

# FDA CLEARED INDICATIONS FOR Z-MEDICA® AND MEDTRADE PRODUCTS

The US Food and Drug Administration (FDA) states “that” “you are only permitted to promote and distribute your devices with the specific indications for use cleared in your 510(k)s.”<sup>1</sup>

The FDA has stated “manufacturers or distributors may not narrow the intended use of a device to a specific body site, tissue, specific patient population, or disease state without the submission and prior clearance of a new 510(k) premarket notification.”<sup>2</sup>

Patients on anticoagulants represent a specific patient population, therefore a device cannot be promoted or distributed for use in this population without a specific indication.

PRODUCT	INDICATION	FOR USE WITH PATIENTS ON ANTICOAG MEDS
QuikClot Combat Gauze®	“Intended for temporary external use to control traumatic bleeding.” <sup>3</sup>	✗
QuikClot® Interventional®	“Applied topically 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 7 Fr. <b>in patients on drug-induced anticoagulation treatment.</b> ” <sup>4</sup>	✓
QuikClot® Hemostatic Dressing	“Intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations, and abrasions.” <sup>5</sup>	✗
Celox™ Rapid	“Indicated for temporary external use to control moderate to severe bleeding.” <sup>6</sup>	✗
Celox™ Gauze Pro/Celox™ Pro Hemostatic Gauze/OMNI-STAT™ Gauze/OMNI-STAT™	“Indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding to exudate from sutures and/or surgical procedures.” <sup>7</sup>	✗
Celox™ Gauze PRO/Celox™ PRO Hemostatic Gauze/OMNI-STAT™ Gauze/OMNI-STAT™	“Indicated for temporary external treatment for controlling moderate to severe bleeding.” <sup>7</sup>	✗
Celox™ Antibacterial Trauma Gauze	“Indicated for temporary external use to control moderate to severe bleeding.” <sup>8</sup> “May be used for the management of partial and full thickness wounds 1st and 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology and pressure ulcers/sores (partial and full thickness), surgical wounds and donor sites.” <sup>8</sup>	✗
Celox™ PRO	“Indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.” <sup>9</sup> “Indicated for temporary external treatment for controlling moderate to severe bleeding.” <sup>9</sup>	✗
Celox™ Vascular	“Indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 16 French.” <sup>10</sup>	✗
Celox™ Trauma Gauze	“OTC: Indicated for temporary external use to control bleeding of lacerations, minor cuts and abrasions.” <sup>11</sup> “Prescription Use: Indicated for temporary external use to control moderate to severe bleeding.” <sup>11</sup>	✗

## REFERENCES

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