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Looking for written information on the recommendations for multi use sealant and etch syringes. Where can I find documentation that states changing the tip and wiping the barrel down with disinfectant is not sufficient and a plastic barrier should be used to prevent contamination?

The FDA website contains some information on multiple-use dental dispenser devices. 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. <sup>1</sup>

This information can be accessed at:

https://www.fda.gov/medicaldevices/productsandmedicalprocedures/dentalproducts/ucm40447 2.htm <sup>1</sup>

It states, in part:

Tips for Dental Practitioners

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers.

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. <sup>1</sup>

The product's instructions for use (IFU) should also provide you with further information pertaining to the use and handling of the product. Further questions should be directed to the product manufacturer.

Resources

1) U.S. Food and Drug Administration. Multiple-Use Dental Dispenser Devices. <u>https://www.fda</u>.<u>.gov/medicaldevices/productsandmedicalprocedures/dentalproducts/ucm404472.htm</u> Accessed on April 9, 2019.

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