



INSTRUCTIONS FOR USE ENGLISH

DEVICE NAME: Attachments & Auxiliaries

INDICATIONS FOR USE

The following Orthodontic Attachments and Auxiliary product families are covered by this Instructions for Use document:
The following Orthodontic Attachments and Auxiliary product families are covered by this Instructions for Use document:

- Orthodontic Buttons
- Orthodontic Hooks
- Orthodontic Cleats
- Orthodontic Crimpable Hooks
- Orthodontic Crimpable Stops
- Orthodontic Traction Auxiliaries
- Orthodontic Lingual Attachments
- Orthodontic Kobayashi-Type Hooks
- Orthodontic Ball Hooks
- Orthodontic Auxiliary Tubes
- Orthodontic Elastic Hooks
- Orthodontic Auxiliary Retention Components
- Orthodontic Bondable Auxiliaries
- Orthodontic Crimpable Auxiliaries
- Orthodontic Mechanically Retained Auxiliaries

Orthodontic Attachments and Auxiliaries are indicated for use during orthodontic treatment in order to support, retain, direct, transfer, or enhance orthodontic treatment mechanics through interaction with Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Archwires, Orthodontic Elastics, Orthodontic Elastomeric Devices, and associated orthodontic appliance systems.

Orthodontic Attachments and Auxiliaries may be used to facilitate elastic attachment, traction mechanics, rotational correction, space management, appliance stabilization, force transfer, arch coordination, eruption assistance, and correction of malocclusions during orthodontic treatment.

INTENDED PURPOSE

Orthodontic Attachments and Auxiliaries are non-sterile, single-use medical devices intended for professional orthodontic use during active orthodontic treatment. The devices are intended to be bonded, crimped, mechanically retained, or otherwise attached to orthodontic appliance systems or teeth in order to support orthodontic force application, appliance stabilization, ligation, traction mechanics, and associated orthodontic treatment procedures.

EXPECTED LIFETIME

Orthodontic Attachments and Auxiliaries are intended for temporary intraoral use during active orthodontic treatment and remain in place until adjusted, replaced, or removed by the qualified dental or orthodontic professional as part of the prescribed orthodontic treatment plan.

The expected duration of intraoral use may vary depending on:

- the Orthodontic Attachment or Auxiliary type and material,
- method of attachment or retention,
- stage of orthodontic treatment,
- applied orthodontic mechanics,
- patient-specific oral conditions,
- practitioner treatment objectives and clinical judgment.







Devices may remain in clinical use from several days to multiple months depending on the specific orthodontic treatment application and prescribed orthodontic mechanics.

INTENDED PATIENT POPULATION

The intended patient population includes patients of any age presenting with malocclusions, orthodontic alignment abnormalities, spacing abnormalities, crowding, occlusal irregularities, impacted teeth, eruption abnormalities, or other orthodontic conditions requiring professional orthodontic treatment, including pediatric, adolescent, adult, and geriatric patients.

The qualified Orthodontist or dental professional is responsible for determining:

- patient suitability for orthodontic treatment,
- appropriate treatment timing and treatment duration,
- suitability of specific Orthodontic Attachment and Auxiliary types, materials, retention methods, and force systems,
- suitability of traction, retention, ligation, stabilization, elastic attachment, or auxiliary orthodontic mechanics appropriate for the individual patient,
- patient-specific risks including oral health status, material sensitivities, periodontal condition, skeletal development, tooth eruption status, and anticipated patient compliance throughout treatment.

WARNINGS	
All Orthodontic Attachments and Auxiliaries are single-use devices. Any reuse may result in cross-contamination, loss of mechanical performance, material degradation, increased fracture risk, or increased risk of infection.	
Orthodontic Attachments and Auxiliaries may be manufactured from stainless steel, nickel-containing alloys, medical-grade metallic materials, polymers, or associated orthodontic materials. Certain materials may contain nickel and/or chromium which have been associated with allergic or sensitivity reactions in susceptible individuals. Patients with known material sensitivities should be evaluated 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 use. 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.	
Orthodontic Attachments and Auxiliaries may contain small components, sharp edges, hooks, projections, or cut surfaces which may cause injury to oral soft tissues during placement, adjustment, clinical use, or removal procedures. Appropriate clinical precautions should be exercised during handling and use.	
Improper bonding, crimping, attachment, positioning, adjustment, or use of Orthodontic Attachments and Auxiliaries may result in appliance instability, unintended force transfer, treatment inefficiency, soft tissue injury, patient discomfort, or damage to associated orthodontic appliance systems. Excessive force application, repeated adjustment, improper instrument use, notching, scratching, bending, or overloading of Orthodontic Attachments and Auxiliaries may result in deformation, loosening, fracture, debonding, disengagement, or loss of intended mechanical performance during treatment. Detached or fractured Orthodontic Attachments and Auxiliaries may present a risk of soft tissue injury, swallowing, or accidental aspiration. Appropriate precautions should be used during placement, adjustment, and removal procedures.	
Orthodontic Attachments and Auxiliaries are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect selection, positioning, attachment, activation, or adjustment may result in excessive orthodontic forces, unintended tooth movement, appliance instability, prolonged treatment, root resorption, or damage to oral tissues.	
Orthodontic Attachments and Auxiliaries used in conjunction with Orthodontic Archwires, Orthodontic Springs, Orthodontic Elastics, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, or associated orthodontic appliance systems should be evaluated for compatibility and appropriate orthodontic mechanics prior to clinical use.	
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.	
Orthodontic treatment involving Orthodontic Attachments and Auxiliaries may contribute to plaque accumulation, oral hygiene difficulties, 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 Attachments and Auxiliaries may include:

- localized soft tissue irritation or discomfort,
- irritation or ulceration associated with contact between Orthodontic Attachments or Auxiliaries and oral soft tissues,
- temporary discomfort associated with orthodontic tooth movement,
- debonding, loosening, disengagement, or detachment of Orthodontic Attachments or Auxiliaries during treatment,
- deformation or fracture of Orthodontic Attachments or Auxiliaries during clinical use or adjustment,
- swallowing or aspiration of detached or fractured appliance components,
- allergic reaction or sensitivity to metallic materials including nickel and chromium where applicable,
- corrosion-related effects or ion release associated with prolonged intraoral exposure,
- plaque accumulation around orthodontic appliances,
- enamel decalcification or periodontal irritation associated with inadequate oral hygiene during treatment,
- unintended tooth movement, appliance instability, or treatment inefficiency associated with improper selection, positioning, attachment, activation, or patient non-compliance,
- irritation associated with prolonged intraoral use,
- localized irritation associated with hooks, cleats, lingual auxiliaries, crimpable auxiliaries, or associated orthodontic projections,
- soft tissue trauma associated with auxiliary disengagement, fracture, or improper positioning during treatment.

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 Attachments and Auxiliaries are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect selection, positioning, bonding, crimping, attachment, adjustment, activation, or removal may result in excessive force application, appliance instability, treatment inefficiency, root resorption, soft tissue injury, or unintended tooth movement.

The Practitioner is responsible for selecting the appropriate Orthodontic Attachment or Auxiliary type, material, dimensions, retention method, and force characteristics suitable for the stage of orthodontic treatment and individual patient requirements.

Care should be exercised during handling, placement, adjustment, crimping, bonding, activation, and removal procedures to minimize the risk of injury from sharp edges, hooks, projections, fractured components, or detached appliance segments.

Excessive bending, repeated adjustment, overloading, improper instrument use, notching, scratching, or improper crimping or bonding techniques may damage the surface integrity and mechanical properties of Orthodontic Attachments and Auxiliaries and may increase the risk of deformation, loosening, fracture, debonding, or disengagement during treatment. Patients must adhere to the Practitioner's instructions regarding oral hygiene, appliance care, dietary restrictions, and scheduled orthodontic appointments throughout treatment in order to reduce the risk of plaque accumulation, enamel decalcification, periodontal complications, appliance damage, and treatment delays.

Orthodontic Attachments and Auxiliaries should be inspected during routine orthodontic appointments for deformation, corrosion, fracture, debonding, loosening, disengagement, wear, or other signs of damage or deterioration. Damaged or degraded devices should be replaced where clinically indicated.

Orthodontic Attachments and Auxiliaries used in conjunction with Orthodontic Archwires, Orthodontic Springs, Orthodontic Elastics, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, or associated orthodontic appliance systems should be evaluated for compatibility and appropriate orthodontic force mechanics prior to clinical use.

Only clinically accepted orthodontic instruments, bonding procedures, crimping techniques, activation methods, adjustment procedures, and removal methods should be used during orthodontic treatment involving Orthodontic Attachments and Auxiliaries.

INSTRUCTIONS FOR USE – PRACTITIONER / ORTHODONTIST

Orthodontic Attachments and Auxiliaries are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. The Practitioner is responsible for selecting the appropriate Orthodontic Attachment or Auxiliary type, material, dimensions, retention method, and associated orthodontic appliance components appropriate for the patient and treatment objectives.

Prior to placement:

- inspect the Orthodontic Attachment or Auxiliary for visible damage, deformation, contamination, surface defects, or packaging compromise,
- verify that the selected Orthodontic Attachment or Auxiliary type and dimensions are appropriate for the intended orthodontic treatment stage and planned orthodontic mechanics,
- confirm compatibility with Orthodontic Archwires, Orthodontic Brackets, Orthodontic Buccal Tubes, Orthodontic Bands, Orthodontic Springs, Orthodontic Elastics, and associated orthodontic appliance systems being used.

During placement of bondable Orthodontic Attachments and Auxiliaries:

- prepare the tooth surface according to accepted orthodontic bonding procedures,
- apply the appropriate orthodontic bonding material according to the bonding material manufacturer's instructions,
- position the Orthodontic Attachment or Auxiliary in the intended clinical location,
- remove excess bonding material where appropriate,
- verify secure attachment and correct positioning prior to completion of the procedure.

During placement of crimpable Orthodontic Attachments and Auxiliaries:

- position the Orthodontic Attachment or Auxiliary at the intended location on the Orthodontic Archwire or associated appliance component,
- secure the device using clinically accepted orthodontic crimping instruments and procedures,
- verify stable retention and appropriate positioning following crimping.

During placement of traction or elastic Orthodontic Attachments and Auxiliaries:

- verify compatibility with Orthodontic Elastics, Orthodontic Springs, Orthodontic Archwires, or associated appliance systems,
- avoid excessive activation or loading which may result in appliance instability or unintended force transfer,
- verify stable engagement and appropriate orthodontic force application prior to completion of the procedure.

During treatment:

- monitor appliance integrity, attachment stability, orthodontic force application, and treatment progression during routine orthodontic appointments,
- inspect Orthodontic Attachments and Auxiliaries for deformation, fracture, corrosion, loosening, debonding, disengagement, wear, or other signs of deterioration,
- replace damaged, deformed, fractured, loose, or degraded devices where clinically indicated,
- perform adjustments, repositioning, reactivation, or replacement procedures according to accepted orthodontic treatment protocols.

When adjusting or removing Orthodontic Attachments and Auxiliaries:

- use only clinically accepted orthodontic instruments and procedures,
- exercise caution to minimize the risk of injury from sharp edges, hooks, projections, fractured components, or detached appliance segments,
- avoid excessive force or improper instrument use which may compromise appliance integrity or damage tooth structure or oral tissues,
- verify that all Orthodontic Attachment or Auxiliary components have been removed from the oral cavity following removal procedures.

Following placement or adjustment:

- verify patient comfort,
- confirm appropriate appliance stability and orthodontic force application,
- inspect surrounding oral tissues for irritation, impingement, or soft tissue trauma where clinically indicated.

INSTRUCTIONS FOR USE – PATIENT

- Orthodontic Attachments and Auxiliaries 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, disengage, deform, or fracture Orthodontic Attachments, Orthodontic Auxiliaries, or associated orthodontic appliance components.
- Avoid biting directly into hard foods or objects which may place excessive force on Orthodontic Attachments and Auxiliaries and increase the risk of appliance breakage, debonding, disengagement, or soft tissue injury.
- 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, displaced, damaged, bent, broken, or irritating appliance components, particularly following impact or injury to the mouth area.
- Contact your Orthodontist promptly if an Orthodontic Attachment, Orthodontic Auxiliary, Orthodontic Bracket, Orthodontic Archwire, or associated appliance component becomes loose, disengaged, fractured, causes irritation, or becomes uncomfortable.
- Do not attempt to remove, reposition, bend, repair, reactivate, or adjust Orthodontic Attachments, Orthodontic Auxiliaries, or associated orthodontic appliance components yourself.
- Mild discomfort or pressure may occur temporarily following orthodontic adjustments as part of normal orthodontic tooth movement.
- If an Orthodontic Attachment or Auxiliary causes irritation to the cheeks, lips, tongue, gingiva, or other oral tissues, contact your Orthodontist for evaluation or adjustment as soon as possible.
- If an appliance component becomes detached or fractured, avoid swallowing the component and contact your Orthodontist immediately for further instructions.

CONTRAINDICATIONS

While Orthodontic Attachments and Auxiliaries, Orthodontic Archwires, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Springs, Orthodontic Elastics, 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 Attachments and Auxiliaries 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.

Material Sensitivity

Orthodontic Attachments and Auxiliaries should not be used in patients with known hypersensitivity or allergic reactions to stainless steel, nickel-containing materials, chromium-containing materials, polymers, bonding materials, or other materials used in orthodontic appliance systems.

Insufficient Tooth or Periodontal Support

Orthodontic treatment involving Orthodontic Attachments and Auxiliaries may not be appropriate where insufficient tooth support, compromised periodontal condition, severe mobility, inadequate anchorage, significant enamel loss, or other structural deficiencies may adversely affect appliance retention, stability, force application, or treatment predictability.

Severe Occlusal or Functional Conditions














Certain severe occlusal abnormalities, parafunctional habits, bruxism, temporomandibular joint (TMJ) disorders, eruption abnormalities, impacted teeth requiring surgical management, or other functional conditions may increase the risk of appliance failure, debonding, disengagement, fracture, soft tissue injury, 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 treatment involving Orthodontic Attachments and Auxiliaries 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 involving Orthodontic Attachments and Auxiliaries shall be made by a qualified Orthodontist or dental professional based on individual patient assessment, oral health condition, treatment objectives, and risk-benefit evaluation.

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
	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



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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.



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