



INSTRUCTIONS FOR USE ENGLISH

DEVICE NAME: Orthodontic Archwires and Orthodontic Ligature wires

INDICATIONS FOR USE

The following Orthodontic Archwire and Orthodontic Ligature Wire product families are covered by this Instructions for Use document:

- Orthodontic Stainless Steel Archwires
- Orthodontic Nickel Titanium (NiTi) Archwires
- Orthodontic Copper Nickel Titanium (CuNiTi) Archwires
- Orthodontic Beta Titanium (Beta Ti) Archwires
- Orthodontic Cobalt Chromium (CoCr) Archwires
- Orthodontic Australian-Style Archwires
- Orthodontic Multistrand Archwires
- Orthodontic Reverse Curve Archwires
- Orthodontic Straight Length Wires
- Orthodontic Preformed Archwires
- Orthodontic Rectangular Archwires
- Orthodontic Round Archwires
- Orthodontic Esthetic / Coated Archwires
- Orthodontic Ligature Wires
- Orthodontic Stainless Steel Ligature Wires
- Orthodontic Spool Ligature Wires



Orthodontic Archwires and Orthodontic Ligature Wires are intended for use during orthodontic treatment in order to deliver, maintain, direct, or transfer controlled orthodontic forces to teeth through engagement with Orthodontic Brackets, Orthodontic Buccal Tubes, Orthodontic Bands, Orthodontic Attachments, and associated orthodontic appliance systems.

Orthodontic Archwires are used to facilitate tooth movement, leveling, alignment, rotational correction, arch development, torque control, stabilization, space closure, space opening, and correction of malocclusions during orthodontic treatment.

Orthodontic Ligature Wires are intended to secure Orthodontic Archwires within Orthodontic Brackets or associated orthodontic appliance systems during treatment and may also be used to assist with ligation, stabilization, rotational control, force application, and auxiliary orthodontic mechanics where clinically indicated.

INTENDED PURPOSE

Orthodontic Archwires and Orthodontic Ligature Wires are non-sterile, single-use medical devices intended for professional orthodontic use during active orthodontic treatment. The devices are intended to engage with Orthodontic Brackets, Orthodontic Buccal Tubes, Orthodontic Bands, Orthodontic Attachments, and associated orthodontic appliance systems in order to facilitate controlled orthodontic tooth movement and correction of malocclusions.

Depending on the material composition, wire geometry, dimensional configuration, and mechanical properties, the devices may be used during different stages of orthodontic treatment including initial leveling and alignment, rotational correction, space management, torque expression, stabilization, finishing, detailing, and retention support.

EXPECTED LIFETIME

Orthodontic Archwires and Orthodontic Ligature Wires 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 Archwire or Orthodontic Ligature Wire material type,
- wire dimensions and mechanical properties,
- stage of orthodontic treatment,
- applied orthodontic forces,
- patient-specific oral conditions,
- practitioner treatment objectives and clinical judgment.

Devices may remain in clinical use from several weeks to multiple months depending on the treatment stage 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, 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 Archwire and Orthodontic Ligature Wire materials and force systems,
- patient-specific risks including oral health status, material sensitivities, periodontal condition, skeletal development, and anticipated patient compliance throughout treatment.

WARNINGS

All Orthodontic Archwires and Orthodontic Ligature Wires 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 Archwires and Orthodontic Ligature Wires may be manufactured from stainless steel, nickel titanium (NiTi), copper nickel titanium (CuNiTi), beta titanium, cobalt chromium (CoCr), multistrand metallic alloys, coated metallic materials, or other medical-grade metallic 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 Archwires and Orthodontic Ligature Wires may contain sharp ends following cutting, adjustment, ligation, or placement procedures. Care should be exercised during handling and clinical use to avoid injury to oral soft tissues, gingiva, lips, cheeks, or tongue.

Excessive bending, repeated adjustment, over-activation, notching, scratching, or improper handling of Orthodontic Archwires or Orthodontic Ligature Wires may result in permanent deformation, mechanical failure, wire fracture, or loss of intended force characteristics.

Fractured wire segments or detached components may present a risk of soft tissue injury, swallowing, or accidental aspiration. Appropriate clinical precautions should be used during placement, adjustment, and removal procedures.



Orthodontic Archwires and Orthodontic Ligature Wires are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect wire selection, wire sequencing, activation, adjustment, ligation, or placement may result in unintended tooth movement, excessive orthodontic forces, patient discomfort, root resorption, appliance instability, prolonged treatment, or damage to oral tissues.

Certain Orthodontic Archwire materials, including nickel titanium-based wires, may generate continuous force levels over extended periods. Care should be taken to select the appropriate wire type, dimensions, and force characteristics suitable for the stage of orthodontic treatment and patient condition.

Coated or esthetic Orthodontic Archwires may exhibit coating wear, chipping, discoloration, or surface degradation during clinical use due to frictional interaction and intraoral exposure.

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 Archwires and Orthodontic Ligature Wires 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 Archwires and Orthodontic Ligature Wires may include:

- localized soft tissue irritation or discomfort,
- irritation or ulceration associated with wire contact with oral soft tissues,
- temporary discomfort associated with orthodontic tooth movement,
- wire deformation, permanent set, or loss of force characteristics during treatment,
- fracture of Orthodontic Archwires or Orthodontic Ligature Wires during clinical use or adjustment,
- swallowing or aspiration of detached wire segments or 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 or treatment inefficiency associated with improper wire selection, activation, or patient non-compliance,
- irritation associated with prolonged intraoral use,
- coating wear, discoloration, or surface degradation of coated or esthetic Orthodontic Archwires where applicable.

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 Archwires and Orthodontic Ligature Wires are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect wire selection, sequencing, activation, ligation, adjustment, or placement 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 Archwire or Orthodontic Ligature Wire material, dimensions, mechanical properties, and force characteristics suitable for the stage of orthodontic treatment and individual patient requirements.

Care should be exercised during handling, placement, adjustment, cutting, ligation, and removal procedures to minimize the risk of injury from sharp wire ends or fractured wire segments.

Excessive bending, repeated adjustment, notching, scratching, or improper instrument use may damage the surface integrity and mechanical properties of Orthodontic Archwires and Orthodontic Ligature Wires and may increase the risk of wire deformation or fracture 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 Archwires and Orthodontic Ligature Wires should be inspected during routine orthodontic appointments for deformation, corrosion, coating wear, fracture, loss of force characteristics, or other signs of damage or deterioration. Damaged or degraded devices should be replaced where clinically indicated.

Coated or esthetic Orthodontic Archwires may exhibit surface wear, discoloration, or coating degradation during clinical use due to frictional interaction and normal intraoral conditions.

Only clinically accepted orthodontic instruments, ligation techniques, adjustment procedures, and debonding/removal methods should be used during orthodontic treatment involving Orthodontic Archwires and Orthodontic Ligature Wires.

INSTRUCTIONS FOR USE – PRACTITIONER / ORTHODONTIST

Orthodontic Archwires and Orthodontic Ligature Wires are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. The Practitioner is responsible for selecting the appropriate wire material, dimensions, mechanical properties, wire sequence, and associated orthodontic appliance components appropriate for the patient and treatment objectives.

Prior to placement:

- inspect the Orthodontic Archwire or Orthodontic Ligature Wire for visible damage, deformation, contamination, surface defects, or packaging compromise,
- verify that the selected wire type and dimensions are appropriate for the planned stage of orthodontic treatment,
- confirm compatibility with the Orthodontic Brackets, Orthodontic Buccal Tubes, Orthodontic Bands, Orthodontic Attachments, and associated orthodontic appliance systems being used.

During placement of Orthodontic Archwires:

- engage the Orthodontic Archwire fully into the bracket slots and associated appliance components,
- secure the Orthodontic Archwire using appropriate Orthodontic Ligature Wires, elastomeric ligatures, or self-retaining appliance mechanisms where applicable,
- verify complete seating and stable engagement of the Orthodontic Archwire throughout the appliance system,
- trim and secure distal wire ends as appropriate to minimize soft tissue irritation.

During placement of Orthodontic Ligature Wires:

- apply ligature wires using clinically accepted orthodontic ligation techniques,
- avoid excessive tightening or manipulation which may damage the appliance system or generate excessive orthodontic forces,
- ensure cut ligature ends are positioned appropriately to minimize soft tissue irritation or injury.

During treatment:

- monitor appliance integrity, wire engagement, force application, and treatment progression during routine orthodontic appointments,
- inspect Orthodontic Archwires and Orthodontic Ligature Wires for deformation, fracture, corrosion, coating wear, loss of force characteristics, excessive wear, or other signs of deterioration,
- replace damaged, deformed, fractured, or degraded devices where clinically indicated,
- perform wire adjustments, wire progression, activation, and ligation procedures according to accepted orthodontic treatment protocols.



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When adjusting or cutting wires:

- use only clinically accepted orthodontic instruments,
- exercise caution to prevent injury from sharp wire ends or wire fragments,
- avoid excessive bending, repeated notching, scratching, or improper handling which may compromise wire integrity or mechanical performance.

During removal:

- remove Orthodontic Archwires and Orthodontic Ligature Wires using accepted orthodontic procedures and instruments,
- verify that all wire fragments and appliance components have been removed from the oral cavity,
- inspect oral tissues and appliance components for any signs of damage or irritation following removal.

INSTRUCTIONS FOR USE – PATIENT

- Orthodontic Archwires and Orthodontic Ligature Wires 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, bend, loosen, deform, or fracture Orthodontic Archwires, Orthodontic Ligature Wires, brackets, or associated orthodontic appliance components.
- Avoid biting directly into hard foods or objects which may place excessive force on orthodontic appliances and increase the risk of wire deformation, appliance breakage, 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, bent, protruding, broken, or damaged wires or appliance components, particularly following impact or injury to the mouth area.
- Contact your Orthodontist promptly if an Orthodontic Archwire, Orthodontic Ligature Wire, bracket, or associated appliance component becomes loose, bent, fractured, displaced, causes irritation, or becomes uncomfortable.
- Do not attempt to cut, bend, remove, reposition, or repair Orthodontic Archwires, Orthodontic Ligature Wires, or associated orthodontic appliance components yourself.
- Mild discomfort or pressure may occur temporarily following orthodontic adjustments as part of normal orthodontic tooth movement.
- If a wire end causes irritation to the cheek, lips, tongue, or oral tissues, contact your Orthodontist for adjustment as soon as possible.

CONTRAINDICATIONS

While Orthodontic Archwires, Orthodontic Ligature Wires, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Attachments, Orthodontic Springs, 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 Archwires and Orthodontic Ligature Wires 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 Archwires and Orthodontic Ligature Wires should not be used in patients with known hypersensitivity or allergic reactions to stainless steel, nickel titanium, copper nickel titanium, cobalt chromium, beta titanium, nickel-containing materials, chromium-containing materials, coated metallic materials, or other materials used in orthodontic appliance systems.

Insufficient Tooth or Periodontal Support

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

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, wire deformation, 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 Archwires and Orthodontic Ligature Wires 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 Archwires and Orthodontic Ligature Wires 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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