



INSTRUCTIONS FOR USE ENGLISH

Orthodontic Ceramic & Polymer Brackets

The following groups of products are covered by this instruction for use:

- Phantom LP
- Phantom Luxe
- Phantom plus

PHANTOM[™]
Luxe

PHANTOM[™]
LP

PHANTOM[™]
plus



INDICATIONS FOR USE

Orthodontic ceramic & Silver slot Brackets are devices intended for use in orthodontic treatment. The bracket is intended to be temporarily affixed to the teeth in order to exert pressure to create movement of the teeth during treatment. Also known as redevelopment of oral malocclusions (crooked teeth). Orthodontic ceramic brackets are bonded to the teeth using orthodontic adhesive, and either self-ligating or ligated with archwire, elastomers, and other ligatures to facilitate the movement of teeth

WARNINGS

All brackets and attachments are single-use devices. Any reuse can risk cross contamination to patients.

All brackets and attachments are supplied non-sterile.

When placing the bracket Use caution to prevent the instrument from slipping from the bracket, thus injuring the patient's mucous membrane

PRECAUTIONS

All brackets are to be fitted by a trained/qualified Practitioner to ensure accurate fitting. Patients must adhere to the Practitioners recommended hygiene care and check-ups to prevent damage to teeth and Periodontitis from poor hygiene between patient visits.

Practitioner is to select the correct bracket size, shape and function to ensure correct tension on teeth for movement and direction.

The use of incorrect instruments might result in damage to the bracket.

Do not force any instrument into the bracket's archwire slot as this may result in bracket damage.



INSTRUCTIONS FOR USE – PRACTITIONER/ORTHODONTIST

These devices are sold under prescription/order to qualified Practitioners/Orthodontists and Doctors who are trained in Orthodontic treatment and have knowledge of their use.

The Practitioner/Orthodontist/Dentist makes the determination on the selection of the correct size and shape of the brackets for each unique patient treatment to be performed and tooth position. The professional knows which devices to use at each stage of patient treatment.



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INSTRUCTIONS FOR USE - PATIENT

Chewing of hard foods can cause a device or related appliance to break, come off or loosen.

Some sports may cause damage to an orthodontic device and/or related appliance, and which may present a risk of harm in the event of certain sports related injuries. Consult with an orthodontic specialist for recommended safeguards.

Check braces once a week for anything loose or bent or if you are involved in an injury to the mouth area. If a bracket or band comes loose or you break a wire and contact your Practitioner if any problems or uncomfortable.

DISPOSAL

Disassembly: If possible, the devices can be disassembled before disposal. This can help ensure that all components are properly sterilized or decontaminated, and it can also make disposal easier and safer.

Decontamination: Before disposal it is recommended where possible that removed braces (combination of our devices) should be thoroughly cleaned and decontaminated to remove any potential infectious agents using a clinical autoclave sterilization method already approved.

Sharps disposal: Devices should be disposed of in either a medical waste container or a sharps container that is clearly labeled and meets all regulatory requirements for safe disposal.

Transportation and disposal: All containers of medical waste or sharps should be transported and disposed of according to local regulations and guidelines. This may involve working with a licensed medical waste disposal service or contacting local health authorities for guidance. It is important to follow all appropriate guidelines and regulations for safe disposal to protect both human health and the environment.

4.0 CONTRA-INDICATIONS:

While orthodontic bands, brackets, wires, and attachments are widely used in orthodontic treatment, there are certain contraindications or situations where their use may not be recommended. Some common contraindications include:

- 4.1 Poor Oral Health:** If a patient has significant oral health issues, such as severe gum disease (periodontitis) or extensive tooth decay, it may be necessary to address these conditions before initiating orthodontic treatment. In such cases, the orthodontic devices may impede proper oral hygiene practices and worsen the existing oral health problems.
- 4.2 Insufficient Tooth Structure:** In situations where the teeth have insufficient enamel, tooth structure, or significant damage, the application of orthodontic bands, brackets, wires, or attachments may not be feasible. The compromised tooth structure may not provide sufficient support for the devices, leading to increased risk of tooth fracture or other complications.
- 4.3 Skeletal Growth Concerns:** If a patient is still experiencing active skeletal growth, particularly in the jawbones, certain orthodontic treatments may not be recommended. In such cases, the orthodontist may advise postponing or modifying the treatment plan until skeletal growth is complete or until a more appropriate time.
- 4.4 Temporomandibular Joint (TMJ) Issues:** Patients with severe temporomandibular joint disorders or dysfunction may require specialized evaluation and management before orthodontic treatment. The presence of TMJ issues can affect treatment outcomes and may require a multidisciplinary approach involving orthodontists and TMJ specialists.
- 4.5 Inadequate Patient Compliance:** Orthodontic treatment requires active patient cooperation, including regular visits, proper oral hygiene practices, wearing of elastics, and adherence to dietary restrictions. If a patient is unable or unwilling to comply with the treatment requirements, it may affect the effectiveness and success of the orthodontic treatment.

It's important to note that the determination of contraindications for orthodontic treatment should be made by a qualified orthodontist based on a thorough evaluation of the patient's oral health, dental condition, and individual circumstances. The orthodontist will consider these factors and develop a personalized treatment plan that addresses any contraindications and ensures the best possible outcome for the patient.

REPORTING INCIDENTS

If there are any issues with the performance or safety of the device then in the 1st instance please contact at the contact details below:

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