WoundClot® Hemostatic Gauze Biocompatibility

A Summary of ISO 10993 Test Findings

WOUNDCLOT®
Advanced Bleeding Control™

Core Scientific Creations Ltd.
September 2019

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Biocompatibility Testing

- WoundClot® Hemostatic Gauze is engineered to be effective in the management of mild, moderate, and severe bleeding.
- WoundClot® is also effective in the temporary management of severe bleeding during surgical procedures as well as postoperative and donor site bleeding.
- WoundClot® is a CE Class III Surgical Implantable device, for sizes up to 4" x 4" (10 cm x 10 cm).
- Test results show that the WoundClot® Hemostatic Gauze is biocompatible for its intended use and duration of use.
- This White Paper summarizes the findings of Biocompatibility studies conducted on WoundClot® Hemostatic Gauze, utilizing ISO 10993 -2010 standards for biocompatibility testing of medical devices.
- WoundClot® is an FDA cleared, next generation hemostatic gauze that converts from a dry flexible gauze to a thick, tenancious, expanding 3D gel matrix.

BIOCOMPATIBILITY TESTING FOR WOUNDCLOT® HEMOSTATIC GAUZE WAS PERFORMED:
Pyrogenicity Testing
Cytotoxicity Study
Irritation/ ISO Intracutaneous Study
Sensitization
Acute Systemic Toxicity study

Test results show that WoundClot® is biocompatible for its intended use and duration of use.

WoundClot® Biocompatibility Testing Summary

PYROGENICITY TESTING

Pyrogenicity Tests were performed as part of sterilization validation studies. Acceptance criteria for Endotoxin units: ≤20 EU/device. The test article results were <0.4EU per each device sample tested. Result: WoundClot® was found to be non-pyrogenic.

CYTOTOXICITY STUDY

WoundClot® was evaluated for potential cytotoxic effects utilizing ISO 10993-5, "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity" guidelines. A single WoundClot® test article preparation was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control was similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

Result: The WoundClot® test article extract showed no evidence of causing cell lysis or toxicity. Results were grade 0 (no reactivity) for all test articles. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

IRRITATION STUDY

WoundClot® was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993-10, "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization". Two 25 mm x 25 mm sections of WoundClot® gauze and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application.

Results: all animals were clinically normal throughout the study. There was very slight erythema and no edema reactions observed on the skin of the animals treated with WoundClot®. The Primary Irritation Index for WoundClot® was calculated to be 0.0. The response to WoundClot® was categorized as negligible.

SENSITIZATION

WoundClot® was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993- 10, "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization". Dose determination was performed to determine a suitable test article concentration for testing. The highest concentration of test article solution was chosen for both the injection and dermal applications for the definitive study as it did not produce apparent system toxicity, local neurosis, ulceration, or excessive dermal irritation. The test solution was intradermally injected and the occlusive patch was applied to ten test guinea pigs.

The control article was similarly prepared and injected to vet control guinea pigs with the application of occlusive patch to the injection sites. Following a recovery period, the test and control animals received challenge patches of the test solution and the control article. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

Result: all test animals remained clinically normal throughout the study. The test article solution showed no evidence of delayed dermal contact sensitization in any of the ten test guinea pigs.

ACUTE SYSTEMIC TOXICITY STUDY

WoundClot® was evaluated for acute systemic toxicity in mice. A single 20 mL/kg dose of WoundClot® based solution was injected into a group of test animals by intravenous route. Similarly, a separate group of test animals was dosed with 0.9% sodium chloride USP solution as the control condition. The animals were observed immediately, at 4 hours after dosing, and daily for 7 days. The animals were weighed prior to dosing and daily for 7 days thereafter.

Result: all animals were clinically normal during the study. There was no mortality or evidence of systemic toxicity due to the WoundClot® based solution injected into mice. WoundClot® met the test requirements.

Conclusions

The ISO standard testing conducted concludes that WoundClot® Hemostatic Gauze can be considered biocompatible for its intended use applications.

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