International Orthodontic Services
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INSTRUCTIONS FOR USE ENGLISH

DEVICE NAME: Orthodontic Springs

INDICATIONS FOR USE

The following Orthodontic Spring product families are covered by this Instructions for Use document:

- Orthodontic Open Coil Springs
- Orthodontic Closed Coil Springs
- Orthodontic Closed Nickel Titanium (NiTi) Springs with Eyelets
- Orthodontic Infinity Closed Coil NiTi Springs
- Orthodontic Separating Springs

Orthodontic Springs are indicated for use during orthodontic treatment to apply, maintain, or distribute controlled orthodontic forces in order to support tooth movement, space opening, space closure, arch development, traction mechanics, alignment, and correction of malocclusions.
Orthodontic Open Coil Springs are used to create or maintain space between teeth or orthodontic appliance components.
Orthodontic Closed Coil Springs, Orthodontic Closed NiTi Springs with Eyelets, and Orthodontic Infinity Closed Coil NiTi Springs are used to apply continuous traction or closing forces during orthodontic treatment, including space closure and tooth movement procedures.
Orthodontic Separating Springs are used to create temporary interproximal tooth separation prior to placement of orthodontic bands or associated orthodontic appliances.

INTENDED PURPOSE

Orthodontic Springs are non-sterile, single-use medical devices intended for professional orthodontic use during active orthodontic treatment. The devices are intended to be used in combination with Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Archwires, Orthodontic Attachments and Auxiliaries, and other associated orthodontic appliance components in order to apply controlled orthodontic forces and support correction of malocclusions.

EXPECTED LIFETIME

Orthodontic Springs 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 Spring type and material,
- force level and activation range,
- 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 several months depending on the spring type, treatment stage, and prescribed orthodontic mechanics.

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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, 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 Spring types, materials, and force systems,
- suitability of space opening, space closure, traction, or separating 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 Springs 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 Springs may be manufactured from stainless steel, nickel titanium (NiTi), 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 Springs store mechanical energy during activation and clinical use. Improper handling, excessive activation, over-compression, overstretching, or sudden release may result in spring recoil and may cause injury to oral soft tissues, eyes, or surrounding tissues. Appropriate clinical precautions and protective measures should be used during placement, adjustment, and removal procedures.

Excessive activation, repeated adjustment, improper handling, notching, scratching, or overloading of Orthodontic Springs may result in permanent deformation, loss of force characteristics, material fatigue, or spring fracture during treatment.
Fractured spring components or detached appliance segments may present a risk of soft tissue injury, swallowing, or accidental aspiration. Appropriate precautions should be used during clinical procedures and patient monitoring throughout treatment.

Orthodontic Springs are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect spring selection, placement, activation, attachment, adjustment, or removal may result in excessive orthodontic forces, unintended tooth movement, appliance instability, root resorption, treatment inefficiency, patient discomfort, or damage to oral tissues.

Open Coil Orthodontic Springs may generate excessive separating forces if over-compressed during placement or treatment.
Closed Coil Orthodontic Springs may fracture or lose force characteristics if overstretched beyond their intended activation range.
Orthodontic Springs used in conjunction with Orthodontic Archwires, Orthodontic Attachments, Orthodontic Elastics, or associated orthodontic appliance systems should be evaluated for compatibility and appropriate force 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 Springs 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.

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RESIDUAL RISKS

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

- localized soft tissue irritation or discomfort,
- irritation or ulceration associated with Orthodontic Spring contact with oral soft tissues,
- temporary discomfort associated with orthodontic tooth movement,
- Orthodontic Spring deformation, permanent set, or loss of force characteristics during treatment,
- fracture or fatigue failure of Orthodontic Springs during clinical use or adjustment,
- recoil of Orthodontic Springs during placement, activation, adjustment, or removal procedures,
- swallowing or aspiration of detached spring components or associated appliance segments,
- 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 Orthodontic Spring selection, activation, or patient non-compliance,
- irritation associated with prolonged intraoral use,
- appliance instability or treatment interruption associated with disengagement or displacement of Orthodontic Springs 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 Springs are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect Orthodontic Spring selection, placement, activation, attachment, adjustment, 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 Spring type, material, dimensions, activation range, and force characteristics suitable for the stage of orthodontic treatment and individual patient requirements.

Care should be exercised during handling, placement, activation, adjustment, and removal procedures to minimize the risk of injury from spring recoil, sharp spring ends, fractured spring components, or associated appliance segments.

Excessive compression, overstretching, repeated adjustment, notching, scratching, or improper instrument use may damage the surface integrity and mechanical properties of Orthodontic Springs and may increase the risk of spring deformation, fatigue failure, fracture, or loss of force characteristics during treatment.

Open Coil Orthodontic Springs and Closed Coil Orthodontic Springs should be activated only within clinically accepted activation ranges appropriate for the specific spring design and material characteristics.

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 Springs should be inspected during routine orthodontic appointments for deformation, corrosion, loss of elasticity, fatigue, fracture, disengagement, or other signs of damage or deterioration. Damaged or degraded devices should be replaced where clinically indicated.

Orthodontic Springs used in conjunction with Orthodontic Archwires, Orthodontic Attachments, Orthodontic Elastics, 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, activation techniques, adjustment procedures, and removal methods should be used during orthodontic treatment involving Orthodontic Springs.

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INSTRUCTIONS FOR USE – PRACTITIONER / ORTHODONTIST

Orthodontic Springs 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 Spring type, material, dimensions, activation range, and associated orthodontic appliance components appropriate for the patient and treatment objectives.

Prior to placement:

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

During placement of Orthodontic Open Coil Springs:

• cut the Orthodontic Open Coil Spring to the required clinical length where applicable,
• place the Orthodontic Open Coil Spring onto the Orthodontic Archwire according to the planned treatment mechanics,
• activate the Orthodontic Open Coil Spring within clinically accepted activation ranges appropriate for the spring design and material characteristics,
• verify stable engagement and appropriate force application prior to completion of the procedure.

During placement of Orthodontic Closed Coil Springs and Orthodontic Closed NiTi Springs:

• attach the Orthodontic Spring securely to the designated orthodontic appliance components using clinically accepted attachment techniques,
• avoid overstretching beyond the intended activation range,
• verify stable attachment and appropriate force delivery throughout the appliance system.

During placement of Orthodontic Separating Springs:

• place the Orthodontic Separating Spring carefully between teeth using accepted orthodontic placement procedures,
• verify correct positioning and patient comfort following placement,
• monitor separation progress and remove the device when clinically indicated.

During treatment:

• monitor appliance integrity, spring activation, force delivery, and treatment progression during routine orthodontic appointments,
• inspect Orthodontic Springs for deformation, fracture, corrosion, fatigue, disengagement, loss of elasticity, or other signs of deterioration,
• replace damaged, deformed, fractured, or degraded Orthodontic Springs where clinically indicated,
• perform spring adjustments, reactivation, or replacement procedures according to accepted orthodontic treatment protocols.

When adjusting or removing Orthodontic Springs:

• use only clinically accepted orthodontic instruments and procedures,
• exercise caution to minimize the risk of injury from spring recoil, sharp ends, or detached spring components,
• avoid excessive activation, repeated over-adjustment, or improper instrument use which may compromise spring integrity or mechanical performance,
• verify that all spring components and associated appliance segments have been removed from the oral cavity following removal procedures.

Following adjustment or placement:

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

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INSTRUCTIONS FOR USE – PATIENT

• Orthodontic Springs 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, distort, loosen, disengage, or fracture Orthodontic Springs or associated orthodontic appliance components.
• Avoid biting directly into hard foods or objects which may place excessive force on Orthodontic Springs and increase the risk of spring deformation, disengagement, 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, displaced, bent, damaged, or broken spring components, particularly following impact or injury to the mouth area.
• Contact your Orthodontist promptly if an Orthodontic Spring becomes loose, disengaged, distorted, fractured, causes irritation, or becomes uncomfortable.
• Do not attempt to remove, reposition, reactivate, stretch, compress, cut, or repair Orthodontic Springs or associated orthodontic appliance components yourself.
• Mild discomfort or pressure may occur temporarily following placement, activation, or adjustment of Orthodontic Springs as part of normal orthodontic tooth movement.
• If an Orthodontic Spring or associated appliance component causes irritation to the cheeks, lips, tongue, gingiva, or other oral tissues, contact your Orthodontist for evaluation or adjustment as soon as possible.
• If a spring component becomes detached or fractured, avoid swallowing the component and contact your Orthodontist immediately for further instructions.

CONTRAINDICATIONS

While Orthodontic Springs, Orthodontic Archwires, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Attachments, 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 Springs 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 Springs should not be used in patients with known hypersensitivity or allergic reactions to stainless steel, nickel titanium (NiTi), nickel-containing materials, chromium-containing materials, or other materials used in orthodontic appliance systems.

Insufficient Tooth or Periodontal Support

Orthodontic treatment involving Orthodontic Springs 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 stability, force application, or treatment predictability.

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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, Orthodontic Spring deformation, 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 Springs 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 Springs 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.

EU REP

EU AUTHORIZED REPRESENTATIVE
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