








## INSTRUCTIONS FOR USE      ENGLISH

### DEVICE NAME: Orthodontic Bands

	INDICATIONS FOR USE
<p>The following groups of products are covered by this instruction for use:</p> <ul style="list-style-type: none"> <li>- Molar Bands (SS 12-4)</li> <li>- Molar Kits</li> <li>- Plain Orthodontic Bands</li> </ul>	<p>Orthodontic Bands anchor an appliance to the teeth or secure an orthodontic archwire to the molars. Used on the molars and in some cases the premolars. Bands come in different sizes and are custom fit to the tooth using the appropriate dental instruments. They are temporarily cemented on the teeth with cement designed specifically for the use with orthodontic bands. Orthodontic Bands have orthodontic attachments similar to a hook to allow for the use of removable orthodontic elastics or other orthodontic attachments. The orthodontic archwire slides into a small sleeve on the cheek side of the orthodontic band. This allows for the movement or stabilization of the molars.</p> <p><b>INTENDED PURPOSE:</b> Orthodontic bands are non-sterile, single-use medical devices intended to secure orthodontic appliances to teeth during professional orthodontic treatment.</p> <p><b>EXPECTED LIFETIME</b>          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.</p>
	
<p><b>WARNINGS</b>          Materials: Medical-grade stainless steel can contain nickel and/or chromium which have been known to cause sensitivity reactions.</p>	
<p>All Orthodontic Bands and orthodontic attachments are single-use devices. Any reuse can risk cross contamination to patients.</p>	
<p>Devices are supplied in a clean condition suitable for intraoral use by dental professionals. The device is intentionally supplied in a non-sterile condition and is 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.</p>	
<p>When using an Orthodontic band pusher, exercise caution to prevent the instrument from slipping from the orthodontic band, 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.</p>	
<p><b>RESIDUAL RISKS</b>          Despite implementation of risk control measures, residual risks associated with Orthodontic Bands may include:</p> <ul style="list-style-type: none"> <li>• localized soft tissue irritation or discomfort,</li> <li>• allergic reaction or sensitivity to metallic materials including nickel,</li> <li>• loosening or detachment of orthodontic bands or associated orthodontic attachments,</li> <li>• swallowing of detached components,</li> <li>• plaque accumulation around orthodontic band margins,</li> <li>• temporary discomfort associated with orthodontic tooth movement,</li> <li>• irritation associated with prolonged intraoral use.</li> </ul> <p>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.</p>	



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## PRECAUTIONS

All Orthodontic Bands and Orthodontic 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 band size to ensure precise placement and secure to the teeth for maximum retention.

## INSTRUCTIONS FOR USE – PRACTITIONER/ORTHODONTIST

These devices are sold under prescription/order to qualified dental and orthodontic professionals, who are trained in Orthodontic treatment and have knowledge of their use.

The Practitioner/Orthodontist/Dentist makes the determination on the selection of the correct size and shape of the orthodontic bands for each unique patient treatment to be performed. If any doubts are raised on the treatment plan coordinate with other professionals such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists before proceeding.

Follow the manufacturer's instructions for any orthodontic cements, instruments or other materials used in the orthodontic treatment.

Use conventional orthodontic band cement following manufacturer's instructions. Place it using the instrument of your choice. Remove excess cement from around the band and from the occlusal of the tooth.

- Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement and removal.
- Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.
- Oral hygiene is of particular importance for immunocompromised patients.
- Closely monitor oral hygiene on immunocompromised patients.
- Assess whether further orthodontic treatment is advisable in the presence of root resorption.

## 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 wire 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 an orthodontic bracket, orthodontic band, orthodontic attachment, or orthodontic archwire becomes loose, damaged, or broken, contact your Practitioner or Orthodontist immediately.

## DISPOSAL

**Sharps disposal:** Removed devices should be handled as potentially contaminated medical waste and disposed of in accordance with local regulations. These devices are single-use and are not intended to be reprocessed or sterilized.

**Transportation and disposal:** All containers of medical waste or sharps should be transported and disposed of according to local regulations and guidelines. This may involve working with a licensed medical waste disposal service or contacting local health authorities for guidance.

It is important to follow all appropriate guidelines and regulations for safe disposal to protect both human health and the environment.

**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



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



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Ni / Cr – Indicates the device contains Nickel and Chromium



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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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