

## **PULPDENT CORPORATION**

80 Oakland Street  
Watertown, MA 02472  
USA

TEL: 617-926-6666  
FAX: 617-926-6262  
Email: [Pulpdent@pulpdent.com](mailto:Pulpdent@pulpdent.com)

---

June 26, 2020

### **FDA Policy on Multiple-Use Dental Dispensers**

Multiple-use dental dispensers, sometimes called dental “syringes” are devices used to deliver various dental products including impression materials, adhesives, dental composites, and endodontic (root canal) materials to a treatment site in the mouth. Manufacturers typically supply multiple-use dental dispensers as pre-filled syringes with disposable tips. The tips are intended to be discarded after each patient use, but the dispensers containing the remaining dental material often are reused. Contamination or infection control issues arise for patients when the body or housing of multiple-use dental dispensers comes in contact with a previous patient’s cheek or lips, or when the dispenser is handled by a dental practitioner whose gloves have become contaminated with previous patient’s blood or saliva.

To deal with this situation, the FDA has published the following guidance:

<https://www.fda.gov/medical-devices/dental-devices/multiple-use-dental-dispenser-devices>

#### **DO:**

- ♦ **Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient.**
- ♦ **Use new, uncontaminated gloves when handling multiple-use dental dispensers.**
- ♦ **Utilize dental assistants to dispense material for the dentist.**
- ♦ **Avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient’s mouth.**

#### **DO NOT:**

- ♦ **Reuse the multiple-use dental dispenser if it becomes contaminated.**
- ♦ **Reprocess a contaminated multiple-use dental dispenser by using chemical wipes or disinfectants.**
- ♦ **Immerse multiple-use dental dispensers in a high level chemical disinfectant. This may damage the dispenser and the material contained in the device.**
- ♦ **Sterilize multiple-use dental dispensers. This may damage the material contained in the device.**

Sincerely,



Marjorie Coté  
Director of Quality Assurance and Regulatory Affairs  
Pulpdent Corporation