

## Joint Position Statement on

### Safe In-Office Preparation of Buffered Lidocaine as a Local Anesthetic

(Approved by the AAD Board of Directors on 3/21/2019; ACMS Board of Directors on 3/14/2019;  
ASDS Board of Directors on 3/19/2019; ASMS Board of Directors on 3/18/2019)

*This position statement has been adopted by the American Academy of Dermatology, the American College of Mohs Surgery, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery. It was developed in response to the increased oversight of compounding and safety concerns of the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and U.S. Pharmacopeial Convention (USP).*

Buffered lidocaine is defined as a preparation of lidocaine with epinephrine containing preservative and sodium bicarbonate which is injected subcutaneously or intradermally as a local anesthetic. Buffered lidocaine is routinely prepared in syringes in advance of patient visits with a beyond-use date (BUD) of at least 12 hours to facilitate patient access and patient comfort. While each of the two constituent medications used to prepare buffered lidocaine are approved by the FDA, their combination is not specified in the labeling for these drug products. As such, the preparation of buffered lidocaine is subject to compounding regulation at the federal level and possibly at the state level.

The buffering of lidocaine significantly decreases the subjective pain of the anesthetic injection and speeds the onset of the local anesthesia for the patient.<sup>1</sup> According to the American Academy of Dermatology's *Guidelines for the use of local anesthesia in office-based dermatologic surgery*: "The addition of sodium bicarbonate to local anesthetic, particularly lidocaine with epinephrine, is recommended to decrease the pain of delivery by subcutaneous or intradermal infiltration."<sup>2</sup> The strength of this recommendation was denoted as "A" in this guideline, meaning that the "[r]ecommendation [is] based on consistent and good quality patient-oriented evidence." Local anesthetics exhibit antimicrobial (bactericidal, fungicidal, and sporicidal) activity against human pathogens, contributing to the safety of the injection.<sup>3,4</sup> Lidocaine, lidocaine with epinephrine, and buffered lidocaine were found not to be prone to bacterial or fungal contamination when prepared using aseptic technique and stored at room temperature or

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<sup>1</sup> Afolabi O, Murphy A, Chung B, Lalonde DH. The effect of buffering on pain and duration of local anesthetic in the face: A double-blind, randomized controlled trial. *Can J Plast Surg.* 2013 Winter;21(4): 209–212.

<sup>2</sup> Kouba DJ, LoPiccolo MC, Alam M, Bordeaux JS, Cohen B, Hanke CW, et al. Guidelines for the use of local anesthesia in office-based dermatologic surgery. *J Am Acad Dermatol.* 2016 Feb 27. pii:S0190-9622(16)00074.

<sup>3</sup> Razavi BM, Bazzaz BSF. A review and new insights to antimicrobial action of local anesthetics. *Eur J Clin Microbiol Infect Dis.* Published online January 24, 2019.

<sup>4</sup> Johnson SM, Saint John BE, Dine AP. Local Anesthetics as Antimicrobial Agents: A Review. *Surg Infect.* 2008;9:205–213.

refrigerated.<sup>5,6</sup> Further, the addition of sodium bicarbonate was found to enhance the rate of organism killing.<sup>7</sup> While remaining safe and stable, buffered lidocaine begins to lose its vasoconstrictive efficacy after seven days and should be administered by then.<sup>8,9</sup>

## **SAFETY CONDITIONS**

Our organizations recommend that dermatologists and their clinical staff meet or exceed the safety conditions described below when buffering lidocaine. These safety standards are based on USP's *General Chapter <797> Pharmaceutical Compounding – Sterile Preparations* and FDA's *Insanitary Conditions* guidance.

### **I. Personnel Qualifications**

- A. A designated person with training in aseptic technique is responsible for ensuring that personnel who will be preparing buffered lidocaine are trained, evaluated, and supervised.
- B. Before beginning to prepare buffered lidocaine, all personnel should complete training and be able to demonstrate knowledge of principles and skills for sterile preparation.
- C. Documentation of personnel training and competency should occur annually.
- D. Personnel preparing buffered lidocaine should have their aseptic technique and related practices evaluated every 12 months.
- E. Personnel who fail competency evaluations after appropriate remediation should successfully pass reevaluations in the deficient area(s) before they can resume preparing buffered lidocaine. The designated person should identify the cause of failure and determine appropriate retraining requirements.
- F. Personnel who have not prepared buffered lidocaine in more than 6 months should be evaluated in all core competencies before resuming preparation duties.

### **II. Personnel Hygiene and Garbing**

- A. Before beginning buffered lidocaine preparation, personnel should perform hand hygiene and garbing procedures according to the physician office or department standard operating procedures (SOPs).
- B. The minimum garb requirements include:
  1. Eye protection
  2. Face mask
  3. Non-sterile powder-free gloves

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<sup>5</sup> Pate DA, Shimizu I, Akin R, Snodgrass K, Emrick A. Safety of Prefilled Buffered Lidocaine Syringes With and Without Epinephrine. *Dermatol Surg*. 2016 Mar;42(3):361-65.

<sup>6</sup> Melman D, Siegel DM. Prefilled Syringes: Safe and Effective. *1999 Dermatol Surg* 25(6):492-93.

<sup>7</sup> Thompson KD, Welykyj S, Massa MC. Antibacterial activity of lidocaine in combination with a bicarbonate buffer. *J Dermatol Surg Oncol*. 1993 Mar;19(3):216-20.

<sup>8</sup> Larson PO et al. Stability of buffered lidocaine and epinephrine used for local anesthesia. *J Dermatol Surg Oncol* 1991;17: 411-4.

<sup>9</sup> Pascuet E, Donnelly RF, Garceau D, Vaillancourt R. Buffered Lidocaine Hydrochloride Solution With and Without Epinephrine: Stability in Polypropylene Syringes. *The Canadian Journal of Hospital Pharmacy*. 2009;62(5):375-80.

**III. Facilities**

- A. The preparation process should occur in an ISO Class 5 primary engineering control (PEC) or in a segregated compounding area (SCA). The PEC or SCA used to prepare buffered lidocaine should be located away from unsealed windows, doors that connect to the outdoors, and traffic flow during preparation, all of which may adversely affect the air quality. Neither a PEC nor an SCA may be located adjacent to environmental control challenges, such as restrooms, warehouses, or food preparation areas.
1. If used, the PEC should be certified every 6 months.
  2. If used, regarding the SCA, during preparation:
    - a. Access to the SCA should be restricted to authorized personnel.
    - b. No other activity is permitted in the SCA.
    - c. The surfaces of counters in the SCA should be cleanable.
    - d. Carpet is not allowed in the SCA.

**IV. Cleaning and Disinfecting**

- A. If a PEC is used, all interior surfaces of the PEC should be cleaned and disinfected at the beginning and end of each shift of preparation, when there are spills, and when surface contamination is known or suspected.
- B. If an SCA is used, the counters should be cleaned and disinfected at the beginning and end of each shift of preparation, when there are spills, and when surface contamination is known or suspected.
- C. Vial stoppers on packages of conventionally manufactured sterile ingredients should be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to prepare buffered lidocaine.

**V. Establishing BUDs**

- A. The BUD for the buffered lidocaine is at least 12 hours and a maximum of 7 days at room temperature.

**VI. Labeling**

- A. The label of each syringe of buffered preserved lidocaine should display the following both prominently and understandably:
1. Content of syringe
  2. Date and time of preparation
  3. Initials of preparer

**VII. Documentation**

- A. All facilities where buffered lidocaine is prepared should have and maintain written or electronic documentation to include, but not limited to, the following:
1. SOPs describing all aspects of the preparation process
  2. Personnel training records, competency assessments, and qualification records including corrective actions for any failures

3. Certification reports of the PEC, if used, including corrective actions for any failures
  4. Information related to complaints and adverse events
  5. Investigations and corrective actions
- B. Buffered lidocaine records should include at least the following information:
1. Date and time of preparation of the buffered lidocaine
  2. Identity of the preparer
  3. Total quantity prepared

### **PREPARATION PROCESS**

Our organizations recommend that dermatologists and their clinical staff adhere to the following preparation process when buffering lidocaine.

1. Determine desired total amount of sodium bicarbonate needed to buffer lidocaine with epinephrine containing preservative. For buffering lidocaine, we recommend adding 1 part 8.4% sodium bicarbonate to 10 parts lidocaine with epinephrine.
2. Enter the sodium bicarbonate vial once to withdraw this amount and inject it into the vial(s) of lidocaine with epinephrine.
3. Withdraw the buffered lidocaine from the vial into syringes.
4. Discard the punctured sodium bicarbonate vial (if labeled as single-use).
5. Depending on the jurisdiction, the BUD of the buffered lidocaine syringes should be between 12 hours and 7 days.

*This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these recommendations and applying them to the particular circumstances of their individual practice arrangements.*