Classification of Wound Dressings
General and Plastic Surgery Devices Advisory Panel
Meeting September 20-21, 2016

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Objective

• Review ConvaTec’s written comments
  • Clarify the intended purpose of antimicrobial dressings
  • Brief review of safety and effectiveness
  • Discuss resistance concerns
  • Propose optimal regulatory pathway for antimicrobial dressings (Class II)
Intended purpose

- Primary purpose of antimicrobial dressings
  - exudate management
  - optimize wound environment

- Secondary purpose
  - Antimicrobial barrier
  - Control bioburden within dressing

- No therapeutic action

- Intended for short term use to gain control
  - Where wound infection is already established
  - Where excessive wound bioburden may be contributing to delayed closure
Safety and Effectiveness

• Peer reviewed controlled studies on thousands of patients published
  • A 76% reduction in surgical site infection following joint arthroplasty¹.
  • A reduction in surgical site infections from 16% to 4% in cases of excised pilonidal sinus².
• Post Market Surveillance data reveals that Adverse Events are infrequent (0.0007%), well characterized and similar to Class I dressings.


Silver Resistance

- Antiseptics in general have a far lower propensity to induce bacterial resistance than antibiotics (multiple target sites)
- Ionic silver has a broader spectrum of antimicrobial activity than antibiotics and is effective against antibiotic resistant bacteria such as MRSA, VRE, ESBL, CRE, KPC\textsuperscript{3,4}.
- No evidence to suggest cross-resistance between silver and antibiotics

\textsuperscript{3} Percival, Prevalence of Silver Resistance in Bacteria Isolated from Diabetic Foot Ulcers and Efficacy of Silver Containing Wound Dressings, Ostomy Wound Management, 2008, 54 (3), 30-40

\textsuperscript{4} Bowler, Multidrug-resistant organisms, wounds and topical antimicrobial protection, International Wound Journal, 2012 (9), 387-396
Recommendations on Classification

- Case for upregulating to Class III has not been made
  - Widespread evidence confirming safe and effective
  - No evidence that they pose serious risk to health
- Class II with special controls is appropriate for antimicrobial dressings
  - Allows appropriate scrutiny and robust evidence from manufacturer to demonstrate safety and effectiveness
  - Upholds least burdensome principle
- Recommend FDA develops specific, special controls for antimicrobial dressings, in conjunction with all relevant stakeholders, to ensure transparent and consistent approach to regulating these devices
Conclusion

• Antimicrobial dressings are designed as barriers that manage exudate: they are not intended to be therapeutic
• Safety and effectiveness has been established
• No evidence that antibiotic resistance is being driven by silver
• No evidence that up-regulation of antimicrobial dressings to class III will decrease antibiotic resistance