



## INSTRUCTIONS FOR USE

ENGLISH

### DEVICE NAME: Orthodontic Elastics & Elastomeric Devices

#### DEVICE IDENTIFICATION

##### Commercial Product Families Covered:

- Intraoral Orthodontic Elastics (Latex and Non-Latex)
- Extraoral Orthodontic Elastics
- Elastomeric Ligatures
- Elastomeric Chains
- Elastic Spacers – Cyber-SEPO
- Radio-Opaque Separators
- Duraseps (Durable Elastomeric Separators)
- Bracket Guard Elastics
- Rotation Wedges

#### INDICATIONS FOR USE, INTENDED PURPOSE, AND EXPECTED LIFETIME

##### 1. INTRAORAL ORTHODONTIC ELASTICS (LATEX AND NON-LATEX)

###### INDICATIONS FOR USE:

Intraoral Orthodontic Elastics are indicated for use during orthodontic treatment to apply controlled orthodontic forces between teeth, dental arches, or orthodontic appliance components in order to support tooth movement, correction of malocclusions, space closure, arch coordination, midline correction, and bite correction.

###### INTENDED PURPOSE:

The devices are intended for temporary intraoral use in combination with fixed or removable orthodontic appliances to generate controlled elastic force vectors during orthodontic treatment.

###### EXPECTED LIFETIME:

The devices are intended for short-term clinical use and are typically replaced daily or as directed by the treating orthodontic professional depending on treatment requirements and force degradation characteristics.



##### 2. Extraoral orthodontic elastics

###### Indications for use:

Extraoral Orthodontic Elastics are indicated for use in conjunction with extraoral orthodontic appliances including headgear and facebow systems to apply orthopedic or orthodontic traction forces during correction of malocclusions and jaw alignment discrepancies.

###### INTENDED PURPOSE:

The devices are intended for temporary extraoral orthodontic force application in combination with orthodontic headgear systems under supervision of qualified orthodontic professionals.

###### EXPECTED LIFETIME:

The devices are intended for short-term clinical use and are replaced periodically according to the orthodontic treatment plan, force degradation, and clinical performance requirements.



##### 3. ELASTOMERIC LIGATURES

**INDICATIONS FOR USE:**

Elastomeric Ligatures are indicated for ligation of orthodontic archwires into orthodontic brackets during fixed orthodontic treatment in order to maintain engagement of the archwire and facilitate controlled tooth movement.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use as orthodontic ligation components within fixed orthodontic appliance systems.

**EXPECTED LIFETIME:**

The devices are intended for short-term intraoral use and are typically replaced during routine orthodontic adjustment appointments based on clinical performance and force retention characteristics.



**4. ELASTOMERIC CHAINS**

**INDICATIONS FOR USE:**

Elastomeric Chains are indicated for use during orthodontic treatment to apply continuous controlled force for space closure, tooth movement, rotational correction, and maintenance of orthodontic treatment mechanics.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use in conjunction with orthodontic brackets, hooks, and other orthodontic appliance components to deliver continuous orthodontic forces.

**EXPECTED LIFETIME:**

The devices are intended for short-term intraoral use and are replaced periodically during orthodontic treatment based on force degradation and clinical treatment requirements.



**5. ELASTIC SPACERS – CYBER-SEPO**

**INDICATIONS FOR USE:**

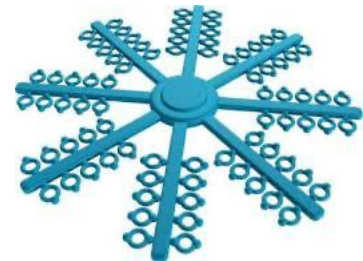
Elastic Spacers – Cyber-SEPO are indicated for temporary interproximal tooth separation prior to placement of orthodontic bands and associated orthodontic appliances.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral interproximal separation of teeth during orthodontic treatment procedures.

**EXPECTED LIFETIME:**

The devices are intended for temporary short-term intraoral use, typically for several days prior to orthodontic band placement.



**6. RADIO-OPAQUE SEPARATORS**

**INDICATIONS FOR USE:**

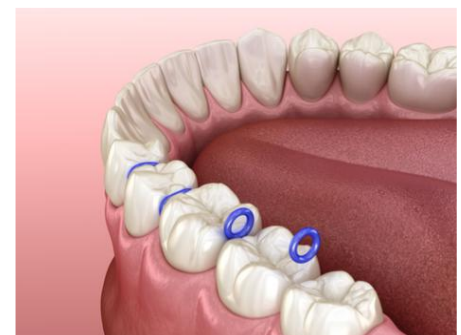
Radio-Opaque Separators are indicated for temporary interproximal tooth separation prior to placement of orthodontic bands where radiographic detectability of the separator is desired.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use to create interproximal separation of teeth while permitting radiographic visualization if displaced or unintentionally retained.

**EXPECTED LIFETIME:**

The devices are intended for temporary short-term intraoral use, typically for several days prior to orthodontic band placement or removal.



**7. DURASEPS (DURABLE ELASTOMERIC SEPARATORS)**

**INDICATIONS FOR USE:**

Duraseps are indicated for temporary interproximal tooth separation and maintenance of orthodontic treatment spacing during orthodontic procedures requiring increased separator durability.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use to create or maintain interproximal spacing during orthodontic treatment.

**EXPECTED LIFETIME:**

The devices are intended for temporary short-term intraoral use and are removed or replaced according to the orthodontic treatment plan and clinical performance requirements.

**8. BRACKET GUARD ELASTICS**

**INDICATIONS FOR USE:**

Bracket Guard Elastics are indicated for temporary coverage or protection of orthodontic brackets and associated appliance components in order to reduce irritation to oral soft tissues during orthodontic treatment.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use as protective elastomeric coverings for orthodontic appliance components.

**EXPECTED LIFETIME:**

The devices are intended for short-term temporary intraoral use and are replaced as required based on clinical condition and patient comfort.

**9. ROTATION WEDGES**

**INDICATIONS FOR USE:**

Rotation Wedges are indicated for use during orthodontic treatment to assist rotational correction of teeth, improve bracket engagement, and support directional orthodontic force application.

**INTENDED PURPOSE:**

The devices are intended for temporary intraoral use in conjunction with orthodontic brackets and archwires to assist rotational tooth movement and appliance engagement during orthodontic treatment.

**EXPECTED LIFETIME:**

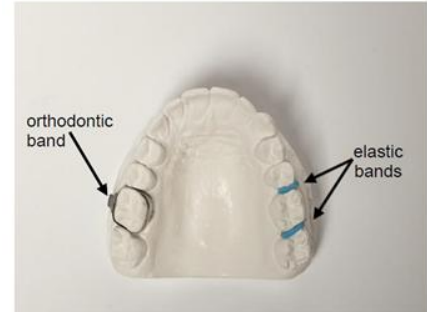
The devices are intended for temporary short-term intraoral use and are replaced or removed according to orthodontic treatment progression and clinical requirements.

**INTENDED PATIENT POPULATION**

The intended patient population for Orthodontic Elastics and Orthodontic Elastomeric Devices includes pediatric, adolescent, and adult patients requiring orthodontic treatment for correction of malocclusions, tooth alignment, space management, arch coordination, bite correction, or associated orthodontic treatment procedures.

The devices are intended for use in patients undergoing orthodontic treatment under the supervision of qualified dental or orthodontic professionals. The treating orthodontist or dental professional is responsible for determining patient suitability for treatment, including assessment of oral health condition, stage of dental development, treatment compliance, and any known sensitivities or allergies to device materials including latex where applicable.

Use in patients with poor oral hygiene, active periodontal disease, significant oral pathology, known material hypersensitivity, or poor compliance may increase treatment-related risks and shall be evaluated by the treating professional prior to use.



**Picture 1** Separators: blue elastic bands on right. Orthodontic band on left.



## **WARNINGS**

Some Orthodontic Elastics and Orthodontic Elastomeric Devices may contain natural latex. Latex-containing devices may cause allergic reactions, including serious hypersensitivity reactions, in susceptible individuals. Latex-free variants should be selected where appropriate.

Certain device variants may contain pigments, additives, or polymeric materials which may cause sensitivity or irritation in susceptible individuals. Patients with known material sensitivities should be evaluated by the treating orthodontic professional prior to use.

All Orthodontic Elastics and Orthodontic Elastomeric Devices are single-use devices. Any reuse can risk cross-contamination, degradation of mechanical performance, loss of force characteristics, and increased risk of infection or device failure.

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 Elastics and Elastomeric Devices may degrade, lose elasticity, deform, or fracture during clinical use. Devices should be replaced at intervals recommended by the treating orthodontic professional to maintain intended clinical performance.

Patients should be instructed not to stretch, modify, chew, or misuse elastomeric devices, as this may result in device breakage, unintended force application, swallowing, aspiration, or treatment complications.

Swallowing or aspiration of detached elastics, separators, ligatures, chains, wedges, or associated elastomeric components may occur during orthodontic treatment. Patients should seek immediate medical attention if aspiration is suspected.

Use of Orthodontic Elastics and Elastomeric Devices may contribute to plaque accumulation, difficulty maintaining oral hygiene, localized irritation, enamel decalcification, or periodontal complications during orthodontic treatment. Patients should maintain appropriate oral hygiene throughout treatment.

Extraoral Orthodontic Elastics used with headgear or extraoral traction systems may create risk of injury if improperly attached, excessively stretched, or accidentally released. Appropriate professional instruction and patient compliance are required during use.

Radio-Opaque Separators are designed to permit radiographic detection if displaced; however, all separator devices should be clinically monitored and accounted for during treatment.

## **RESIDUAL RISKS**

Despite implementation of risk control measures, residual risks associated with Orthodontic Elastics and Orthodontic Elastomeric Devices may include:

- localized soft tissue irritation or discomfort,
- allergic reaction or hypersensitivity to latex, polymeric materials, pigments, or additives where applicable,
- temporary discomfort associated with orthodontic tooth movement and force application,
- degradation, force decay, deformation, or fracture of elastomeric devices during use,
- swallowing or aspiration of detached elastics or elastomeric components,
- plaque accumulation and difficulty maintaining oral hygiene during orthodontic treatment,
- enamel decalcification or periodontal irritation associated with inadequate oral hygiene,
- irritation associated with prolonged intraoral use,
- treatment inefficiencies associated with improper elastic wear, misuse, poor patient compliance, or incorrect placement,
- soft tissue irritation associated with elastomeric separators, wedges, ligatures, or traction devices.

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 Elastics and Orthodontic Elastomeric Devices are intended for use only by qualified dental or orthodontic professionals trained in orthodontic treatment procedures. Incorrect selection, placement, activation, or use may result in treatment inefficiency, unintended tooth movement, soft tissue irritation, or device failure.

The Practitioner is responsible for selecting the appropriate elastic or elastomeric device type, size, force level, configuration, and placement method appropriate for the individual patient and treatment objectives.

Patients must adhere to the Practitioner's instructions regarding elastic wear, replacement intervals, oral hygiene, and scheduled follow-up visits in order to maintain treatment effectiveness and reduce the risk of complications during orthodontic treatment.

Patients should be instructed to avoid stretching, chewing, pulling, or otherwise misusing elastomeric devices, as this may result in breakage, force degradation, swallowing, aspiration, or treatment complications.

Care should be taken when placing or removing elastomeric separators, chains, ligatures, wedges, or traction devices to avoid soft tissue injury or accidental displacement of the device.

Patients with known latex sensitivity or hypersensitivity should only use non-latex device variants where appropriate.

Orthodontic Elastics and Orthodontic Elastomeric Devices may lose elasticity, deform, or degrade during clinical use and should be replaced at intervals recommended by the treating orthodontic professional.

## INSTRUCTIONS FOR USE – PRACTITIONER / ORTHODONTIST

### 1. Intraoral Orthodontic Elastics (Latex and Non-Latex)

- Select the appropriate elastic size, force level, and configuration according to the orthodontic treatment plan.
- Confirm whether the patient has any known latex sensitivity prior to selecting latex-containing products.
- Attach elastics securely to the designated orthodontic appliance components including hooks, brackets, buttons, or auxiliaries.
- Instruct the patient regarding correct placement, wear duration, replacement frequency, and oral hygiene requirements.
- Monitor the patient regularly for force degradation, patient compliance, irritation, appliance compatibility, and treatment progression.
- Replace elastics at intervals determined by the treatment plan and clinical performance requirements.

### 2. Extraoral Orthodontic Elastics

- Select the appropriate extraoral elastic force and configuration compatible with the prescribed headgear or extraoral appliance system.
- Verify secure attachment to facebow or headgear components prior to patient use.
- Instruct the patient regarding safe attachment, removal, wear duration, storage, and precautions against accidental release or overstretching.
- Monitor appliance integrity, patient compliance, force application, and soft tissue condition throughout treatment.
- Replace elastics periodically according to force degradation and clinical requirements.

### 3. Elastomeric Ligatures

- Select the appropriate ligature size and configuration compatible with the bracket and archwire system.
- Apply the ligature securely around the orthodontic bracket to engage the archwire.
- Inspect for complete archwire engagement and proper seating following placement.
- Monitor for deformation, discoloration, force degradation, or breakage during routine orthodontic appointments.
- Replace ligatures during adjustment visits or as clinically indicated.

### 4. Elastomeric Chains

- Select the appropriate elastomeric chain configuration and force characteristics according to treatment objectives.
- Cut chain segments to the required length using appropriate orthodontic instruments.
- Attach the chain securely to brackets, hooks, or auxiliaries to achieve the desired orthodontic force.
- Avoid excessive stretching beyond intended activation limits.
- Monitor for force decay, deformation, plaque accumulation, and treatment progression during follow-up visits.
- Replace elastomeric chains periodically according to clinical performance and treatment requirements.

#### **5. Elastic Spacers – Cyber-SEPO**

- Select the appropriate separator size for the intended interproximal space.
- Place the separator carefully between teeth using appropriate orthodontic placement instruments.
- Verify stable positioning following insertion.
- Instruct the patient regarding possible temporary discomfort and oral hygiene precautions.
- Monitor separator position prior to orthodontic band placement.
- Remove separators before placement of orthodontic bands or when clinically indicated.

#### **6. Radio-Opaque Separators**

- Select the appropriate separator size and configuration for the intended orthodontic application.
- Insert separators interproximally using appropriate orthodontic instruments and techniques.
- Confirm placement and retention following insertion.
- Instruct the patient regarding separator care and symptoms requiring professional review.
- Monitor clinically and radiographically where necessary to confirm separator location.
- Remove separators prior to orthodontic band placement or when clinically indicated.

#### **7. Duraseps (Durable Elastomeric Separators)**

- Select the appropriate separator configuration based on required spacing and treatment duration.
- Insert separators carefully between teeth using approved orthodontic techniques.
- Verify proper retention and patient comfort following placement.
- Monitor for displacement, tissue irritation, and treatment progression during follow-up examinations.
- Remove or replace separators according to the orthodontic treatment plan and clinical requirements.

#### **8. Bracket Guard Elastics**

- Select the appropriate protective elastomeric device compatible with the orthodontic appliance configuration.
- Place the device over or around the designated bracket or appliance component requiring protection.
- Verify correct positioning and absence of excessive pressure on surrounding tissues.
- Instruct the patient regarding temporary use and replacement where applicable.
- Remove or replace the device according to clinical requirements and patient comfort.

#### **9. Rotation Wedges**

- Select the appropriate wedge size and configuration according to the desired rotational correction and appliance system.
- Position the wedge carefully between the bracket and archwire or adjacent orthodontic components as clinically indicated.
- Verify correct force direction and appliance engagement following placement.
- Monitor tooth movement, tissue condition, and wedge stability during treatment.
- Replace or remove wedges according to treatment progression and clinical objectives.

#### **PATIENT INSTRUCTIONS**

- Use Orthodontic Elastics and Orthodontic Elastomeric Devices only as instructed by your Orthodontist or dental professional.
- Follow all instructions regarding placement, wear time, replacement frequency, and removal procedures.
- Maintain good oral hygiene throughout orthodontic treatment to reduce the risk of plaque accumulation, irritation, enamel decalcification, and periodontal complications.
- Avoid stretching, chewing, pulling, or manipulating elastomeric devices unless instructed by your Orthodontist.
- Avoid hard, sticky, or chewy foods that may damage orthodontic appliances or dislodge elastomeric devices.
- Mild pressure, discomfort, or irritation may occur temporarily during orthodontic treatment and following placement or replacement of elastomeric devices.
- Contact your Orthodontist immediately if a device becomes loose, damaged, broken, displaced, swallowed, or causes excessive discomfort or irritation.
- Patients with known latex sensitivity should use only non-latex products where appropriate.
- Keep unused elastomeric devices away from small children.

**Additional Instructions for Extraoral Elastics**

- Extraoral elastics must be attached and removed carefully following instructions provided by the Orthodontist.
- Avoid overstretching or suddenly releasing extraoral elastics, as injury may occur.
- Do not use damaged or worn extraoral elastics.

**Additional Instructions for Separators and Rotation Wedges**

- Do not attempt to remove, reposition, or manipulate separators or wedges yourself.
- Avoid flossing between teeth where separators are placed unless instructed otherwise by your Orthodontist.
- Contact your Orthodontist if separators or wedges become displaced or lost.

**Additional Instructions for Bracket Guard Elastics**

- Use bracket guard devices only as directed by your Orthodontist.
- Remove or replace the device according to professional instructions.

**CONTRAINDICATIONS**

Orthodontic Elastics and Orthodontic Elastomeric Devices are contraindicated in patients with known hypersensitivity or allergic reactions to latex, elastomeric materials, pigments, additives, or other constituent materials used in the devices. Non-latex alternatives should be used where clinically appropriate.

The devices should not be used in patients with poor oral hygiene, active periodontal disease, uncontrolled dental caries, untreated oral infection, or other oral conditions where orthodontic treatment may compromise oral health or increase the risk of adverse clinical outcomes.

Orthodontic Elastics and Orthodontic Elastomeric Devices should not be used where insufficient tooth support, compromised dentition, inadequate anchorage, or unstable orthodontic appliance systems may result in ineffective treatment, unintended tooth movement, device failure, or increased risk of complications.


















The devices should not be used in situations where patient compliance with orthodontic instructions, elastic wear schedules, oral hygiene requirements, or follow-up visits is unlikely, as non-compliance may adversely affect treatment effectiveness and increase treatment-related risks.

Extraoral Orthodontic Elastics should not be used in patients unable to safely manage extraoral appliance systems or where there is increased risk of misuse, accidental release, or injury associated with extraoral traction devices.

Orthodontic treatment involving elastomeric devices may not be appropriate in patients with certain temporomandibular joint (TMJ) disorders, severe occlusal instability, or other clinical conditions where orthodontic force application may adversely affect the patient's condition.

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

**SYMBOLS USED ON LABELING**

	<b>MD</b> – Medical Device Classification: Class IIa according to MDR (EU) 2017/745
	<b>REF</b> – Catalogue / Reference Number
	<b>LOT</b> – Batch / Lot Number
	<b>Manufacturer</b> – Indicates the medical device manufacturer
	<b>EU REP</b> – Authorized Representative in the European Community
	<b>Consult Instructions for Use</b> – Indicates the need for the user to consult the Instructions for Use
	<b>Single Use</b> – Indicates a medical device intended for one use only
	<b>CE 1304</b> - Indicates conformity with applicable European Union Medical Device Regulation requirements together with the applicable Notified Body number
	<b>Rx Only</b> – Federal law restricts this device to sale by or on the order of a licensed dental or orthodontic professional
	<b>Product shelf life</b> (Use-by Date – Indicates the date after which the device should not be used. Product shelf life under recommended storage conditions is 3 years from the date of manufacture. The manufacture date can be determined from the lot number. The Use-by date is printed as Year-Month-Day (YYYY-MM-DD) or Year-Month (YYYY-MM).
	<b>Temperature Limit</b> – Indicates the acceptable storage temperature range of 6 °C to 25 °C.
	<b>Keep Dry</b> – Indicates the device should be protected from moisture.
	<b>Keep Away from Sunlight</b> – Indicates the device should be protected from direct sunlight or strong light exposure.
	<b>LATEX</b> – Indicates the product contains natural rubber latex.
	<b>NON LATEX</b> - Indicates the product is not intentionally manufactured with natural rubber latex.
	<b>Do Not Use if Package is Damaged</b> – Indicates the device should not be used if packaging has been opened, damaged, or compromised
	<b>UDI</b> – 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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