International Orthodontic Services
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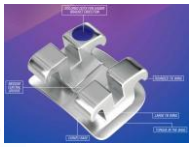
INSTRUCTIONS FOR USE ENGLISH

DEVICE NAME: Orthodontic Brackets

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

- Pactive™ SLB
- MAX Line™
- Razor™
- Majestic™
- Royal



MAX line
razor
MAJESTIC

INDICATIONS FOR USE

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

INTENDED PURPOSE: Orthodontic brackets are non-sterile, single-use medical devices intended to be bonded to teeth in order to secure orthodontic archwires and associated components during professional orthodontic treatment.

EXPECTED LIFETIME

The device is intended for use during the active orthodontic treatment phase and remains in place until removal by the dental professional as part of the prescribed 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

Ni
Cr

Materials: Medical-grade stainless steel can contain nickel and/or chromium which have been known to cause sensitivity reactions.

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

Devices are supplied in a clean condition suitable for intraoral use by dental professionals. These devices are not sterile 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.

When using a SLB Open tool, exercise caution to prevent the instrument from slipping from the bracket, thus injuring the patient's mucous membrane.

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.

MR

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RESIDUAL RISKS

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

- localized soft tissue irritation or discomfort,
- irritation or ulceration associated with bracket contact with oral soft tissues,
- allergic reaction or sensitivity to metallic materials including nickel where applicable,
- debonding or detachment of orthodontic brackets,
- swallowing of detached components,
- temporary discomfort associated with orthodontic tooth movement,
- plaque accumulation around orthodontic brackets,
- enamel decalcification associated with inadequate oral hygiene during treatment,
- irritation associated with prolonged intraoral use.

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.

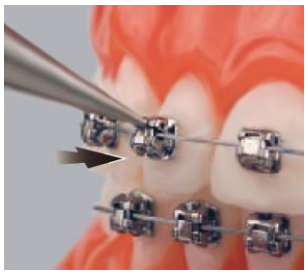
PRECAUTIONS

All brackets and attachments 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.

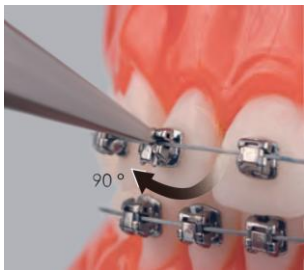
Practitioner is to select the correct bracket size, shape and function to ensure correct tension on teeth for movement and direction.

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.



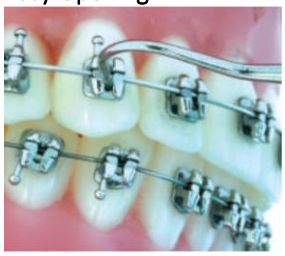
Insert the instrument (explorer) into the clip hole, located below the slot.



To open the clip, turn the instrument gently 45º. You can also open the clip by pulling it (gently). Insert the instrument inside the clip opening and pull it vertically and parallel to the lower fins of the bracket.

Simply open the clip by twisting the opening instrument 90°, engage the wire and then slide the clip closed. An explorer may also be used to open the door.

Easy Opening



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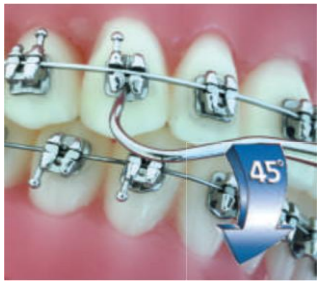

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INSTRUCTIONS FOR USE - PATIENT

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

CONTRA-INDICATIONS:

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

- 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.
- 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.
- 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.
- 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.
- 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.

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

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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

Ni / Cr – Indicates the device contains Nickel and Chromium

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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