Sterilization of Non-Sterile Dental Products: Guidance for Healthcare Facilities

Purpose

This document provides general information for healthcare facilities that may choose to sterilize Richmond Dental & Medical non-sterile products prior to clinical use.

In dental and clinical settings, effective sterilization is a critical component of infection control. Richmond offers a range of products supplied in non-sterile form. In certain cases, healthcare facilities may elect to sterilize these products in accordance with their internal procedures and applicable standards.

Common Steam Sterilization Parameters

Steam sterilization (autoclaving) is widely used in healthcare environments. The following parameters are commonly applied for porous loads and dental consumables:

Sterilizer Type	Temperature	Exposure Time	Minimum Drying Time
Gravity Displacement	121°C (250°F)	30 minutes	15–30 minutes
Pre-vacuum	132°C (270°F)	4 minutes	≥20 minutes

Note: These parameters reflect commonly used practices and recognized standards (e.g., ANSI/AAMI ST79). Actual sterilization conditions must be established, validated, and routinely controlled by the healthcare facility.

Critical Considerations for Richmond Products

Richmond non-sterile products (e.g., cotton rolls, pellets, gauze) are intended for **single use**. If a healthcare facility elects to sterilize these products, the following factors should be evaluated:

- **Material Integrity -** High temperature, pressure, and moisture exposure may affect material properties.
- **Moisture Management -** Adequate drying is essential. Residual moisture (“wet packs”) may compromise sterility assurance, promote microbial growth and affect packaging integrity.

Process Validation

Sterilization processes must be validated and routinely monitored by the healthcare facility in accordance with applicable standards, such as ISO 17665 and local regulatory requirements.

Regulatory and Safety Notice

This information is provided for **general educational purposes only**.

Non-Validated Status

Richmond products are supplied non-sterile. Richmond has **not validated specific sterilization methods or cycles** for these products and does not provide validated sterilization instructions.

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Facility Responsibility
Any sterilization activity is the **sole responsibility of the healthcare facility**, including:

- Selection of sterilization method
- Validation and qualification of the process
- Routine monitoring and release of sterilized loads
- Verification that product safety and performance are not adversely affected

Single-Use Limitation
Sterilization does not alter the product's **single-use designation**. Products must be discarded after one clinical use.

Use of Product Information
Users should always refer to applicable product labeling and available documentation when determining suitability for use.

Summary

Steam sterilization is a widely applied method in healthcare settings. When applied to non-sterile consumables, its effectiveness depends on proper validation and control by the healthcare facility. Facilities should ensure that sterilization processes are appropriate for the specific product and do not compromise material integrity, performance, or safety.

For additional information or product specifications, please contact Richmond Dental & Medical.

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