

Splints

Instructions for Use

Description:

A dental device chosen for a certain patient, that is designed with various configurations, having many sizes and types. They are made from acrylic resin, polymer, thermoformed polymer, 3D-printed polymer, or a combination of these materials.

Indications:

These devices are used to treat a range of oral conditions such as occlusal dysfunction, bruxism, temporomandibular joint dysfunction and clenching due to stress or parafunctional behaviors. Decisions 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 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.

If required, the treating dental professional is expected to prepare the patient's mouth 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.
- Further Temporomandibular joint discomfort.
- Occlusal changes.
- Tooth movement

These would be managed and addressed by the treating dental professional.

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 is being conducted.

How Supplied:

This device is to be provided to the end user according to the laboratory work sheet details. This service is provided by the Modern Dental Group to ensure the patient needs and requirements are addressed. 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
2. Product Type
 - a. Occlusal Splint (Hard / Hard)
 - b. Occlusal Splint (Hard / Soft)
 - c. Night Splint (Soft / Soft)
3. Finishing and Polishing
4. Fitting









Contact Information:

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



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Alexandria NSW 2015 Australia
www.moderndentalpacific.com

Symbols Used in Labeling

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