

Dental Crowns, Ceramics (ISO 6872)

Instructions for Use

Product Description:

Dental Crowns are custom-made devices specifically made in accordance with a written prescription of a registered dental practitioner for individual patients, using patient-specific impressions or digital scans. Dental Crowns are supplied in a non-sterile condition for immediate use after production and are not intended for long-term storage.

A dental device chosen for a certain patient, that is designed with various configurations, having many sizes, varying colours, that aims to restore the anatomical function and aesthetics of a single tooth or multiple teeth. Following the loss of tooth structure, a qualified user will determine the most appropriate device to use to restore the damaged or missing tooth to full function and an aesthetic appearance that blends with the remaining dentition. The clinical decision will indicate the form of the device, the most appropriate materials from which it should be manufactured, and the specifications to ensure it meets the functional and aesthetic needs of the patient. This information is communicated to the manufacturing laboratory by way of a laboratory requisition form.

Models:

Dental Crowns, Ceramics (ISO 6872) Models are:

Model. No.	Model	Material of Construction
DC0	Dental crown, Lithium Disilicate (ISO 6872)	Lithium Disilicate
DA0	Dental crown, Zirconia (ISO 6872)	Zirconia

Intended Use and Indications:

Intended Use:

Dental Crowns are intended to replace a missing or damaged clinical crown to restore form and function for patients.

Indications:

Dental Crowns are indicated for use in the following clinical situations:

- Missing teeth or tooth
- To replace lost tooth structure
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Contraindications:

Dental Crowns are not recommended in the following cases:

- **Insufficient Clinical Crown Height or Support** – Inadequate tooth structure for proper crown retention.

- **Severe Bruxism or Parafunctional Habits** – High risk of wear, fractures, or debonding.
- **Material Hypersensitivity** – Documented allergies to crown materials.
- **Untreated Malocclusion or Occlusal Instability** – Can lead to excessive stress, fractures, or loosening.
- **Poor Compliance with Post-Treatment Care** – Neglecting hygiene, follow-ups, or maintenance, compromising long-term crown performance.

Precautions:

- This device is custom-made for single patient use only and is not intended for reuse or reprocessing.
- The treating clinician is expected to prepare the nominated tooth/teeth following an accepted protocol to ensure the capability to manufacture a device that meets the required specifications and limitations of the chosen design and materials parameters
 - Dental Crowns should be stored in a clean storage container.
 - Refrain from biting ice and hard candy.
 - Expected lifetime: The actual performance and longevity of the Dental Crowns may vary depending on individual patient factors, oral hygiene, and clinical conditions. Regular dental check-ups are recommended to monitor the condition and functionality of the device.

Warnings for use

- This product is to be used by a Dental Professional only.
- There is an expected level of knowledge in the use of this device that is part of their dental training and education.
- This product is not designed, sold, or intended for use except as indicated. Keep out of reach of children.

Potential Complications:

The complications that may occur, related to Dental Crowns, are well known and well documented in the literature.

The adverse effects associated with crowns are described in the following:

- Salivary fluctuations.
- Tooth pain.
- Temporomandibular joint discomfort.
- Occlusal changes.

These would be managed and addressed by the treating dentist.

Clinical Applications:

This is a single-use medical device only to be used by a dental professional in a location deemed fit to conduct the procedure. This is to be determined by the dental professional. It is the responsibility of the dentist to ensure that regular maintenance (if required) is being conducted.

How Supplied:

This device is to be provided to the end user according to the laboratory requisition form details. The product should be processed using the health facility practices. This service is provided by AstraDent Digital Dental Solutions to ensure that the dental professional's needs and the patient's needs are met.

Directions for Use:**1. Tooth Preparation**

- a. Coronal Support
- b. Axial Wall Preparation
- c. Tooth reduction on incisal/occlusal surfaces
- d. Tooth Form
- e. Total Occlusal Convergence (TOC)
- f. Tooth Height
- g. Margin Design
- h. Margin Placement

2. Product Type

- a. Crown
- b. Bridge
- c. Implant (if required)
- d. Inlay or Onlay

3. Finishing and Polishing**4. Installation**

- a. Identify any special requirements based on the selection of adhesive.

Storage and Handling:

There are no special storage conditions required. Store at room temperature.

Dental Crowns should not be used after the **Use-by date**, which is **30 days from the date of manufacture**, to ensure optimal material integrity, precise fit, and consistent performance.

Expected Clinical Lifetime:

Dental Crowns are custom-made dental prostheses designed and manufactured for long-term intraoral use. Based on material properties, clinical data, and intended use, the expected clinical lifetime of this device is **15 years** under normal conditions of use and maintenance.

Disposal Instruction:

Temporary Crowns are considered non-hazardous but biologically contaminated medical waste and should be disposed of in accordance with standard clinical and local regulations for dental appliances.

Symbols Used in Labeling

#	Symbol	Title	Description
1		Manufacturer	Indicates the medical device manufacturer and address.
2		Country of manufacture and Date of manufacture	- Indicates the date when the medical device was manufactured. - IN - identify the country 'India' where the product was manufactured as defined in ISO 3166-1.
3		Health Care Centre or Doctor	To indicate the address of the health care centre or doctor where medical information about the patient may be found.
4		Patient Name	Indicates the name of the patient.
5		Importer	Indicates the entity importing the medical device into the locale.
6		Distributor	Indicates the entity distributing the medical device into the locale.
7		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
8		Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
9		Keep dry	Indicates a medical device that needs to be protected from moisture.
10		Medical device	Indicates the item is a medical device.
11		Do not use if the package is damaged, and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened, and that the user should consult the instructions for use for additional information.
12	R only	Prescription device	United States Federal Law restricts this device to sale by or on the order of a dentist.
13	Mfg. Lic. No	Manufacturing Licence Number	Manufacturing licence granted by the State Licensing Authority or the Central Licensing Authority of India.
14	"Custom-made device"	Custom-made devices	"Custom-made medical device" means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialised in the relevant area, under his responsibility for the sole use of a particular

#	Symbol	Title	Description
			patient, but does not include a mass production of such a device.
15		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
16		Use-by date	Indicates the date after which the medical device is not to be used.

Contact Information:

For any questions regarding this product, please contact the manufacturer:



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