

## Dentures

### Instructions for Use

#### **Product Description:**

Dentures 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. Dentures are supplied in a non-sterile condition for immediate use after production and are not intended for long-term storage. Denture prostheses can be non-implant-retained (either complete or partial, depending on whether or not all teeth are missing) or implant-retained dentures.

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:**

Denture models are:

| Reference | Model             | Material of Construction                                                                                       |
|-----------|-------------------|----------------------------------------------------------------------------------------------------------------|
| DG01      | Complete Dentures | Denture Base: Poly(methyl methacrylate) (PMMA)<br>Denture Teeth: Cross-linked Poly(methyl methacrylate) (PMMA) |
| DG0       | Partial Dentures  | Denture Base: Cobalt-Chromium Alloy;<br>Denture Teeth: Cross-linked Poly(methyl methacrylate) (PMMA)           |

#### **Intended Use and Indications:**

##### **Intended Use:**

Dentures are intended to replace missing teeth and surrounding oral tissues to restore form and function for patients.

##### **Indications:**

Dentures are dental devices that are indicated for use in the following clinical situations:

- To replace lost teeth and associated structures in partially and completely edentulous arches.

**Contraindications:**

Dentures are not recommended in the following cases:

- Poor oral health
- Lack of suitable teeth in the arch to support, stabilize, and retain the removable prosthesis
- Lacking cooperation of the patient with respect to follow-up /recall instructions.
- Material Hypersensitivity – Documented allergies to denture 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 denture performance.

**Precautions:**

- This device is custom-made for single patient use only and is not intended for reprocessing between patients. Careful daily removal of the bacterial biofilm present in the oral cavity and on complete dentures is of paramount importance to minimize denture stomatitis and to help contribute to good oral and general health.
- To reduce levels of biofilm and potentially harmful bacteria and fungi, patients who wear dentures should do the following:
  - Dentures should be cleaned daily by soaking and brushing with an effective, nonabrasive denture cleanser.
  - Denture cleansers should only be used to clean dentures outside of the mouth.
  - Dentures should always be thoroughly rinsed after soaking and brushing with denture-cleansing solutions prior to reinsertion into the oral cavity.
  - Brush dentures thoroughly with a non-abrasive denture cleanser and a soft denture brush.
  - Dentures should be stored in a clean storage container/box.
  - Dentures should be cleaned annually by a dentist or dental professional using ultrasonic cleaners to minimize biofilm accumulation over time.
  - Dentures should never be placed in boiling water.
  - Dentures should be stored immersed in water after cleaning, when not replaced in the oral cavity, to avoid warping.
  - Denture adhesives, when properly used, can improve the retention and stability of dentures and help seal out the accumulation of food particles beneath the dentures, even in well-fitting dentures.

**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.
- Patients who wear dentures should be checked annually by the dentist, prosthodontist, or dental professional for the maintenance of optimum denture fit and function, for evaluation of oral lesions and bone loss, and assessment of oral health status.

#### **Potential Complications:**

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

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

- Denture stomatitis.
- Denture biofilms.

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.

#### **Denture Care and Maintenance:**

- Placing a denture in water (or a denture cleanser solution) when it is not being worn helps the denture retain its shape, remain pliable, and keeps it from drying out.
- Dentures should never be placed in hot or boiling water, which could cause them to warp.
- Denture adhesives are not a remedy for ill-fitting dentures, which may need to be relined or replaced to prevent oral sores from developing.

#### **Storage and Handling:**

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

Dentures 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:**

Dentures 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 **10 years** under normal conditions of use and maintenance.

### **Disposal Instruction:**

Temporary Dentures 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                          | <ul style="list-style-type: none"> <li>Indicates the date when the medical device was manufactured.</li> <li>IN - identify the country 'India' where the product was manufactured as defined in ISO 3166-1.</li> </ul> |
| 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.                                                                                                                                                                                |

| #  | Symbol                                                                              | Title                                                                  | Description                                                                                                                                                                                                                                                     |
|----|-------------------------------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 | <b>Rx only</b>                                                                      | Prescription device                                                    | United States Federal Law restricts this device to sale by or on the order of a dentist.                                                                                                                                                                        |
| 13 | <b>Mfg. Lic. No</b>                                                                 | Manufacturing Licence Number                                           | Manufacturing licence granted by the State Licensing Authority or the Central Licensing Authority of India. "custom-made medical device" means a medical device                                                                                                 |
| 14 | <b>"Custom-made device"</b>                                                         | Custom-made devices                                                    | 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 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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