artery occlusion, StatSeal use may aid in both reducing complications and time to discharge.	X	Opinion

Interventional Radiology

Title	Author	Source	Year	Summary	Investigator Initiated	Study Type
Distal Transradial Artery Access for Neuroangiography and Neurointerventions	Rodriguez Caamaño I, et al.	Clinical Neuro-radiology	2021	A retrospective analysis of diagnostic and interventional procedures performed via dTRA using an optimized protocol for puncture and postpuncture compression of the dTRA was performed. A total of 100 distal radial procedures were carried out: 53 diagnostic angiograms (53%) and 47 interventional procedures (47%). Of the patients, 3 presented puncture site hematomas (3%) with no intervention required, 61 patients (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.	X	Retrospective Observational Study
Safety and Efficacy of a Truncated Deflation Algorithm for Distal Transradial Access	Hadjivassiliou A, et al.	Journal of Vascular and Interventional Radiology	2020	Dr. Darren Klass is a contributing author in this study which investigated a 25- minute 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 minutes. No radial artery occlusions were observed; 1.2% patients experienced clinically insignificant minor hematomas. The authors conclude that the accelerated 25-minute deflation algorithm is safe and effective for distal TRA hemostasis with no increased risk of complications and significantly reduced nursing intensity.	X	Retrospective Observational Study
Meta-Analysis of Radial Hemostasis Trials Using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc	Khuddus MA, et al.	Journal of The American College of Cardiology	2019	Investigator initiated clinical trials from both interventional radiology and interventional cardiology used StatSeal to minimize the duration of compression and to minimize related RAO. If the bands were not too tight (patent hemostasis), the only remaining variable was the duration of the compression. This more than 2,000-patient meta-analysis combined patent hemostasis and a very short time to hemostasis of 50.7 min (SD 13.70 min) to produce a very low RAO rate of 1.9% (95% CI 0.08%-6.1%). The only other complications were some (5.9%) minor, clinically insignificant, Class 1 and Class 2 hematomas that were immediately remedied by 10-15 minutes of additional compression.	X	Multi-disciplinary, Intercontinen-tal Meta-analysis
Safety and efficacy of a rapid deflation algorithm for patent hemostasis following radial intervention (PROTEA)	De Korompay N, et al.	Journal of Vascular and Interventional Radiology	2017	Dr. Darren Klass was an additional author of this study which evaluated a deflation protocol using StatSeal in conjunction with the Safeguard hemostatic band in 323 radial procedures. The protocol resulted in a 25 minute hemostasis time and 2-hour “same day” discharge in all patients. Presented at SIR 2017.	X	Case Series
Comparative Evaluation of Noninvasive Com-pression Adjuncts for Hemostasis in Percutaneous Arterial, Venous, and Arteriovenous Dialysis Access Procedures	Wang DS, et al.	Journal of Vascular and Interventional Radiology	2008	Study found that StatSeal Advanced (formerly QR Powder) outperformed DStat in various vascular procedures. Use of StatSeal significantly shortened hemostasis time (by ~ 50%) without increasing complications. Despite fast time to hemostasis, there was a very low hematoma rate of 2.8%, all smaller than 5 cm. Various blood thinners did not alter the effectiveness of StatSeal.		Randomized Controlled Trial

Vascular Access

Title	Author	Source	Year	Summary	Investigator Initiated	Study Type
Rapid haemostasis to achieve dressing longevity: Evaluation trial results using StatSeal catheter exit site protection	Hastings A, et al.	British Journal of Nursing	2024	Andrew Barton is a contributing author in this study at Frimley Health NHS Foundation Trust which 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.	X	Retrospective Observational Study
StatSeal Decreases Central Line Bleeding in Blood and Marrow Transplant Patients	Karska C	Oncology Nursing Society Annual Bridge Virtual Meeting	2020	A root cause analysis identified that over 50% of blood and marrow transplant (BMT) patients at this facility required multiple dressing changes within the first week, when dressed with a CHG gel pad. This study sought to determine if StatSeal could prevent bleeding at the exit site of the central lines placed in these BMT patients. The BMT Unit collaborated with Interventional Radiology (IR) to trial StatSeal on every BMT patient with a central line. Of the pre-trial lines with the CHG dressing, 37% required an unscheduled dressing change due to wet blood beyond the CHG gel pad. Of the trial lines with the StatSeal dressing, there were zero unscheduled dressing changes required. The study concluded that in BMT patients, StatSeal should be part of CLABSI reduction strategy.	X	Prospective Observational Study
Fresh Eyes Focused on Safety: Nurses Partner with Engineering Students to Eliminate CLABSIs in Cardiac Surgery Patients	Olsen M, et al.	Association for Vascular Access, Annual Scientific Meeting	2019	Johns Hopkins performed a root cause analysis to determine if they could further decrease their CLABSI rate. Results from this analysis coupled with a new “Zero Tolerance” for bleeding program led them to start using StatSeal prophylactically on all catheter insertions. This new and improved Johns Hopkins CLABSI reduction program resulted in a 50% reduction in CLABSI in 2017 and an additional 26% reduction in 2018.	X	Case Study
PICC Insertion Protocol for the Hematological Oncology Patient: A Comparison of Biopatch and StatSeal	Ayala M, et al.	Association for Vascular Access, Annual Scientific Meeting	2019	The Oncology ICU at Presbyterian/St. Luke’s identified an issue with unplanned dressing changes, which resulted in increased CLABSI rates. Initially, StatSeal was only used on lines bleeding at insertion and Biopatch was used for all other lines. They found that 80% of the Biopatch lines required unplanned dressing changes. As a result, practice standards were changed to use StatSeal prophylactically on all insertions, and the unit had a CLABSI-free year for the first time in its history.	X	Case Control
Addressing Central Line Infections: Reducing Bloodstream Infections in Neonates with a Focus on Dressings	Wrightson D, et al.	National Association of Neonatal Nurses, Annual Conference	2019	In 2017, Levine Children’s Hospital had increased incidents of CLABSI in their NICU related to dressing disruption. They started using StatSeal prophylactically to attempt to reduce dressing disruption by one third. They were able to substantially reduce their dressing changes and reduced their CLABSI rate by almost 80%, resulting in a cost savings of nearly $2 million annually.	X	Case Control
Hemostatic Disk or Antimicrobial Patch: A Description of Central Line Dressing Change Occurrences in Critically Ill Neonates	Gombold M	National Association of Neonatal Nurses, Annual Conference	2019	This study from Children’s of Omaha was a follow up presentation from NICU Leadership 2017 in which StatSeal was included as part of a new comprehensive CLABSI reduction program that resulted in a 94% reduction in CLABSI. This presentation focused on minimizing dressing disruption with StatSeal as a superior option to Algidex.	X	Case Control

Vascular Access

Title	Author	Source	Year	Summary	Investigator Initiated	Study Type
CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative Integrating Line-Rounding Principles and a Team Approach	Wilder KA, et al.	Clincal Issues in Neonatal Care	2016	The neonatal intensive care unit at Dallas Children's Health initiated a quality improvement project to effectively reduce CLABSI rates. By utilizing a dedicated PICC maintenance team and standardizing CLABSI bundles, which included the prophylactic use of StatSeal in the dressing change protocol, they were able to decrease the CLABSI rate by 92%, equaling a reduction of 7 CLABSI infections over 3 years.	X	Case Control
Achieving Hemostasis Post Insertion of a Peripherally Inserted Central Catheter	Altman K, et al.	Association for Vascular Access, Annual Scientific Meeting	2016	Poster presented at AVA 2016. The Ambulatory Infusion Center at the Mayo Clinic in Phoenix, AZ, trialed StatSeal Disc. Data was collected using a form. StatSeal Disc was placed on all new PICC insertions. The results indicated that using StatSeal Disc eliminated the need for 24-hour dressing changes and decreased the PICC line infection rate in high risk patient populations.	X	Case Series
Sealing Pediatric Access Sites: A Leading Children's Hospital Reduces Frequency and Number of Dressing Changes for Exceptional Atraumatic Care	Runde DA, et al.	Association for Vascular Access, Annual Scientific Meeting	2011	Prior to this trial at St. Louis Children's Hospital, gauze was the standard of care following PICC insertion and dressing changes occurred 24-48 hours post insertion. During a two-month trial period, StatSeal Powder was applied following PICC insertion to 84 patients, ranging in age from 10 days to 26 years. The VAT staff reported that StatSeal effectively stopped leaking and oozing, as compared to gauze, and that 100% of the dressings were dry and intact upon removal. Following this evaluation, the hospital added StatSeal to their PICC insertion protocol and eliminated the 24-48 hour post insertion dressing change.	X	Case Control
The Science of a "Seal" for PICC Line Management: BioSeal CVC Powder an Alternative Hemostatic Agent That Keeps Sites Dry and Intact	Blough L, et al.	The Journal of the Association for Vascular Access	2010	StatSeal Powder was evaluated as gauze replacement for PICC line insertions at Florida Hospital. StatSeal was effective in controlling PICC line access site bleeding and oozing; bleeding was controlled in ≤ 2 minutes in 94% of applications. Extended post trial use of the product demonstrated the complete elimination of the 48-hour dressing change protocol and a significant 40% reduction in CRBSIs.	X	Case Control