Instructions for Use

This document provides instructions for use for orthodontic medical devices made by Auradonics, Inc.

1. **Description of these products:**
   These products are single-use medical devices available by prescription only. They are made of elastic polymers. Colorants are added for cosmetic purposes only. Products have outside diameters or longest dimensions that are each less than 5 mm in length, thickness, and height (except for thread, tubing, and chain products provided on spools in meter-scale lengths).
   - **Orthodontic Elastomeric products** are made of polyurethane in 35 colors;
   - **Orthodontic Latex Elastics** are intra-oral and extra-oral elastic bands (with outside diameters of 3 to 13 mm and 0.8 to 1.6 mm wall thicknesses). These products provide gram-forces (g-f) of approximately 71 to 454 g-f (2.5 to 16 ounce-force) and are made of natural latex rubber. These products contain latex.
   - **Orthodontic Non-Latex Elastics** are intra-oral elastic bands (outside diameter 3 to 13 mm and 0.8 to 1.2 mm wall thickness that provide 71 to 184 g-f (2.5 to 6.5 ounce-force) and are made of synthetic rubber (styrene:butadiene) that contains no latex.

   Elastics are made by slicing hollow rubber tubing crosswise to create circular bands. Elastomeric products are made by injection molding or extrusion of liquid polyurethane or by punching of solid polyurethane ribbon to create circular rings or other shapes. Products are designed to meet standard product specifications (shapes and sizes) widely used for decades by the orthodontic industry:
   - Their design permits exertion of desired range of forces;
   - Materials exert forces with minimal breakage and maximal elastic memory;
   - Materials are high quality food-grade or medical-grade polymers and colorants chosen for minimal leaching from polymer;
   - Latex bands contain natural latex rubber.
   - All Auradonics orthodontic products and materials are state-of-the-art, are standard in the industry, and have been well-tolerated by patients for over 40 years.
   - Latex bands are processed in a dedicated factory area to prevent latex contamination of other non-latex products.
   - No BPA, BPF, BPS, DEHP, plasticizers, or wheat gluten were added during manufacture of products or to packaging.
   - These devices do not contain or incorporate medicinal substances or tissues or cells of human origin or animal origin;
   - These devices do not emit radiation and do not require an external power source for their intended use;
   - Please refer to www.auradonics.com for additional product information.

2. **Trade names for devices manufactured by Auradonics, Inc. (www.auradonics.com) include:**
   FOR ELASTICS:
   LATEX ORTHODONTIC ELASTICS are circular bands made of natural latex rubber;
   NON-LATEX ORTHODONTIC ELASTICS (LATEX-FREE ELASTICS) are circular bands made of synthetic rubber (styrene:butadiene polymer);

   FOR ELASTOMERIC PRODUCTS (made of polyurethane)**:**
   LIGATURES (ELAST-O-TIES, BITE-SIZE TIES, TEN-TIES, MINI-TIES, FIGURE 8s, or
   LIGATURES LOADED ONTO CANES or supplied in **BULK)**
   ELASTOMERIC CHAIN (long, short, or continuous);
   SEPARATORS (including **SEP-O-LOOPS, SEPO LOOPS, SEPO I, SEPO II,** or **BULK SEPOS);**
   ROTATION WEDGES;
   LIP-BUMPERS;
   ARCHWIRE SLEEVES;
   THREAD;
   TUBING.

3. **Intended purpose (same as intended use) of the devices and clinical benefits:**
Devices are designed and manufactured for use for treatment of patients with orthodontic disorders by dental professionals who are qualified to provide orthodontic treatment and who understand how to use the devices properly. These devices are not intended to be implanted; their intended use is in the mouth only; they should contact but not penetrate mucous membranes in the mouth;

These devices (elastics and elastomerics) are used with fixed orthodontic braces (dental brackets glued to teeth that are used with archwires, springs, wires, or other orthodontic accessories and appliances). Unique device configurations are customized for each patient and are selected by the orthodontist to apply forces to teeth to reposition them in the jaw to improve tooth alignment and create a healthy bite. A healthy bite is obtained when teeth in one jaw are aligned to properly meet teeth in the other jaw and thus can provide the patient with cosmetic benefits that result from improved alignment and leveling of the teeth. In addition, better oral hygiene and dental health, more efficient chewing and swallowing, improved digestion, prevention of jaw problems, and better speech and breathing can be benefits of appropriate orthodontic treatment.

Figure 1. Orthodontic devices (similar to those made by Auradonics) shown in patient mouth during treatment. Top left: colorful elastomeric ligatures (arrow A) attached to archwire (arrow B) and brackets (arrow C) glued to teeth; Top right: rubber band (2 arrows) attached to archwire hooks are replaced by patient daily; Bottom left: gray elastomeric chain (arrow) connecting brackets glued to teeth; Bottom right: blue elastomeric separators used between teeth showing insertion sequence from left separator to right final placement (arrow).

4. **Performance characteristics of the devices:**
Generally orthodontic treatment lasts from 1 to 3 years depending on patient needs. The intended use of these devices is for correction of orthodontic malocclusions and to achieve a healthy bite. Benefits outweigh risks when devices are used for their intended use and when treatment is supervised by dental professionals qualified to provide orthodontic treatment.

5. **Limitations of the devices:**
The goal of orthodontic treatment, to improve the bite and tooth alignment, has limitations that may be beyond control of the patient and orthodontist. Jaw growth and development ultimately affect tooth/bite position and may be beyond the control of the orthodontist, while patient compliance is not under control of the orthodontist.

6. **Users who install the devices:**
   Devices are available by prescription only and must be installed under supervision of dental professionals with orthodontic training and professional certification. Qualified professionals supervise patient care throughout treatment for 1-3 years and see patients every few weeks to monitor treatment. They also teach patients to correctly replace elastics daily at home between visits, to properly store devices, to maintain oral hygiene, and to detect and report adverse reactions and events. Qualified dental professionals with appropriate orthodontic education, certification, and experience do not require instructions for use to administer these devices during orthodontic treatment. They select materials and devices for treatment based on their knowledge and experience acquired during training and according to the specific diagnosis and treatment plan for each patient. Use of these devices by untrained and/or unsupervised individuals may result in irreversible health outcomes, adverse reactions, serious incidents, and increased risk of harm.

7. **Intended patient groups:**
   Orthodontic elastic bands are used to treat adults (including pregnant women), teens, and children after evaluation by orthodontic/dental professionals to confirm they would benefit from orthodontic treatment, can receive treatment safely and effectively, and will comply with instructions on daily care, oral hygiene, and completion of activities that minimize risk of harm. The orthodontist may reject a patient who might not comply with instructions. Patients must be able to change their elastic bands daily as needed; for some patients a caregiver is required to comply with the treating professional's instructions for daily care at home.

8. **Contraindications:**
   It is the primary responsibility of the orthodontic treatment professional to identify any possible contraindication barring use of these products. These devices should not be used in the following situations:
   - To treat patients with poor oral hygiene;
   - To treat patients with inability or lack of assistance to comply with treatment;
   - If patients have known allergies to polymers or dyes in the devices;
   - To treat patients with diseases or limitations that might interfere with successful treatment;
   - To treat patients with existing bone or root resorption, existing decalcification of dental enamel, or existing periodontal complications;
   - If defects in form or function are observed (if defects are observed, patients must notify orthodontist and orthodontist must contact, Auradonics, Inc. as soon as possible);
   - If those with known allergies are installing the devices unless safety precautions are taken;

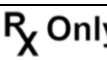
9. **Any residual risks etc. to be communicated to patients:**
   During orthodontic treatment there is a low risk of harm to patients of:
   - Treatment relapse;
   - Allergic reactions to the devices (especially to latex);
   - Swallowing or aspiration of the devices;
   - Discoloration or decalcification of teeth;
   - Bone and root resorption, periodontal complications;
   - Infection related to device issues;
   - Difficulties in maintaining oral hygiene;
   - Oral and mucosal damage;
   - Difficulty in speaking or chewing, discomfort, and pain;
   - Breakage or loss of device function with use of oral hygiene products, whitening toothpastes, or certain foods.

10. **A notice that serious incidents must be reported:**
    Patients must receive appropriate medical attention in the case of adverse events such as:
    - Allergic reactions, including trouble breathing, rashes, hives, swelling;
    - Infection (swelling, fever, pain associated with the devices);
    - Aspiration (device entry into respiratory tract);
    - Product issues causing safety or serious performance issues.

Important Note: Patients should be instructed when beginning treatment to discontinue use of devices and seek immediate medical attention in the event of serious illness. After resolution of the serious event, the patient should visit the orthodontic professional to determine the cause of the adverse event as soon as possible. If the adverse event was shown to be caused by the devices, the orthodontic professional should report the adverse event to the distributor, including the product quality issue, lot number(s), and other product information needed to investigate the adverse event. The distributor then decides whether to report the issue to regulatory authorities and/or contact the manufacturer. Because these products are medical devices, regulations require that these products be traceable from the patient to the manufacturer and also traceable to the raw materials supplier if necessary. To ensure product traceability during a product recall (a rare occurrence), orthodontic professionals must record product lot numbers in patient files.

We strongly advise orthodontists and patients to be aware that if allergies to latex or other product ingredients are observed or suspected that product use by the affected patient be discontinued immediately. An allergic patient should consult an allergist to determine which products are safe for that patient. Allergies to dyes and additives are uncommon, differ among patients and among products, and should be addressed by orthodontic and/or allergy specialists. If a customer (distributor, orthodontist, or patient) identifies a product quality and/or safety issue, the customer should relay product information, lot number, use-by date, and description of the product quality or safety issue as soon as possible to auradonics@aol.com or call 856-764-8866.

11. Information provided on medical device labels affixed to device packaging:

Symbol	Symbol meaning	Information about the manufacturer and the orthodontic medical device products in the package
	Manufacturer information	Devices are manufactured by Auradonics, Inc., located at 439 Saint Mihiel Drive, Riverside, NJ 08075 USA
	European Union Representative	EC Certification Service, Sandgasse 39a A-9300 St. Veit/Glan Austria, phone: 011-43-4212 6094, office@ec-c.at, www.ec-c.at
	CE mark (#1304)	Notified Body: The Slovenian Institute of Standards and Metrology, Tržaška cesta 2, 1000 Ljubljana, Slovenia, www.siq.si
	Medical device	These devices are medical devices. They are installed by trained orthodontic or dental professionals and to a limited extent by patients supervised by trained professionals.
	By prescription only	These medical devices are available by prescription only; their intended use is for orthodontic treatment under supervision of a trained orthodontist or dental professional.
	Do not use if packaging of unopened product is damaged	Products are shipped in plastic bags made of polyethylene plastic film with zippers made of ethylene-vinyl acetate copolymer. If packaging is breached upon receipt, the patient or orthodontic professional must not use the product and should provide lot number and product information to the product distributor for investigation of the issue.
	Non-sterile	These devices are not sterile and are not intended to be used in a sterile state. Sterilization can compromise product safety and performance and is not recommended.
	Not for reuse	These devices are not to be reused (single-use only); the devices lose their effectiveness with use and cannot be sterilized to prevent microbial transmission without losing function, so reuse is not intended.
	Storage temperature	These devices should be stored between 6 °C and 25 °C.
	Store away from sunlight	Exposure of products to sunlight or strong light shortens shelf-life.
	Keep dry	Store products in a dry place to maintain cleanliness.
	Use-by date:	Product shelf life (under proper storage conditions) is 3 years from manufacture date. 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).
	Lot number	**Latex Elastics:** lot numbers have 6 or 7 digits. The 4th and 5th digits from the left are the week number, the 6th digit is the last digit of the year. The 7th digit is ignored. Thus, a product with lot # 1284111 was made on the 41st week of 2011. **Non-Latex Elastics:** lot numbers have 6 digits. The 1st and 3rd digits from the left are the week, the 2nd and 4th digits are the year. Thus, lot # 116313 is the 16th week of 2013. **Elastomerics Products**: lot numbers have 6 digits. The 1st and 3rd digits are the week, the 2nd and 4th are the year. The last 2 digits are ignored. Thus, lot # 117406 is the 17th week of 2014.
	Product number	Product number is the same as the catalog number.
QUAN.	Quantity	Number of units of the device per package (bag).
	Warning/ Caution	This symbol is used with a warning statement on package labels for latex products with the warning statement “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions. If irritation occurs, discontinue use and consult physician.”
	Product contains latex	Latex Elastics contain natural latex rubber.
	Product does not contain latex	Labels on packaging of Non-Latex Elastics and Elastomeric products have this symbol since products contain no latex.
	Consult instructions for use	Instructions for use are found at www.auradonics.com.

Sample Label for Latex Elastics Product:

Manufacturer information and medical device symbol (MD), prescription symbol (Rx Only), USE BY date:

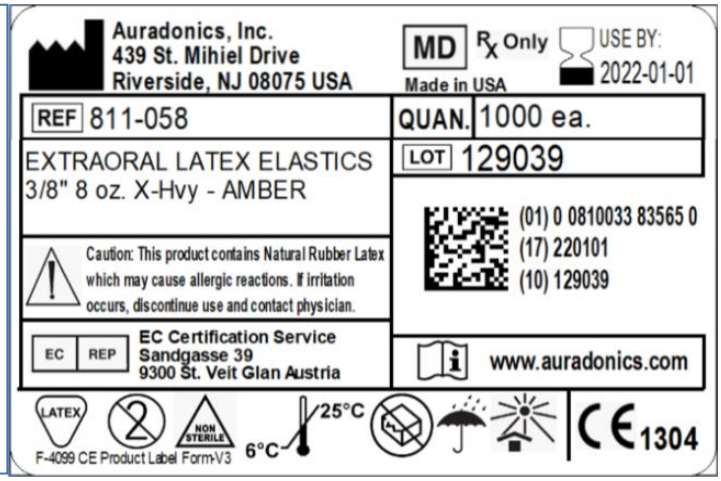
Product information (REF. is catalog #), quantity/pkg.:

Product description; Lot #:

Caution statement about Natural Rubber Latex; Barcode (01) Global Trade Identification #, (17) Expiration Date, (10) Lot/batch #:

European representative, address; Information symbol and website:

Storage / handling symbols (see legend above), CE mark (1304): Form #:



Sample Label for Non-Latex Elastics Product:

Manufacturer information and medical device symbol (MD), prescription symbol (Rx Only), USE BY date:

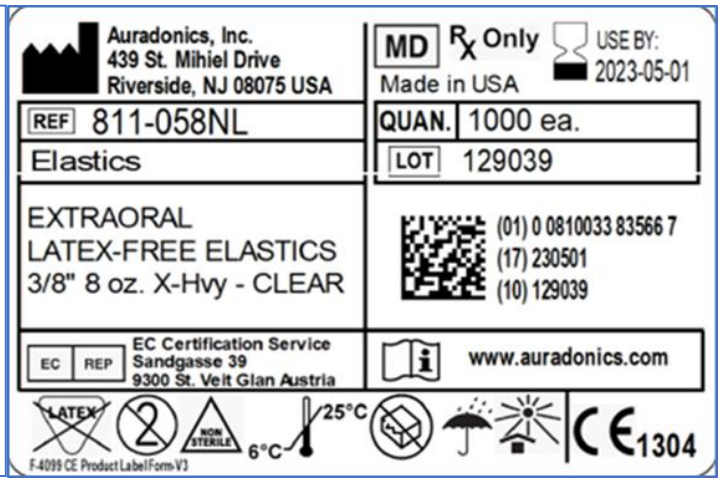
Product information (REF. is catalog #), quantity/pkg.:

Product category; Lot #:

Product description; Barcode (01) Global Trade Identification #, (17) Expiration Date, (10) Lot/batch #:

European representative, address; Information symbol and website:

Storage / handling symbols (see legend above), CE mark (1304): Form #:



Sample Label for Elastomeric Product:

Manufacturer information and medical device symbol (MD), prescription symbol (Rx Only), USE BY date:

Product information (REF. is catalog #), quantity/pkg.:

Product category; Lot #:

Product description; Barcode (01) Global Trade Identification #, (17) Expiration Date, (10) Lot/batch #:

European representative, address; Information symbol and website:

Storage / handling symbols (see legend above), CE mark (1304): Form #: