Validation Responsibility in Reprocessing of Dental Instruments

Instrument reprocessing is a critical component of an office's infection control protocols. It is essential for clinicians to follow the manufacturer's Instructions For Use Manual (IFU) of each device to minimize any risks of cross-contamination. Labeling regulations pertaining to medical devices are found in the Parts of Title 21 of the Code of Federal Regulations (CFR). The general labeling requirements for medical devices are contained in 21 CFR Part 801. These regulations specify the minimum requirements for all devices. In this session, we will discuss the General Labeling Provisions in the Code of Federal Regulation pertaining to medical devices, adequate directions for use and its exemption, and its application in medical device reprocessing Instructions for Use. We will also review the process a manufacturer follows to develop usable validated reprocessing instructions for the reuse of medical devices.

LEARNING OBJECTIVES:

1. Describe steps the manufacturer follows to develop validated reprocessing instructions
2. Apply knowledge of manufacturers IFU validation processes and the importance of following IFU's for medical devices in infection prevention training for dental office team members
3. Review the definition of Medical Device Labeling
4. Identify the General Labeling Provisions for medical devices found Parts of Title 21 of the Code of Federal Regulations (CFR), 21 CFR Part 801.
5. Recognize the elements of comprehensive reprocessing instructions per the FDA Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17, 2015.

CONTINUING EDUCATION

CE CREDITS: 1

EDUCATIONAL METHOD: Lecture, Recorded, Self-instructional (self-study)

LOCATION: Online

ORIGINAL RELEASE DATE: June 2022
EXPIRATION DATE: June 30, 2025

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SPEAKERS:

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Mr. Kierce is the Senior Global Product Manager for the Infection Prevention, Scaling and Diagnostic Platform for Dentsply Sirona. He is responsible for new product development in all global markets. He has been with Dentsply Sirona for 29 years holding various sales and marketing positions with increased responsibilities. Prior to joining Dentsply Sirona, he held positions at GMAC and Kraft General Foods.

Disclosures: Stock Shareholder - Dentsply Sirona

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Disclosures: No relevant financial relationships to disclose.