

**Document F**  
**Rationalization Document: Why SilvaSorb® Site is Deemed to be A Wound Dressing and Regulated As Such:**

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**Background:**

An opinion is frequently sought about the regulatory status of SilvaSorb® Site dressings, and whether current FDA clearances allow its sale for the application around puncture sites or device entry points in general.

**Discussion:**

The SilvaSorb® Site dressing is a member of the SilvaSorb® family of products, all of which are based on a **Microlattice®** technology where silver chloride particles are suspended in a hydrogel matrix. Upon exposure to moisture, (liquid moisture or transpired moisture), the silver chloride particles dissociate. The dissociation releases potent silver ions leading to antimicrobial action in the dressings' environment. Zones of Inhibition data show that the antimicrobial action likely extends beyond the periphery of the dressings. The SilvaSorb® product line is useful for the management for full thickness wounds such as pressure sores, ulcers, cuts and abrasions. Because intravenous (I.V.) puncture sites are essentially full thickness dermal wounds, the product's use per current FDA clearances is allowable. The SilvaSorb Site packaging therefore obviously refers to the use of the product in management of IV puncture sites (and other puncture sites) in specific terms. The product is indicated for general use in the brochure, with no specific indication for use on children. A separate filing with the FDA has been made for the use of the SilvaSorb® line of wound dressings for specific use on children (Safe for Pediatric Use claim), and when approved will cover the SilvaSorb Site product. In the meantime there is no contraindication for use on children. A risk assessment around the issue of silver toxicity with the SilvaSorb Site dressing on neonates has shown that there is no real risk to the use of the product on neonates from the point of view of silver related toxicity. An analysis of the feedback/complaints from the market shows no evidence of any safety problems around the use of the Silvasorb products on children, though many thousands of product units have been used in last few years.

**Conclusion:**

A review of the regulatory approvals on the SilvaSorb® product line has shown that the SilvaSorb® Site product is correctly indicated for IV Puncture Sites. Further filings are in progress for claiming safety for pediatric use for the entire range of SilvaSorb products. In the meanwhile there exists no contraindications for use on children for the entire range and the dressings continue to be safely used for all populations per the feedback/complaints from the market that are registered with the Medline regulatory group on a formal basis.