

What is QuikClot Control+ indicated for?

QuikClot Control+ is the first and only hemostatic dressing indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

What is the definition of class III or class IV bleeding?

SA: Class III and class IV bleeding indicates severe blood loss.

LA: Class III and class IV bleeding indicates severe blood loss. Class III hemorrhage involves losing 30-40% of total blood volume. Class IV hemorrhage involves losing >40% of total blood volume.

What is the definition of organ space bleeding?

Internal bleeding from within the chest, abdomen, pelvis, or retroperitoneum.

What is the difference between the QuikClot products I have now and Control+?

SA: Control+ is a new hemostatic dressing that utilizes a novel kaolin impregnation process. Control+ is the only product line from Z-Medica that is cleared by the FDA for internal use. The original QuikClot kaolin gauze products are FDA cleared for external or surgical wound use.

LA: Control+ is a new hemostatic dressing that utilizes a novel kaolin impregnation process. Control+ is formulated with more kaolin and utilizes a non-water soluble binder which allows the kaolin to remain on the gauze more permanently without masking efficacy. Control+ is FDA cleared for internal use, has double X-ray thread identifiers, and can be left in place for up to 48 hours. The original QuikClot kaolin gauze products are FDA cleared for external use, have a single X-ray thread identifier, and can be left in place for only 24 hours.

Can kaolin come off of the original QuikClot gauze?

Yes, kaolin can come off the original QuikClot gauze products. The amount depends on the type of injury, bleed, and severity. No product related adverse events have been reported for original QuikClot kaolin gauze products.

Is it dangerous if kaolin comes off the gauze and gets into the bloodstream?

Several studies have been performed to assess the safety of kaolin-based products including intravenous or intraperitoneal injection of kaolin and implantation of kaolin gauze. Lack of thrombus formation, toxicity (local or systemic), or adverse reactions confirmed the safety of kaolin in preclinical studies.

Since kaolin is safe, why can't I just use the original QuikClot gauze products internally?

The original QuikClot kaolin-based products are FDA cleared for external or surgical wound use. Using the product internally would be considered off-label use. QuikClot Control+ is Z-Medica's only line of products with an FDA clearance specifically for internal use to control severe bleeding in organ space.

Is this the same product the military uses?

No, it is not the same product, but it does have the same active ingredient (kaolin) that is used in QuikClot Combat Gauze®. It is also produced by and sold from the same manufacturer, Z-Medica.

Do the original products still have a place in my practice or should I switch to QuikClot Control+?

You should switch to Control+. Having one product line that covers both internal and external use will aid in SKU reduction and eliminate confusion.

Do you plan on discontinuing the QuikClot products we currently use?

Z-Medica plans to eventually phase out the majority of the original QuikClot kaolin gauze hospital product line. The 4x4, Interventional, and Radial products will remain available for sale. It has not been decided yet if 2x2 will be discontinued.

Why is there such a price difference between QuikClot and QuikClot Control+?

Significant time and money was spent on research and development to gain FDA clearance for Control+ so we could bring this first-in-class hemostatic dressing to market. The manufacturing process is more complicated and the raw materials are more expensive which has contributed to an increase in our cost of goods.

What specialties could Control+ be appropriate for?

Control+ could be beneficial in specialties such as trauma, cardiothoracic, OB/GYN, surgical oncology, transplants, and general surgery.

Does Control+ have any contraindications, warnings or precautions?

Yes.

- Contraindications
 - Do not leave Control+ in place for more than 48 hours
 - Control+ is not indicated for intraluminal vascular use
- Warnings:
 - Adhesion formation associated with Control+ use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesion elicited by Control+ are equivalent to those caused by control materials.
 - Control+ is not absorbable and must be removed from the wound prior to wound closure
- Precautions:
 - If bleeding persists additional product may be applied to the wound