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I am trying to find out who imposed the single use bur and does it only apply to diamond burs.

Ask OSAP can provide you with some general information on this topic.

The instructions for use (IFU) for burs are approved by the FDA.

At the 2015 OSAP Annual Conference, Dr. Susan Runner, Chief of the Dental Devices Branch at FDA, addressed re-use and single use dental care items in her presentation. Below is the link to her presentation:

http://c.ymcdn.com/sites/www.osap.org/resource/resmgr/ Symposium_2015_-_Presentations/FDA.pdf ¹

Regarding instructions for reprocessing (slide #4), it states that it is incumbent upon the manufacturer to provide validated cleaning and sterilization instructions. Slide #9 goes on to state that devices with no reprocessing instructions should be considered as single use.

Additionally, the CDC Division of Oral Health states in its website:

Some devices such as burs, endodontic files, and broaches may be practical to consider single-use because the way they are constructed makes them hard to clean. In addition, cleaning and heat sterilization can lead to deterioration on the cutting surfaces and raise the potential for breakage during patient treatment. The Food and Drug Administration (FDA) considers all diamond-coated burs and scaler tips single-use unless their manufacturers have submitted a 510(k) for reprocessing. FDA maintains a searchable database for 510(k)

premarket notifications.

Dental health care personnel (DHCP) should always refer to manufacturer instructions to determine if a device is single-use. If a device does not have validated reprocessing (i.e., cleaning and disinfection or sterilization) instructions, it is considered single-use (i.e., disposable). If DHCP have a question about product labeling, manufacturer instructions, or whether manufacturer instructions should have been included with a product, they should contact the manufacturer directly. ²

This information can be accessed at:

https://www.cdc.gov/oralhealth/infectioncontrol/faqs/single-use-devices.html ²

Resources

- 1) Organization for Safety, Asepsis and Prevention. Regulatory Panel Presentation by Dr. Susan Runner. http://c.ymcdn.com/sites/www.osap.org/resource/resmgr/ Symposium 2015 Presentations/FDA.pdf Accessed on July 22, 2019.
- 2) US Centers for Disease Control and Prevention. Single-Use (Disposable) Devices. https://www.cdc.gov/oralhealth/infectioncontrol/faqs/single-use-devices.html
 Accessed on July 22, 2019.

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