



## **URGENT: Zingo™ Non-Safety Recall & Market Withdrawal**

November 11, 2008

Dear Healthcare Provider:

We are writing to inform you of an Anesiva-initiated **non-safety** recall of Zingo (lidocaine hydrochloride monohydrate) powder intradermal injection system containing 0.5 mg of sterile lidocaine hydrochloride monohydrate. You have received this letter because your institution has purchased or may have purchased Zingo devices. Effective today, November 11, 2008, you should no longer fill orders for Zingo and you must return unused Zingo devices according to the instructions below.

Zingo is indicated for use on intact skin to provide topical local analgesia prior to venipuncture or peripheral intravenous cannulation, in children three to 18 years of age.

This recall addresses a **non-safety** related regulatory compliance issue that recently arose which could affect product shelf life. This issue was identified in a Zingo lot that has not been released into commercial distribution. Please note that there are no safety implications for patients who have received Zingo, however, due to regulatory requirements we must perform this recall.

All lots manufactured by Anesiva, NDC 2800010512, will be recalled or withdrawn from the market. The affected Zingo lots released to the market and which will be recalled are # A000057 and # A000058. The lot number is found printed on the top of the Zingo 12-pack carton, on the outside of each individual device foil pouch, as well as on the device itself. The Zingo devices were distributed between July and November, 2008 and are the only two lots of Zingo which have been released to market by Anesiva.

### **To implement this recall, please take the following actions:**

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately discontinue distribution of all Zingo devices. Please contact Anesiva customer service at **1-866-ZINGORX (1-866-946-4679) option #1** to request a Return Goods Authorization and obtain a Call Tag. Then return all units to us at the following address: c/o DDN, 4580 Mendenhall Rd, Memphis, TN 38141. A credit memo will be issued covering the quantity of your product returned.
3. If you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please note that all Zingo devices (full or partial cartons) should be returned.

This recall should be carried out to the consumer-user level.

We do not plan to resupply Zingo in the future. The Food and Drug Administration has been notified of this product recall.

• HEADQUARTERS:  
650 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080  
PHONE (650) 624-9600  
FAX (650) 624-7540  
WWW.ANESIVA.COM

We appreciate your assistance in this matter and regret any inconvenience this may cause. If you have any questions, you may contact us at **1-866-ZINGORX (1-866-946-4679) option #1**.

Sincerely,

A handwritten signature in black ink that reads "M. Sadeghi". The signature is written in a cursive style with a small dot above the final letter.

**Mitra Sadeghi, Pharm.D.**  
**Sr. Director, Medical Affairs**  
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