QuikClot

CONTROL+®

HEMOSTATIC DRESSING

Instructions for Use

Product Information

REF 4010 2-Ply, 8 in x 8 in (20.32 cm x 20.32 cm)
REF 4020 1-Ply, 3 in x 2 yds (7.6 cm x 1.8 m)
REF 4030 3-Ply, 12 in x 12 in (30.48 cm x 30.48 cm)
REF 4040 8-Ply, 4 in x 8 in (10.2 cm x 20.3 cm)
REF 4050 4-Ply, 5 in x 5 in (12.7 cm x 12.7 cm)

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CONTROL+®
HEMOSTATIC DRESSING

Description
QuikClot Control+® Hemostatic Dressing consists of a white to off-white to yellow, sterile, X-Ray detectable hemostatic dressing and is packaged for aseptic removal.

Indications
QuikClot Control+ Dressing is 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.

Cardiac surgical procedures: for temporary control of mild and moderate bleeding in cardiac surgical procedures, as well as in patients displaying class III or class IV bleeding.

Bone surfaces following sternotomy: to control bleeding from bone surfaces following a sternotomy.

Intended Use
The device is intended:
- To control internal and external bleeding.
- May be used on patients on anticoagulation / antiplatelet medication.
- To control bone surface bleeding at the sternotomy access site.
- To control suture line bleeding following cardiac surgical procedures, such as but not limited to, heart valve repairs or replacements, coronary artery bypass graft surgery (CABG), or aortic aneurysm repairs.
- To control bleeding due to tears, lacerations, and abrasions to include epicardial repairs with or without sutures.
- To be used with or without the use of cardiopulmonary bypass systems. The dressing can be applied to control bleeding while the patient is 'on or off pump'.
- To be used with or without autotransfusion (blood salvage) equipment.

Contraindications
- Do not leave QuikClot Control+ Dressing in place for more than 48 hours.
- QuikClot Control+ Dressing is not indicated for intraluminal vascular use.

⚠ Warnings
- Adhesion formation associated with QuikClot Control+ Dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesions elicited by QuikClot Control+ Dressing are equivalent to those caused by control materials.
- QuikClot Control+ Dressing is not absorbable and must be removed from the wound prior to wound closure.
- Warning: Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.
- Warning: Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.

Precautions
• If bleeding persists, additional product may be applied to the wound.

Directions for Use
1. Open package and remove QuikClot Control+® Dressing.

2. Apply QuikClot Control+ Dressing to the wound and apply compression until bleeding is controlled. The dressing may be left in place for the duration of the procedure at the discretion of the clinician. More than one dressing may be required.

NOTE: If needed, additional gauze or a pressure dressing may be applied to maintain compression. The time for formation of a stable clot may vary depending on several patient factors.

3. Remove the dressing and repair the wound, if necessary. If the dressing is adhered to the wound, hydrate with sterile saline to aid in removal.

REF	Catalog Number		Do Not Re-sterilize
LOT	Batch Code		Do Not Use if Package is Damaged
	Date of Manufacture	STERILE R	Sterilized Using Irradiation
	Manufacturer		Keep Away From Sunlight
	Use By Date		Keep Dry
	Caution	Rx ONLY	Prescription Only
	Do Not Reuse	MR	MR Safe
	Consult Instructions for Use		

Clinical Study Summary

Study Name/Objective	A Pre-Market, Prospective, Controlled, Multicenter, Single Blinded, Pivotal Clinical Investigation of QuikClot Control+® Dressing for use in Mild to Moderate Bleeding. The objective of the study was to assess QuikClot Control+ Dressing (test article) in the treatment of mild and moderate bleeding during cardiac surgeries and on bone due to a sternotomy is as safe and effective as the control (standard gauze, disposable surgical sponges or lap sponges).
Number of subjects	231 subjects were randomized and treated at a 2:1 ratio (test article to control). • 153 subjects were treated with the test article • 78 subjects with the control • 21 roll-in subjects were not randomized and treated with the test article
Inclusion/Exclusion	Diagnosis and Main Criteria for Inclusion: 1.Subjects were ≥18 years of age 2.Subject was willing and able to give prior written informed consent 3.Subject required open cardiac surgery
Procedure	Subjects undergoing an open elective cardiac surgical procedure. As such, the surgical wounds evaluated in the trial were created at the sternotomy access site, suture lines (as part of the repair with native or synthetic material), tears, lacerations, abrasions, and epicardial repairs (with or without sutures). The injury types that were evaluated in the study are typical in cardiac surgical procedures, such as: • Coronary artery bypass graft (CABG) with or without valve repair/replacement – open heart sternotomy, thoracotomy or mini sternotomy • Valve repair/replacement – open heart sternotomy, thoracotomy, or mini-sternotomy • Aortic aneurysm surgery During the mentioned surgeries, wounds that meet the mild (grade 1) or moderate (grade 2) bleeding severity criteria had either the test article or control applied during one of the injury types below: • Sternal bleeding • Suture line bleeding (native tissue or synthetic material) • Tears, lacerations or abrasions to include epicardial repairs with for without sutures The follow-up period for each subject was 30 ± 16 days post procedure.

Study endpoints and assessment protocol	• Primary endpoint: Rate at which subjects achieve hemostasis (grade 0 bleed) through up to 10 minutes of application and compression at the bleeding site • Secondary endpoint: Proportion of subjects achieving hemostasis (grade 0 bleed) measured at 5 and 10 minutes of application and compression at the bleeding site
Patient demographics	Mean age was 64.5 ± 12.2 years and subjects were predominantly male (68.8%) and Caucasian (94.8%). Categories of baseline medications were balanced between randomized arms. Of note, 41/153 (26.8%) QuikClot Control+® Dressing subjects and 17/78 (21.8%) control subjects were on an anticoagulant and antiplatelet medication (P=0.258). Accordingly, a higher proportion of QuikClot Control+ Dressing subjects had baseline INR >1.1 (19/91=21%) compared to the control arm (7/47=15%). All baseline subjects completed blood count measurements and vital signs were balanced between randomized arms, except for systolic blood pressure (BP; QuikClot Control+ Dressing: 135.5 ± 19.5; control: 141.4 ± 21.1; P = 0.037).
Study results	QuikClot Control+ Dressing achieved clinical hemostasis in a higher percentage of cardiac surgery patients with mild to moderate bleeding as compared to the control (i.e., standard gauze, standard lap sponges). The safety of QuikClot Control+ Dressing was comparable to control (i.e., standard gauze, standard lap sponges). The clinical investigation evaluated the expanded indications for use and intended uses with confirmation that the subject device is substantially equivalent for its intended use.