

Crown and Bridges

Instructions for Use

Description:

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.

Indications:

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 work sheet.

Contraindications:

From the manufacturing laboratory perspective, there are no contraindications to this device, as long as the laboratory follows the prescription of the dental professional. It is the responsibility of the treating dentist to identify any contraindications for each patient.

Warning:

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.

Precautions:

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.

Adverse Reactions:

- 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 work sheet details. The product should be processed using the health facility practices. This service is provided by the Modern Dental Group to ensure the dental professional's needs and patient's needs are met. Note, that there are no special storage conditions that is required, since the product is intended to be used immediately.

Instructions 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 requirement based on selection of adhesive.

Contact Information:

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











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Symbols Used in Labeling

	<p>Manufacturer's Address</p>		<p>Single-Use Only</p>
	<p>Date of Manufacture (Year and Month)</p>		<p>Non-sterile</p>
	<p>Consult Instructions for Use</p>		<p>Batch Code (Lot Number)</p>
	<p>Do Not Use if Package is Damaged or Opened</p>		<p>Use by Date: Year-Month (YYYY-MM) (if applicable)</p>