

Instructions for Use

Orthodontic Elastomeric Auxiliaries



- Please read these instructions carefully before using this product.
- Keep these instructions for reference.
- In case of any serious incident please report it to the manufacturer and your competent authority.
- These instructions for use are based on experience from physicians and/or their published literature. It is intended to assist in using this device. It is not a reference to surgical techniques.

1. PRODUCT NAME

Orthodontic Elastomeric Auxiliaries

2. DESCRIPTION/INDICATIONS

Orthodontic elastomeric auxiliaries are intra-oral elastomeric rings used to apply forces to teeth. They are used in the field of orthodontics to correct different type of malocclusions.

The many different types of elastics may produce different forces on teeth. Four types of orthodontic elastomeric auxiliaries are available: elastomeric separator (model 650), elastomeric ligature ties (model 300), elastomeric chain (model 280, 220, 160) and elastomeric intra-oral elastics (model 3/8, 5/16, 1/4, 3/16, 1/8).

Elastomeric separators are elastomeric products used to open interproximal spaces between teeth. The separators are ideal for creating spaces between molars for placement of orthodontic bands.

Elastomeric ligature ties are small elastic rings used to affix the archwire to the bracket and retain wires to orthodontic attachments. They are usually changed at each adjustment, these come in many varied colours, including transparent.

Elastomeric chains and elastomeric intra-oral elastics are interconnected elastomeric rings used to apply forces to teeth and pull teeth together with more strength. The chain exerts light and continuous forces for optimal tooth movements.

Orthodontic elastomeric auxiliaries are made from polyurethane (TPU). This is a high-density and high-purity material which is very strong and has a memory effect. The quality of the polyurethane enables these elastomerics to recover 90% of their initial shape after being stretched. The elastomeric intra-oral elastics (model 3/8, 5/16, 1/4, 3/16, 1/8) are made from surgical grade latex. Surgical grade latex has the high flexibility and maintains the excellent mechanical properties of the elastics. It gets precision for consistent force delivery.

Intended Purpose

Orthodontic elastomeric auxiliaries are intended for orthodontic movement of teeth.
This is a single-use device. A re-use of the device is not allowed.

3. SPECIFICATION

Dimensions of Orthodontic Elastomeric Auxiliaries

| Type/Model | Outer diameter (mm) | Inner diameter (mm) |
|---------------------------------------|---------------------|---------------------|
| Elastomeric Separator (model 650) | 4.5±0.2 | 2.0±0.2 |
| Elastomeric ligature ties (model 300) | 2.9±0.2 | 1.3±0.1 |
| Elastomeric Chain | model 280 | 2.8±0.2 |
| | model 220 | 2.8±0.2 |
| | model 160 | 3.0±0.2 |
| Elastomeric intra-oral elastics | model 3/8 | 11.5±0.2 |
| | model 5/16 | 10±0.2 |
| | model 1/4 | 8±0.2 |
| | model 3/16 | 7±0.2 |
| model 1/8 | 5±0.2 | 3±0.2 |

4. CONTRAINDICATIONS

Orthodontic elastomeric auxiliaries are contraindicated for patients with allergy to the materials.
Elastomeric intra-oral elastics are contraindicated for persons with latex allergy.

5. CAUTIONS and WARNINGS

- Select correct size of orthodontic elastomeric auxiliaries according to the orthodontic method used;
- Elastomeric intra-oral elastics contain natural rubber latex which may cause allergic reactions. It should not be used on or by anyone who is sensitive or allergic to latex. Anyone that experiences any adverse reaction to the product, should immediately discontinue its use and consult a physician.
- This is single-use device. A re-use is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used;
- Pay attention to keep the mouth hygiene; During use, use a soft toothbrush to gently brush up and down under the guidance of a dentist;
- Do not use such devices after exceeding the shelf life;
- Do not bite hard or sticky food, do not chew gum;
- The use duration of elastomeric separators should not exceed 48 hours, of other orthodontic elastomeric auxiliaries should not exceed 1 week.
- After use this device may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and with applicable local, state and federal laws and regulations.

6. POTENTIAL COMPLICATIONS














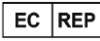
Complications of orthodontic elastomeric auxiliaries are documented. These complications may include:

- Allergic reactions
- Pain during the orthodontic treatment
- Tooth discolorations
- Decalcification
- Root resorption
- Periodontal complications

7. DIRECTIONS FOR USE

- 1) Size selection: corresponding size is selected according to the orthodontic method used: Elastomeric separator (model 650) for opening interproximal spaces between teeth; Elastomeric ligature ties (model 300) for affix the archwire to the bracket; Elastomeric chains (model 280, 220, 160) and elastomeric intra-oral elastics (model 3/8, 5/16, 1/4, 3/16, 1/8) are for applying continuous forces for tooth movements.
- 2) Soak the device for 20-30 minutes in 75% alcohol for disinfection, then rinse the residual disinfectant with sterile water (more than three times, 1 minute each time).
- 3) Clean the tooth surface: use a cup-shaped rubber wheel to finely grind the tooth surface to remove the tartar, color stains, then rinse the surface with water (> 3 times) and dry it with alcohol. Blow the tooth for drying.
- 4) Orthodontic separation method: use orthodontic forceps to insert elastomeric separator (model 650) after stretching into the space between the two teeth. Then take it out after 48 hours (creating spaces between two teeth for placement of orthodontic bands).
- 5) Ligature in orthodontics: use orthodontic forceps to put elastomeric ligature ties (model 300) at the place to ligature (fix) the archwire to the bracket. The use duration of individual ring is limited to one week.
- 6) Traction in orthodontics: use orthodontic forceps to hitch up selected size of elastomeric chains (model 280, 220, 160) or elastomeric intra-oral elastics (model 3/8, 5/16, 1/4, 3/16, 1/8) onto different orthodontic brackets (or orthodontic buccal tubes). It causes a predetermined rotation or movement between the teeth. The use duration of individual ring is limited to one week.

8. EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE:

| | | | |
|---|----------------------------------|---|---|
|  | Catalogue number |  | Caution |
|  | Batch code |  | Consult instructions for use |
|  | Do not re-use |  | Keep away from sunlight |
|  | Use-by date |  | Keep dry |
|  | Do not use if package is damaged |  | Fragile, handle with care |
|  | UDI code |  | Manufacturer |
|  | Medical device |  | Authorized representative in the European Community |



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Date of issue: 2021-05-15 Revision: A/0