# Classification of Wound Dressings

General and Plastic Surgery Devices Advisory Panel

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ConvaTec

# 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)

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# 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 arthroplasty[1].
  - A reduction in surgical site infections from 16% to 4% in cases of excised pilonidal sinus[2].
- Post Market Surveillance data reveals that Adverse Events are infrequent (0.0007%), well characterized and similar to Class I dressings.

1 Cai, J, et al. Aquacel Surgical Dressing Reduces the Rate of Acute PJI Following Total Joint Arthroplasty: A Case-Control Study, J Arthroplasty. 2014 Jun: 29 (6), 1098-1100.

2. Marinovic M, et. al. Application of Wound Dressing Molndal Technique in Clean and Potentially Contaminated Postoperative Wounds – Initial Comparative Study, Coll. Antropol. 2011; 35(2): 103-106

# 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[3,4].
- No evidence to suggest cross-resistance between silver and antibiotics

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

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

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# 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

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