KytoMatrix
Bleeding Control Products

KytoMatrix Radial Compression Band Clinical Evidence Summary

Introduction

The KytoMatrix Radial Compression Band is a safe, effective, and rapid patent hemostasis-achieving device used to control bleeding following transradial catheterizations. Through a unique combination of inflatable radial band technology with a built in Chitosan impregnated patch, accelerated blood clotting[1-3] and infection reducing capabilities are achieved.[4] The quicker bleeding control is independent of the blood-clotting cascade and is complementary to normal clotting, allowing for effective and safe bleeding control in individuals with bleeding disorders, patients on anticoagulant medication, and children.[5-7] **The more efficient control of bleeding decreases the length of stay and time to discharge, owing to the possibility of an increase in procedural cases being scheduled.[8]** A direct correlation exists between a reduction in patient complications and the use of radial access combined with radial band technology; this is facilitated by patent hemostasis achieved with shorter compression times and low compression pressures.[1,9-13]

The approximate use of oral anticoagulants in treatment visits is more than 8 million per year.[46]

Accelerate the recommended times

Continuous firm pressure should be held at the site to obliterate the distal pulse for **3-5 minutes**. After the initial 3-5 minutes pressure must be reduced enough for the healthcare provider to obtain a distal pulse.[44]

- General recommendation is **4 minutes** per French
- Hold pressure for at least **15-20 minutes** for a diagnostic procedure
- Hold pressure for at least **30 minutes** for an interventional procedure
- Hold pressure for at least **45 minutes** for the removal of balloon pump or larger bore sheaths

Suggested cardiac catheterization protocols using the KytoMatrix™ Dressing (Chitosan impregnated patch).[45]	
Compression times diagnostics (5F-8F)	**5-10 minutes**
Compression times interventional (5F-8F)	**10-15 minutes**

Fewer Complications and Better Patient Experience

The radial band is designed with key features that enhance patient outcomes with respect to the incidence of radial artery occlusion (RAO) and hematoma rates as compared to manual compression.[14,15] This is evident through **a statistically significant reduction in RAO and hematoma occurrence with use of band technology.[10,14,16]**

The combination of a band with different hemostasis achieving patches provides a heightened level of reassurance to both the operator and patient, demonstrated through studies that cite **significant reduction in average time to deflation by 115%[3] and average time to discharge by 29 – 33%.[3,8]** Additionally, authors cite that preference from the clinical staff is given to procedures that are quicker in duration and require less manipulation of the device.[17]

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The quicker time to hemostasis is facilitated through an increased clotting capability driven by the interaction of the Chitosan based patch independently of the normal clotting cascade. This benefit is especially apparent in patients with bleeding disorders or those who are on anticoagulant medications.[5,6] Authors studying various clotting enhancing techniques cite significant increases in the ability to achieve initial hemostasis[13], decreased average compression times[1], and reduced time to hemostasis.[2,3,18-20]

In an analysis of Chitosan based patch used in conjunction with radial band technology, authors cite a 35% reduction in time to hemostasis[22] and state that 69% of patients achieve hemostasis in 10 minutes or less.[21] Fewer patient complications are also cited to be correlated with reduced compression time and strength.[1,9-13]

Specifically in femoral artery access site procedures, authors state that **the time to hemostasis is improved by 53%[19] and that 90% of patients were able to achieve hemostasis in 5 minutes or less[20] with the use of a Chitosan based patch** vs. standard gauze manual compression.

The incidence of infections during percutaneous coronary interventions (0.45% - 1.75%)[23,24] is further reduced with the additional contribution of the antimicrobial properties of Chitosan.[4] The radial artery access site provides quicker time to ambulation and authors cite little to no discomfort associated with either the band technology or the patch.[21]

In a comparison of four hemostasis achieving dressings, it was found that Celox, Quikclot, and ActCel were only 50%, 80% and 90% effective, respectfully, and that the Chitosan based patch which is used in the radial band technology was 100% effective in achieving and maintaining hemostasis.[25] Additionally, this patch technology can be employed across a wide range of bleeding control events including: maxillofacial surgery[6,26-30], hemodialysis procedures[5,31], penetrating trauma[30,32,33], emergency medical services (EMS)[25,34,35] and combat related injuries, where Chitosan is shown to be effective against severe hemorrhage.[36-39]

Each year, about 1 in 25 U.S. hospital patients is diagnosed with at least one infection related to hospital care alone.[47]

Estimated cost associated with hospital acquired infection is approximately $20K.[48]

100% effective

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Radial vs Femoral Percutaneous Coronary Intervention (PCI) Access

The adoption rate of the transradial artery (TRA) approach as an adjunct procedure to transfemoral artery (TFA) access across the U.S. is slowly approaching the utilization rate found across Western Countries. The European Society of Cardiology recommends the use of the TRA approach as a class 1A recommendation in experienced radial operators over the TFA approach for non-ST elevated myocardial infarctions (NSTEMI).[2,40]

In an observational study involving over 593,000 patients in the American College of Cardiology (ACC NCDR) CathPCI Registry undergoing femoral or radial procedures, authors demonstrated that **the radial approach was associated with a 67% reduction in bleeding and vascular complications** as compared to the femoral approach, without an increase in procedural failure.[41]

Large meta-analysis and contemporary randomized controlled trials have shown that the risk of major bleeding, all-cause mortality and major adverse cardiovascular events (MACE) are significantly reduced with use of the TRA approach as compared to TFA access.[23]

Lower Cost Associated with TRA access as compared to TFA

As compared to TFA access, the TRA approach is associated with a decreased cost of hospitalization (difference of $830) and total unadjusted procedural cost (difference of $916).[42,43] Additionally, same day discharge procedures are associated with cost differences as high as $3,502.43.

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Medline Industries, LP. Three Lakes Drive, Northfield, IL 60093
Medline United States
1-800-MEDLINE (633-5463)
medline.com | info@medline.com

Medline Canada
1-800-396-6996 | medline.ca | canada@medline.com
Medline México
01-800-831-0898 | medlinemexico.com | mexico@medline.com