

INSTRUCTIONS FOR USE

Kids Tooth Restoration: Zirconia Crowns (KTR: Z-Crowns)

Instructions for Use and Cleaning, Disinfection & Sterilization Instructions for
KTR Zirconia Crowns and Colored Try-On Crowns

1. Intended Use

KTR Zirconia Crowns are intended to provide durable, esthetic full-coverage restoration for primary (deciduous) teeth in pediatric patients.

These crowns are designed for temporary to long-term provisional protection of carious, fractured, or structurally compromised primary teeth.

Intended Users

- Licensed dental professionals, including pediatric dentists, general dentists, and trained dental specialists.

Patient Population

- Pediatric patients with primary dentition.

2. Device Description

KTR Zirconia Crowns are prefabricated, tooth-colored crowns digitally designed and milled from monolithic blocks of high-purity zirconia.

Key Design Features

- Monolithic zirconia construction for strength and fracture resistance
- Smooth, highly polished external surface for esthetics and plaque resistance
- Progressively thinner cervical wall design to promote optimal marginal adaptation
- Pre-sized anatomical contours to replicate natural primary tooth morphology

Device Components

- Individual zirconia crowns supplied in assorted sizes
- Matching colored Try-On Crowns for crown selection and fit verification
- Non-sterile devices intended for professional dental use

3. Warnings & Precautions

WARNINGS

- For professional dental use only.
- Do not use in permanent dentition.
- Both colored Try-On Crowns and white zirconia crowns may be autoclaved.
- Do not cement crowns with excessive force, as this may cause gingival trauma or improper seating.
- Zirconia crowns are brittle under tensile stress. Avoid excessive bending or leverage.

PRECAUTIONS

- Ensure adequate tooth reduction prior to crown selection to avoid internal binding.
- Passive fit is essential; crowns should not require forceful seating.
- Excessive occlusal pressure during seating may result in subgingival displacement.
- Always confirm final seating radiographically.

Contraindications

- Patients with known hypersensitivity to dental luting cements used for cementation
- Teeth with insufficient remaining structure to support a full-coverage restoration

4. Operating Instructions

A. Crown Selection & Try-In

No extensive custom adjustment required.

- Measure the mesio-distal dimension** intraorally using a Boley gauge.
- Select a crown** that best replicates the natural tooth dimensions.
- Verify measurements** against any preoperative records.

4. Try in the matching colored Try-On Crown and assess:

- Passive fit (minimal resistance)
- Marginal integrity using an explorer
- Stability (crown should not spin or rotate excessively)

Slight mesio-distal resistance may be present to ensure proper interproximal contact.

B. Occlusal Verification

- Remove the Try-On Crown** and check occlusal contacts.
- Perform additional tooth reduction** if occlusal interference is detected.
- Re-try** until proper occlusion is achieved.

C. Tooth Preparation & Cementation

- Rinse, isolate, and thoroughly dry** the prepared tooth.
- Achieve hemostasis** prior to cementation.
- Prepare the luting cement** according to the manufacturer's instructions.
- Load the white zirconia crown with cement**, avoiding air entrapment.
- Seat the crown** with light finger pressure only.
- Allow excess cement** to extrude naturally.

D. Final Seating

- Instruct the patient** to gently bite into normal occlusion.
- If using a bite stick or tongue blade**, distribute force across the quadrant. Never concentrate force on a single opposing tooth.
- Maintain pressure** per cement working time.

NOTE

- Both Glass Ionomer and Resin-Modified Glass Ionomer luting cements may be used for anterior zirconia crowns.

E. Cleanup & Evaluation

- After cement set**, remove excess cement using an explorer or scaler.
- Clean interproximal areas** with knotted floss.
- Rinse gingival sulcus** thoroughly.
- Confirm seating**, marginal integrity, contacts, and occlusion.
- Take a radiograph** to verify complete seating and marginal adaptation.

5. Custom Modification (When Necessary)

- Select the closest-fitting** crown size.
- If excessive gingival blanching is observed**, perform minimal cervical adjustment as needed.
- Re-seat and reassess** fit, margins, and contacts.
- Confirm occlusion.**
- Proceed with the cementation steps** outlined above.

6. Cleaning, Sterilization & Maintenance

- Both colored Try-On Crowns and white zirconia crowns may be autoclaved.
- Clean crowns appropriately before sterilization when contamination has occurred.
- Inspect crowns after sterilization and before use. Do not use crowns that are chipped, cracked, or otherwise damaged.
- Do not reuse a white zirconia crown on another patient after clinical use or cementation.

7. Storage & Handling

- Store in original packaging or in crown storage casing until use.
- Keep in a clean, dry environment.
- Avoid exposure to excessive moisture or temperature extremes outside normal storage and sterilization conditions.
- Handle carefully to prevent chipping or fracture.

8. Troubleshooting

Problem	Possible cause	Recommended action
Crown does not seat fully	Inadequate tooth reduction	Reduce tooth structure and re-try.
Excessive gingival blanching	Crown too tight cervically	Perform minimal cervical adjustment.

Problem	Possible cause	Recommended action
Crown spins	Crown size too large	Select a smaller size.
High occlusion	Insufficient occlusal reduction	Adjust tooth and reassess.
Marginal gap	Improper fit or debris	Clean preparation and re-evaluate.

9. Disposal Instructions

- Dispose of contaminated, unused, or removed crowns in accordance with applicable biomedical waste regulations.
- Do not reuse white zirconia crowns on another patient after clinical use or cementation.

IMPORTANT NOTICE

- This device is intended for use by licensed dental professionals only. Proper clinical judgment must be exercised during crown selection, preparation, cementation, cleaning, and sterilization.

Cleaning, Disinfection & Sterilization Instructions

KTR Zirconia Crowns & Colored Try-On Crowns

Kids Tooth Restoration: Zirconia Crowns (KTR: Z-Crowns)

General Information

- KTR Zirconia Crowns are tooth-colored zirconia crowns intended for restoration of primary teeth.
- KTR Colored Try-On Crowns are non-cemented, unglazed zirconia crowns intended solely for intraoral try-in and size verification.
- Colored Try-On Crowns are **NOT** intended for permanent placement and must never be cemented.
- Once tried in a patient's mouth, colored Try-On Crowns must be fully reprocessed before reuse.
- Both KTR white zirconia crowns and colored Try-On Crowns may be steam sterilized (autoclaved) when properly cleaned and processed.
- White zirconia crowns intended for final cementation are single-patient-use devices. They may be autoclaved when necessary before cementation but must not be reused on another patient after clinical use or cementation.
- Zirconia is chemically inert and heat-stable, allowing steam sterilization (autoclaving) when properly cleaned.
- Follow: CDC Guidelines for Infection Control in Dental Health-Care Settings; your autoclave manufacturer's validated cycles; local and state regulations.
- Preferred sterilization method:** steam sterilization (autoclave).

Key Principles

- Classification:** Crowns that have had intraoral contact require appropriate reprocessing before subsequent use.
- Single-use vs. reusable:** White zirconia crowns: single-patient use only; may be autoclaved before final cementation. Colored Try-On Crowns: reusable only after proper cleaning and sterilization.
- Approved method:** Steam sterilization (autoclave).
- Do NOT use:** Glutaraldehyde or cold sterilants; chlorine or bleach solutions; abrasive brushes, metal instruments, or polishing wheels; surface glazing or firing, as this may alter crown fit.

Step-by-Step Reprocessing Protocol

For KTR white zirconia crowns and colored Try-On Crowns.

A. Point-of-Use Handling

- Immediately after try-in:** Remove visible saliva and debris with water-moistened gauze. Place the crown in a covered, leak-proof container designated for contaminated instruments.
- Prevent drying:** If cleaning is delayed, store crowns in water or an appropriate enzymatic holding solution.

B. Cleaning

Cleaning is mandatory before sterilization when a crown has been contaminated. Sterilization may be ineffective if debris remains.

- Pre-rinse:** Rinse crowns under running water to remove gross contaminants.
- Detergent cleaning:** Use one of the following: an ultrasonic cleaner with neutral or enzymatic detergent, or a dental washer-disinfector approved for instruments. Ultrasonic guidelines: fully immerse crowns; do not stack crowns; typical cycle 5–10 minutes, following the detergent and equipment manufacturer's instructions.
- Avoid:** Abrasives, metal brushes, and harsh chemicals.
- Final rinse:** Rinse thoroughly to remove detergent residue.
- Drying:** Use lint-free towels or filtered compressed air. Ensure crowns are completely dry before packaging.

C. Inspection & Sorting

- Visual inspection:** Check for cracks or fractures, surface damage, distortion, and excessive wear.
- Discard if:** Any structural defect is present, or the crown no longer seats passively or has otherwise been compromised.
- Sorting:** Organize crowns by size and tooth type in appropriately labeled cassettes or pouches.

D. Packaging

- Packaging materials:** Use FDA-cleared sterilization pouches or cassettes.
- Indicators:** External chemical indicator and internal chemical indicator.
- Labeling (recommended):** Date; cycle or load number; optional size or kit identifier.

E. Steam Sterilization (Autoclave)

Both KTR white zirconia crowns and colored Try-On Crowns may be autoclaved. Use only validated cycles from your autoclave manufacturer. Typical CDC-referenced wrapped cycles are shown below.

Cycle type	Temperature	Exposure time
Gravity displacement	121 °C (250 °F)	30 minutes
Pre-vacuum	132 °C (270 °F)	5 minutes

- Load pouches on edge,** paper side up.
- Do not overload** the autoclave.
- Monitor:** time, temperature, and pressure; chemical indicators; biological spore testing according to applicable infection-control guidelines.
- Allow the full drying cycle** to complete inside the autoclave chamber.

F. Cooling, Storage & Handling

- Cooling:** Allow packs to cool to room temperature before handling.
- Check integrity:** Inspect packaging for moisture, tears, or failed indicators. Reprocess if packaging or sterilization integrity has been compromised.
- Storage:** Store in a clean, dry, closed cabinet. Follow event-related sterility principles.
- Chairside opening:** Open aseptically. Use sterile forceps or drop the crown onto a sterile tray. Avoid unnecessary direct hand contact.

IMPORTANT LIMITATIONS

- Colored Try-On Crowns are **NOT** intended for permanent placement.
- Do **NOT** cement colored Try-On Crowns.
- Colored Try-On Crowns may be reused only after proper cleaning, inspection, and steam sterilization.
- White KTR Zirconia Crowns may be autoclaved before final cementation.
- White zirconia crowns intended for final restoration are single-patient-use devices and must not be reused on another patient after clinical use or cementation.
- Inspect all crowns before use and discard any crown showing cracks, fractures, surface damage, distortion, or other structural defects.

Compliance Statement

KTR Crowns supports safe, consistent, and compliant infection-control practices. Following these instructions helps support patient safety, staff protection, and preservation of zirconia crown integrity when appropriate cleaning, sterilization, storage, and handling procedures are followed.