Removable Prosthodontics

Instructions for Use

Description:

A dental device chosen for a certain patient, that is designed with various configurations, having many sizes, tooth types and base colors, and replace some or all the teeth in a dental arch (including their supporting gums and soft tissues)

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/teeth 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 treating dental professional. It is the responsibility of the treating dental professional to identify any contraindications for each patient.

Warning and Precautions

This product is to be used by a Dental Professionals only. There is an expected level of knowledge in the use of this device that is part of their dental training and education.

The treating dental professional 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 dental professional.

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 user 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. **Mouth Preparation**
    a. All teeth are of sound structure and are caries-free
    b. All soft tissues are sound and able to bear the functional pressure of the device
    c. Any implants involved are of sound structure and able to bear the functional pressure of the device
2. **Product Type**
    a. Full Acrylic Denture
    b. Full Partial Denture
    c. Flexible Partial Denture
3. **Finishing and Polishing**
4. **Fitting**

Contact Information:

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

Modern Dental Pacific Pty Ltd
Unit 6/190 Bourke Rd,
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www.moderndentalpacific.com

MODERN Dental Pacific

Symbols Used in Labeling

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