Percutaneous interventional therapy is the treatment of choice to address clotting and restore adequate flow in vascular access for hemodialysis. Persistent bleeding at the access site following these interventional procedures is a common complication and may cause prolonged hospitalization. This study introduces a kaolin-based hemostatic device, QuikClot® Interventional™ hemostatic bandage (QCI, Z-Medica Corporation, Wallingford, CT) which is designed to control bleeding at the vascular access site. QCI is directly derived from *QuikClot® Combat Gauze™ which is currently the hemostatic agent of choice for all branches of the U.S Military.

### HEMOSTATIC DEVICE DESCRIPTION

QuikClot® Interventional™ hemostatic bandage (QCI) consists of a non-woven rayon and polyester gauze pad impregnated with kaolin, an inert mineral that does not contain any animal or human proteins. Contact between kaolin and blood initiates the intrinsic clotting cascade by activating Factor XII. Factor XI and prekallikrein are then changed to their activated forms.

*QCI is FDA cleared as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters, or tubes utilizing introducer sheaths up to 12F.

### METHODS

**Preclinical Swine Model:** The femoral artery and vein, carotid artery, and jugular vein in a swine model were accessed percutaneously using the Seldinger technique. Tissue dilators and introducer sheaths were used to produce wound tracts (8-12 F). After the removal of both dilators and sheaths, the QCI pad was placed over the bleeding site. Manual compression was held for 2 minutes and then a Tegaderm™ dressing was applied over the pad for an additional 3 minutes. At 5 minutes the Tegaderm™ and pad were both removed and the site was evaluated for bleeding and/or hematoma formation. **Human Clinical Data:** QCI was used as an adjunct to manual compression in a total of 243 human clinical procedures (Arterial =238 & Venous = 5, Dilator 4-8 F), some in the presence of anti-coagulation, in fifteen different institutions throughout the United States. Use Report Forms were collected from physicians and other health care providers to obtain details of QCI uses.

### RESULTS

QCI successfully controlled surface bleeding within 5 minutes in all preclinical cases (N=25) using 8 and 12 F tissue dilators at the vascular access site and no hematoma formation was observed. QCI successfully controlled bleeding in 97.12 percent of the clinical procedures, even in the presence of anti-coagulation. Physicians and health care providers who filled out the evaluations stated that they were highly satisfied with the product and would use it again.

This data suggests that QCI is very effective in controlling bleeding following vascular access in both experimental animals and for routine clinical use. In combination with brief manual compression, QCI is successful in arresting hemorrhage in almost all instances following arterial and venous interventions for both diagnostic and interventional purposes with no complications even when larger size catheters were used. Prospective clinical trials are currently underway to confirm these preliminary results.

### CONCLUSIONS

QuikClot® Combat Gauze,™
3 inch x 4 yards

QuikClot® Interventional™ hemostatic bandage (QCI) is designed to control bleeding at the vascular access site.