

# Exoxemis, Inc.: Comments about Antiseptics on Open Wounds



- **There are several problems with pre-amendment antiseptics (especially iodine, silver and chlorhexidine-based products) when applied directly or via wound dressings to open wounds:**
  - Potential systemic toxicity concerns due to their systemic absorption because of small molecular weight size (<500 Daltons),
  - Selection for antiseptic and cross-antibiotic resistance (except iodine-based products),
  - Lack of uniform efficacy (exception cadexomer iodine for chronic venous stasis ulcers), and
  - Reduced antimicrobial effects due to presence of blood and exudate.
- **Additional evidentiary safety and efficacy data from well-powered, randomized clinical trials are needed for all pre-amendment antiseptics applied directly or via wound dressings as an antimicrobial preservative to open wounds.**
- **Guidelines for all antiseptics applied to open wounds and wound dressings with antiseptics on open wounds should be uniform. Also, they should be based on scientific principles for wound bed preparation and should focus on wound bioburden reduction, not wound closure *per se*.**

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FDA might consider adopting the following guidelines for an antiseptic that is applied to **open wounds**:

- does not interfere with normal wound healing;
- does not cause local irritation or sensitization;
- is not systemically absorbed after application to the wound bed (thereby eliminating systemic toxicity);
- reduces wound inflammation and exudate;
- has broad microbicidal activity against wound pathogens;
- does not select for antiseptic resistance; and
- has microbicidal activity in wound environments with blood and exudate.

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- **The microbicidal activities of conventional antiseptics (e.g., chlorhexidine-, iodine-, hypochlorous acid, and sodium hypochlorite based products) at concentrations that do not overtly cause cytotoxicity and tissue damage are dramatically reduced in the presence of blood.**
  - For example, reduced bactericidal activity of chlorhexidine against *S. aureus* in increasing concentrations of whole human blood.

