

## Sterilization Guide for Directa Ceramir Pediatric Crown

Directa Ceramir Pediatric Crowns are prefabricated enamel-shell restorations designed for adhesive placement. As with all restorative devices, the sterilization process must ensure microbial safety while maintaining the crown's surface properties, mechanical stability, and bonding performance.

Recommended Method: Steam Sterilization (Autoclave)

Directa Ceramir Pediatric Crown can be autoclaved safely when done correctly.

### STEP-BY-STEP GUIDE

#### 1. Pre-cleaning

- Handle crowns with clean gloves.
- Rinse under distilled or deionized water.
- If needed, gently clean with a soft nylon brush.
- Do not use ultrasonic cleaners with aggressive detergents.
- Do not use alcohol, acetone, or surface disinfectants.

Rationale:

Surface solvents may compromise the micromechanical and chemical bonding surface.

#### 2. Packaging

- Place crowns in a sterilization pouch.
- Crowns should be:
  - Individually packaged or
  - Secured in a perforated sterilization tray
- Avoid direct metal-to-crown contact.

#### 3. Autoclave Parameters (Standard Cycle)

Parameter	Setting
Temperature	121 °C
Pressure	15 psi (1 bar)
Exposure time	15–20 minutes
Drying cycle	Standard

This cycle is preferred for polymer based dental devices.  
Avoid 134 °C flash cycles

#### 4. Cooling & Storage

- Allow crowns to cool inside the sterilization pouch.
- Store in a clean, dry environment.
- Do not open pouch until clinical use.

## Chairside Use After Sterilization

- Open the pouch only immediately prior to use.
- Proceed with manufacturer recommended adhesive protocol.
- No additional surface treatment is required beyond bonding steps.

## Actions to Avoid

Do NOT use chemical cold sterilants such as glutaraldehyde or formaldehyde.

Do NOT use alcohol-based wipes or sprays for disinfection.

Do NOT rely on UV-only disinfection, as it does not ensure full microbial safety.

Do NOT perform high-temperature flash autoclaving (134 °C, short-cycle programs).

Do NOT subject crowns to repeated sterilization cycles unless absolutely necessary.

### Key principle:

Sterility must never come at the cost of surface integrity or bonding performance.

### *Ethical & Regulatory Note*

*This protocol is aligned with CDC / standard dental autoclave principles.*

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## Step-by-step sterilization Guide

### A. Before sterilization (cleaning without damaging the bonding surface)

1. Hand hygiene + gloves. Handle crowns only with clean gloves or sterile tweezers.
2. Rinse: Rinse the crown under distilled/deionized water.
3. Gentle cleaning (only if needed): If visible debris, use a soft nylon brush with water.
4. Do NOT use:
  - Alcohol wipes/sprays
  - Acetone/solvents
  - Cold sterilants (glutaraldehyde, formaldehyde)
  - Abrasive polishing, sandblasting, pumice

### B. Packaging

5. Dry lightly (air-dry or blot; do not rub aggressively).
6. Pouch: Place one crown per sterilization pouch (preferred) or secure crowns in a sterilization cassette so they do not touch metal edges.
7. Seal and label pouch (date/cycle/load if your protocol requires).

### C. Autoclave cycle (recommended)

8. Steam sterilize (standard cycle):
  - 121 °C
  - 15–20 minutes exposure time
  - Standard drying cycle
9. Avoid “flash” cycles (typically 134 °C short cycles) unless you have explicit validation for the crown system in your setting.

**D After sterilization (maintain sterility)**

10. Cool in pouch: Let crowns cool inside the sealed pouch (prevents condensation contamination).

11. Storage: Store pouches dry in a clean cabinet.

12. Chairside: Open the pouch immediately before use, then proceed with the recommended bonding/cementation workflow.

**Key principle: Use steam sterilization for sterility but avoid chemicals/solvents that can unpredictably alter the adhesive bonding surface.**



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