1. Intended Purpose

EZCROWNS are single use, functional full coverage restoration of anterior or posterior primary teeth in infants, children, and adolescents (pediatric); intended to treat decayed or damaged primary teeth, until the adult tooth erupts.

1.1 Condition to be treated: decaying of primary teeth
1.2 Patient population: enfants 2 to 14 years old
1.3 Intended users: dentist
1.4 Part of the body: teeth
1.5 Duration of use: up to 7 years average, crown placed on primary teeth and remain on the teeth until it exfoliates
1.6 Repeat application: no, single use
1.7 Considered implantable with limitation
1.8 Contraindications:
1.9 Precautions required by the manufacturer: proper instruction for used for cleaning prior to use
1.10 Single use

2. Indications for use / Medical indication:

2.1 Restoration of teeth with more than two surfaces affected with carious lesions, or where extensive one or two surface lesions are present
2.2 One and two surface carious lesions in documented high caries risk children;
2.3 Cervical decalcification and/or developmental defects (hypoplasia, hypocalcification, enamel hypoplasia, amelogenesis imperfecta, dentinogenesis imperfecta, etc.)
2.4 Interproximal caries extending beyond line angles
2.5 Following pulpotomy or pulpectomy
2.6 Restoration of a primary tooth that is to be used as an abutment for a space maintainer
2.7 Intermediate restoration of fractured teeth
2.8 Restoration and protection of teeth exhibiting extensive tooth surface loss due to attrition, abrasion or erosion
2.9 In patients with impaired oral hygiene in which the breakdown of intra-coronal restorations is likely
2.10 When the tooth cannot be effectively isolated for amalgam or composite restorations

3. Contraindications

3.1 Loss of vertical tooth
3.2 Class 3 malocclusion in some cases
3.3 Insufficient remaining tooth structure

4. Adverse effects

4.1 Possible increased wear on opposing natural teeth or restorations over time.

5. Intended patient population and medical conditions

5.1 Intended to treat decayed or damaged primary anterior or posterior teeth in infants, children and adolescents.

6. Intended Users

6.1 EZCROWNS® are intended for use by Pediatric dentists for placement in infants, children and adolescents.

7. Key functional elements

7.1 The preformed crown is manufactured in specific sizes for proper fit, which is contained within the range of sizes commonly available for existing preformed crowns. Each crown that corresponds to a specific primary tooth shape comes in six sizes. All posterior crowns contain a "narrow" version of their original shaped counterpart. (e.g. first primary upper molar B5 also comes in a "narrow" space loss (SL) version labelled as B5SL). This is available for all posterior and anterior cuspid crowns.

7.2 EZCROWNS® are delivered non-sterile and free of visible particulates. The dentist is responsible for disinfection.
7.3 Materials: biocompatible yttria-stabilized, tetragonal Zirconia (Y-TZP), dental stain and glaze

8. Principle of operation of the device, mode of action:

8.1 EZCROWNS® are a temporary tooth restoration. The dental crown is a tooth-shaped "cap" that is placed over the tooth, covering the tooth to restore its shape and size, strength, and/or to improve its appearance. The preformed crown is manufactured in specific sizes for proper fit, which is contained within the range of sizes commonly available for existing preformed crowns.
8.2 Each crown that corresponds to a specific primary tooth shape comes in six sizes. All posterior crowns contain a "narrow" version of their original shaped counterpart. (e.g. First primary upper molar B5 also comes in a "narrow" prime SL version labelled as B5'). This is available for all posterior and anterior cuspid crowns.

9. Intended application

9.1 EZCROWNS® are single use, temporary, functional full coverage restoration of anterior or posterior primary teeth in infants, children and adolescents. EZCROWNS® are a cap placed over existing tooth structure.

10. Duration of contact

10.1 EZCROWNS® are single use, long-term contact intended to remain in place until primary tooth exfoliates.

11. Organs, tissues and/or body fluids in contact with device

11.1 EZCROWNS® are in contact with the tongue, oral mucosa and saliva

12. Claim on clinical safety

Clinical Safety	Target	
1. Biocompatible: No risk of hypersensitivity (no nickel content)	Biocompatible	Historical and Current EZCROWNS® data from testing Literature search PMS data
2. Safe components: • Safety of Zirconia (measure toxicological data / literature search) • Safety of Stain (measure toxicological data / literature search) • Safety of Glaze (measure toxicological data / literature search) • Safety of Ink (measure toxicological data / literature search)	Nontoxic	Historical and Current EZCROWNS® crown data from testing Literature search PMS data

13. Clinical performance

Clinical performance	Expected Target	Method of assessment
1. Low plaque/bacterial adhesion: Polished Zirconia and Roughened Zirconia	Polished Zirconia ~10^3–10^4 CFU/cm² Roughened Zirconia ~10^5–10^6 CFU/cm²	Literature search
2. Negligible thermal conductivity	low	Literature search
3. Flat-Fit Design Contour: (less risk of breaking the crown upon fitting) • flattened occlusal profile - less occlusal reduction needed • broader bucco-lingual dimensions - roomier internal cavity • relaxed interproximal undercuts - more space to fit back-to-back crowns	Low breakage of the crown upon fitting < 0.5 %	Literature search PMS data (0.015%)
4. Zir-Lock Retention (improve retention of the crown) • patented retention grooves create mechanical retention • larger internal surface area maximizes cement-surface bond • margin-lock feature prevents marginal cement washout • larger internal surface area maximizes cement-surface bond • margin-lock feature prevents marginal cement washout • use any cement you choose works with both GI and RMGI	Strong retention	Literature search PMS data PMCF Protocol
5. Durability • naturally strong exceeds maximum bite force	40lbs/f	Historical and Current EZCROWNS® data from testing Literature search
6. Space-Loss (less risk of breaking the crown upon fitting) • narrower mesio-distally - matches finished rectangular prep shape • broader bucco-lingually - large enough to fit passively	Easier fit on tooth Low breakage of the crown upon fitting < 0.5 %	PMS data PMCF protocol
7. Polychromatic (reduce wear and tear/durability and better esthetics) • mirror-polished functioning surfaces - ultra-low wear on opposing dentition	Durable Esthetics: similar color than real tooth	Historical and Current EZCROWNS® data from testing Literature search PMS data