

Removable Orthodontic Appliance

Instructions for Use

Description:

A dental device chosen for a certain patient, that is designed with various configurations, having many sizes, base colors, and stainless-steel wires and incorporated elements, designed to move teeth in a controlled fashion to a more functional and aesthetic position within the dental arch, or to stabilize the teeth after orthodontic movement is completed

Indications:

Following patient assessment and need for tooth movement and realignment, and then retention, the most appropriate device to treat the patient's malocclusion and create an aesthetic appearance that blends with the remaining dentition, will be determined. The decision will indicate the form of the device, the most appropriate materials, 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 these devices, as long as the laboratory follows the specifications outlined in the lab sheet. Any contraindications must be outlined on the lab sheet.

Warning and Precautions:

This product is to be used by a dental professional or patient who is aware and has an expected level of knowledge in the use of this device.

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.
- Tooth root resorption

Clinical Applications:

This is a single-use medical device that can be used by the end-user in a location deemed fit to install the product. It is the responsibility of the end-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. It is required that this product is cleaned and sterilized prior to use. 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.

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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
2. Product Type
 - a. Orthodontic Retainer
3. Finishing and Polishing
4. Fitting









Contact Information:

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



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Symbols Used in Labeling

	Manufacturer's Address		Single-Use Only
	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		Use by Date: Year-Month (YYYY-MM) (if applicable)