International Orthodontic Services
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INSTRUCTIONS FOR USE ENGLISH

DEVICE NAME: Orthodontic Ceramic Brackets

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

- Phantom LP
- Phantom Luxe
- Phantom plus

INDICATIONS FOR USE

Orthodontic Ceramic Brackets are indicated for use during orthodontic treatment to facilitate controlled tooth movement and correction of malocclusions by providing attachment points for orthodontic archwires and associated orthodontic auxiliaries. The devices are temporarily bonded to the tooth surface during active orthodontic treatment in order to transmit orthodontic forces required for tooth alignment, arch coordination, bite correction, space management, and associated orthodontic treatment procedures.

Orthodontic Ceramic Brackets may be used in conjunction with orthodontic archwires, elastics, elastomeric ligatures, ligature wires, springs, attachments, and other orthodontic appliance components as part of comprehensive orthodontic treatment.

INTENDED PURPOSE

Orthodontic Ceramic Brackets are non-sterile, single-use medical devices intended to be temporarily bonded to teeth in order to support and secure orthodontic archwires and associated orthodontic appliance components during professional orthodontic treatment.

EXPECTED LIFETIME

The devices are intended for temporary intraoral use during the active phase of orthodontic treatment and remain in place until removal by the qualified dental or orthodontic professional in accordance with the prescribed orthodontic treatment plan.

INTENDED PATIENT POPULATION

Patient population includes any age with malocclusion of the teeth from pediatric to geriatric. The orthodontist will determine the treatment start age in adolescents and suitability of treatment in older patients and any susceptibility to sensitivity in materials and compliance of use.

WARNINGS

All Orthodontic Ceramic Brackets are single-use devices. Any reuse may result in cross-contamination, loss of mechanical performance, or increased risk of infection or device failure.

Materials used in Orthodontic Ceramic Brackets may include polycrystalline alumina ceramic, monocrystalline alumina ceramic, medical-grade polymer materials, and, in some device variants, metallic slot inserts or associated metallic components. Patients with known material sensitivities should be evaluated by the treating orthodontic professional prior to use.

Devices are supplied in a clean condition suitable for intraoral use by dental professionals. The devices are intentionally supplied in a non-sterile condition and are not intended to be sterilized prior to placement. Manufacturing and handling controls are applied to minimize microbial contamination. If packaging is opened, damaged, or compromised prior to use, the device must not be used and should be discarded.

Care should be exercised during placement, adjustment, ligation, and removal procedures to avoid injury to the patient's oral soft tissues. Orthodontic instruments may slip during handling and cause trauma to mucosal tissues.

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Orthodontic Ceramic Brackets are more brittle than metallic orthodontic brackets and may fracture, chip, or crack during placement, ligation, adjustment, debonding, or clinical use.
Fractured ceramic fragments may present a risk of soft tissue injury, eye injury, swallowing, or accidental aspiration. Appropriate protective measures should be used during debonding and removal procedures.
Excessive force during debonding may result in enamel damage, enamel cracking, enamel fracture, or patient discomfort. Only approved orthodontic debonding instruments and clinically accepted debonding techniques should be used.
Orthodontic Ceramic Brackets may require greater debonding forces than metallic orthodontic brackets. Care must be taken during removal procedures to minimize the risk of damage to tooth structure or surrounding tissues.
If electrothermal, ultrasonic, laser-assisted, or other heat-generating debonding techniques are used, excessive temperature rise may result in pulpal injury or thermal damage to adjacent tissues. Thermal exposure should be minimized and clinically monitored.
Swallowing or aspiration of detached brackets or fractured bracket fragments may occur during orthodontic treatment. Patients should seek immediate medical attention if aspiration is suspected.
Orthodontic treatment involving ceramic brackets may contribute to plaque accumulation, difficulty maintaining oral hygiene, localized irritation, enamel decalcification, or periodontal complications during treatment. Patients should maintain appropriate oral hygiene and attend scheduled orthodontic follow-up appointments throughout treatment.

RESIDUAL RISKS

Despite implementation of risk control measures, residual risks associated with Orthodontic Ceramic Brackets may include:

- localized soft tissue irritation or discomfort,
- irritation or ulceration associated with bracket contact with oral soft tissues,
- bracket fracture, chipping, or fragmentation during clinical use or debonding,
- swallowing or aspiration of detached brackets or ceramic fragments,
- enamel damage, enamel cracking, or enamel fracture during bracket removal,
- temporary discomfort associated with orthodontic tooth movement,
- plaque accumulation around orthodontic brackets,
- enamel decalcification or periodontal irritation associated with inadequate oral hygiene during treatment,
- irritation associated with prolonged intraoral use,
- treatment inefficiencies associated with bracket debonding, appliance damage, or poor patient compliance.

These residual risks are well recognized within orthodontic treatment and are considered acceptable when the devices are used as intended by qualified dental professionals in accordance with these Instructions for Use.

PRECAUTIONS

Orthodontic Ceramic Brackets are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect bracket selection, placement, ligation, adjustment, or removal may result in treatment inefficiency, enamel damage, soft tissue injury, bracket fracture, or device failure.
The Practitioner is responsible for selecting the appropriate bracket type, prescription, slot size, torque, angulation, and associated orthodontic appliance components appropriate for the individual patient and treatment objectives.
Patients must adhere to the Practitioner's instructions regarding oral hygiene, dietary restrictions, appliance care, and scheduled orthodontic appointments throughout treatment in order to reduce the risk of plaque accumulation, enamel decalcification, periodontal complications, appliance failure, and treatment delays.
Care should be taken during placement, ligation, adjustment, and debonding procedures to minimize the risk of bracket fracture, enamel damage, or injury to oral soft tissues.
Orthodontic Ceramic Brackets are more brittle than metallic orthodontic brackets and should not be subjected to excessive force, inappropriate instrument use, or improper debonding techniques.
Only clinically accepted orthodontic bonding, ligation, adjustment, and debonding procedures and instruments should be used with Orthodontic Ceramic Brackets.

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INSTRUCTIONS FOR USE – PRACTITIONER / ORTHODONTIST

Orthodontic Ceramic Brackets are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. The Practitioner is responsible for selecting the appropriate bracket prescription, slot size, bonding technique, archwire system, and associated orthodontic appliance components appropriate for the patient and treatment objectives.

Prior to bonding, clean and prepare the tooth surface using clinically accepted orthodontic bonding procedures. Select the appropriate adhesive system compatible with the bracket base design and clinical treatment requirements. Bond the bracket securely to the tooth surface in the prescribed position and orientation. Remove excess adhesive and verify correct orthodontic bracket placement prior to curing and orthodontic archwire engagement.

Following orthodontic bracket placement:

• place the orthodontic archwire fully into the orthodontic bracket slot,
• secure the orthodontic archwire using orthodontic elastomeric ligatures or orthodontic ligature wires according to the orthodontic treatment plan,
• verify complete ligation and stable orthodontic archwire engagement prior to completion of the procedure.

During treatment:

• monitor orthodontic bracket integrity, orthodontic archwire engagement, and appliance stability during routine orthodontic appointments,
• inspect for orthodontic bracket fracture, debonding, excessive wear, plaque accumulation, or soft tissue irritation,
• replace damaged or non-functioning orthodontic brackets where clinically indicated.

During debonding and removal:

• use only clinically accepted orthodontic debonding instruments and procedures intended for orthodontic ceramic brackets,
• apply controlled force to minimize the risk of enamel damage or ceramic fragmentation,
• use appropriate protective measures to prevent injury from detached ceramic fragments,
• remove residual adhesive using accepted finishing and polishing procedures following orthodontic bracket removal.

INSTRUCTIONS FOR USE – PATIENT

• Orthodontic Ceramic Brackets are part of a professional orthodontic treatment system and should only be managed according to the instructions provided by your Orthodontist or dental professional.
• Maintain good oral hygiene throughout treatment to reduce the risk of plaque accumulation, enamel decalcification, gingival irritation, and periodontal complications associated with orthodontic appliances.
• Avoid chewing hard, sticky, or excessively chewy foods, as these may damage, loosen, fracture, or dislodge orthodontic brackets, orthodontic archwires, or associated appliance components.
• Avoid biting directly into hard foods or objects which may place excessive force on orthodontic ceramic brackets and increase the risk of orthodontic bracket fracture or debonding.
• Orthodontic Ceramic Brackets are more brittle than metallic orthodontic brackets and may fracture if subjected to excessive force or trauma.
• Certain sports or physical activities may result in damage to orthodontic appliances or injury to oral tissues. Consult your Orthodontist regarding the use of appropriate protective mouthguards during sports activities.
• Check orthodontic appliances regularly for loose, damaged, bent, or broken components, particularly following impact or injury to the mouth area.
• Contact your Orthodontist promptly if an orthodontic bracket becomes loose, fractured, detached, causes irritation, or if an orthodontic archwire or associated appliance component becomes damaged or uncomfortable.
• Mild discomfort or pressure may occur temporarily following orthodontic adjustments as part of normal orthodontic tooth movement.
• Do not attempt to remove, reposition, or repair orthodontic brackets or appliance components yourself.

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CONTRAINDICATIONS

While Orthodontic Ceramic Brackets, Orthodontic Archwires, Orthodontic Ligatures, Orthodontic Elastics, Orthodontic Attachments, and associated orthodontic appliance components are widely used in orthodontic treatment, there are certain contraindications and clinical situations where their use may not be appropriate or may require special clinical consideration.

Poor Oral Health

Orthodontic Ceramic Brackets should not be used in patients with poor oral hygiene, active periodontal disease, uncontrolled dental caries, untreated oral infections, or other oral health conditions which may compromise treatment outcomes or increase the risk of enamel decalcification, periodontal complications, or deterioration of oral health during orthodontic treatment.

Insufficient Tooth Structure

Use of Orthodontic Ceramic Brackets may not be appropriate where teeth have insufficient enamel, compromised tooth structure, significant restorations, fractures, or other structural deficiencies which may reduce bonding reliability or increase the risk of enamel damage, tooth fracture, or bracket debonding.

Material Sensitivity

Orthodontic Ceramic Brackets should not be used in patients with known hypersensitivity or allergic reactions to ceramic materials, medical-grade polymers, metallic slot inserts, where applicable, adhesives, or associated orthodontic materials used during treatment.

Severe Occlusal or Functional Conditions

Certain severe occlusal abnormalities, parafunctional habits, bruxism, temporomandibular joint (TMJ) disorders, or other functional conditions may increase the risk of appliance failure, bracket fracture, enamel damage, or compromised orthodontic treatment outcomes and may require specialized evaluation prior to treatment.

Inadequate Patient Compliance

Successful orthodontic treatment requires patient cooperation, including maintenance of oral hygiene, adherence to dietary restrictions, attendance at scheduled appointments, and compliance with orthodontic instructions. Orthodontic Ceramic Brackets may not be appropriate where patient compliance is unlikely, as this may adversely affect treatment effectiveness and increase treatment-related risks.

The determination of suitability and any contraindications for orthodontic treatment using Orthodontic Ceramic Brackets shall be made by a qualified Orthodontist or dental professional based on individual patient assessment, oral health condition, treatment objectives, and risk-benefit evaluation.

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SYMBOLS USED ON LABELING

MD – Medical Device
Classification: Class IIa according to MDR (EU) 2017/745

REF – Catalogue / Reference Number

LOT – Batch / Lot Number

MANUFACTURER – Indicates the medical device manufacturer

EU REP – Authorized Representative in the European Community

Consult Instructions for Use – Indicates the need for the user to consult the Instructions for Use

Single Use – Indicates a medical device intended for one use only

CE 1304 - Indicates conformity with applicable European Union Medical Device Regulation requirements together with the applicable Notified Body number

Rx Only – Federal law restricts this device to sale by or on the order of a licensed dental or orthodontic professional

Metallic orthodontic devices may cause image artifacts or localized heating during MRI procedures. Patients should inform healthcare professionals that orthodontic devices are present prior to MRI examination.

Do Not Use if Package is Damaged – Indicates the device should not be used if packaging has been opened, damaged, or compromised

UDI – Unique Device Identifier

REPORTING INCIDENTS

If there are any issues with the performance or safety of the device, please first contact the manufacturer using the details below. Any serious incident occurring in relation to the device must also be reported to the competent authority of the Member State in which the user and/or patient is established.

EU AUTHORIZED REPRESENTATIVE
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