Revision History		
Rev	**Description of Changes**	**Release Date**
A	CO#20085: Initial Release	2020-08-26

CAUTION: Federal law restricts this device to the sale by or on the order of a licensed orthodontist.

1. Product Family

- High-Grade Latex Elastics (also marketed as Xtreme™ Latex Elastics)
- Latex-Free Elastics (also marketed as Xtreme™ Non-Latex Elastics)



2. Product Part Number(s)

- ***High-Grade Latex Elastics***

Catalog Number	Catalog Description	Inner Diameter	Cross section thickness	Initial extension force	24-hour residual force
60.63.833.00025	LE 1/8" 3mm 2.5 Light (50 PK)	.125” ± .010”	.040” ± .015”	70 ± 35 *gf*	Min 40%
60.63.833.31025	CLE 1/8" 3mm 2.5 Light (50 PK)				
60.63.834.00035	LE 1/8"3mm 3.5 Medium (50 PK)		.050” ± .020”	100 ± 35 *gf*	
60.63.834.31035	CLE 1/8"3mm 3.5 Medium (50 PK)				
60.63.835.00045	LE 1/8" 3mm 4.5 Heavy (50 PK)		.060” ± .020”	130 ± 35 *gf*	
60.63.835.31045	CLE 1/8" 3mm 4.5 Heavy (50 PK)				
60.63.836.00060	LE 1/8" 3mm 6.0 X-Heavy (50 PK)		.080” ± .030”	170 ± 35 *gf*	
60.63.836.31060	CLE 1/8" 3mm 6.0 X-Heavy (50 PK)				
60.63.843.00025	LE 3/16" 5mm 2.5 Light (50 PK)	.188” ± .010”	.040” ± .015”	70 ± 35 *gf*	
60.63.843.31025	CLE 3/16" 5mm 2.5 Light (50 PK)				
60.63.844.00035	LE 3/16" 5mm 3.5 Medium (50 PK)		.050” ± .020”	100 ± 35 *gf*	
60.63.844.31035	CLE 3/16" 5mm 3.5 Medium (50 PK)				
60.63.845.00045	LE 3/16" 5mm 4.5 Heavy (50 PK)		.060” ± .020”	130 ± 35 *gf*	
60.63.845.31045	CLE 3/16" 5mm 4.5 Heavy (50 PK)				
60.63.846.00060	LE 3/16" 5mm 6.0 X-Heavy (50 PK)		.080” ± .030”	170 ± 35 *gf*	
60.63.846.31060	CLE 3/16" 5mm 6.0 X-Heavy (50 PK)				
60.63.853.00025	LE 1/4" 6mm 2.5 Light (50 PK)	.250” ± .010”	.040” ± .015”	70 ± 35 *gf*	
60.63.853.31025	CLE 1/4" 6mm 2.5 Light (50 PK)				
60.63.854.00035	LE 1/4" 6mm 3.5 Medium (50 PK)		.050” ± .020”	100 ± 35 *gf*	
60.63.854.31035	CLE 1/4" 6mm 3.5 Medium (50 PK)				
60.63.855.00045	LE 1/4" 6mm 4.5 Heavy (50 PK)		.060” ± .020”	130 ± 35 *gf*	

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60.63.855.31045	CLE 1/4" 6mm 4.5 Heavy (50 PK)				
60.63.856.00060	LE 1/4" 6mm 6.0 X-Heavy (50 PK)		.080" ± .030"	170 ± 35 *gf*	
60.63.856.31060	CLE 1/4" 6mm 6.0 X-Heavy (50 PK)				
60.63.863.00025	LE 5/16" 8mm 2.5 Light (50 PK)	.313" ± .010"	.040" ± .015"	70 ± 35 *gf*	
60.63.863.31025	CLE 5/16" 8mm 2.5 Light (50 PK)				
60.63.864.00035	LE 5/16" 8mm 3.5 Medium (50 PK)		.050" ± .020"	100 ± 35 *gf*	
60.63.864.31035	CLE 5/16" 8mm 3.5 Medium (50 PK)				
60.63.865.00045	LE 5/16" 8mm 4.5 Heavy (50 PK)		.060" ± .020"	130 ± 35 *gf*	
60.63.865.31045	CLE 5/16" 8mm 4.5 Heavy (50 PK)				
60.63.866.00060	LE 5/16" 8mm 6.0 X-Heavy (50 PK)		.080" ± .030"	170 ± 35 *gf*	
60.63.866.31060	CLE 5/16" 8mm 6.0 X-Heavy (50 PK)				
60.63.873.00025	LE 3/8" 9mm 2.5 Light (50 PK)	.375" ± .010"	.040" ± .015"	70 ± 35 *gf*	
60.63.873.31025	CLE 3/8" 9mm 2.5 Light (50 PK)				
60.63.874.00035	LE 3/8" 9mm 3.5 Medium (50 PK)		.050" ± .020"	100 ± 35 *gf*	
60.63.874.31035	CLE 3/8" 9mm 3.5 Medium (50 PK)				
60.63.875.00045	LE 3/8" 9mm 4.5 Heavy (50 PK)		.060" ± .020"	130 ± 35 *gf*	
60.63.875.31045	CLE 3/8" 9mm 4.5 Heavy (50 PK)				
60.63.876.00060	LE 3/8" 9mm 6.0 X-Heavy (50 PK)		.080" ± .030"	170 ± 35 *gf*	
60.63.876.31060	CLE 3/8" 9mm 6.0 X-Heavy (50 PK)				

- ***Latex-Free Elastics***

Catalog Number	Catalog Description	Inner Diameter	Cross section thickness	Initial extension force	24-hour residual force
60.63.933.00025	NLE 1/8" 3mm 2.5 Light (50 PK)	.125" ± .010"	.050" ± .015"	70 ± 35 *gf*	Min 35%
60.63.934.00035	NLE 1/8" 3mm 3.5 Medium (50 PK)		.050" ± .015"	100 ± 35 *gf*	
60.63.935.00045	NLE 1/8" 3mm 4.5 Heavy (50 PK)		.060" ± .015"	130 ± 35 *gf*	
60.63.936.00060	NLE 1/8" 3mm 6.0 X-Heavy (50 PK)		.075" ± .015"	170 ± 35 *gf*	
60.63.943.00025	NLE 3/16" 5mm 2.5 Light (50 PK)	.188" ± .010"	.050" ± .015"	70 ± 35 *gf*	
60.63.944.00035	NLE 3/16" 5mm 3.5 Medium (50 PK)		.050" ± .015"	100 ± 35 *gf*	
60.63.945.00045	NLE 3/16" 5mm 4.5 Heavy (50 PK)		.060" ± .015"	130 ± 35 *gf*	
60.63.946.00060	NLE 3/16" 5mm 6.0 X-Heavy (50 PK)		.075" ± .015"	170 ± 35 *gf*	
60.63.953.00025	NLE 1/4" 6mm 2.5 Light (50 PK)	.250" ± .010"	.050" ± .015"	70 ± 35 *gf*	
60.63.954.00035	NLE 1/4" 6mm 3.5 Medium (50 PK)		.050" ± .015"	100 ± 35 *gf*	
60.63.955.00045	NLE 1/4" 6mm 4.5 Heavy (50 PK)		.060" ± .015"	130 ± 35 *gf*	
60.63.956.00060	NLE 1/4" 6mm 6.0 X-Heavy (50 PK)		.075" ± .015"	170 ± 35 *gf*	
60.63.963.00025	NLE 5/16" 8mm 2.5 Light (50 PK)	.313" ± .010"	.050" ± .015"	70 ± 35 *gf*	
60.63.964.00035	NLE 5/16" 8mm 3.5 Medium (50 PK)		.050" ± .015"	100 ± 35 *gf*	
60.63.965.00045	NLE 5/16" 8mm 4.5 Heavy (50 PK)		.060" ± .015"	130 ± 35 *gf*	
60.63.966.00060	NLE 5/16" 8mm 6.0 X-Heavy (50 PK)		.075" ± .015"	170 ± 35 *gf*	
60.63.973.00025	NLE 3/8" 9mm 2.5 Light (50 PK)	.375" ± .010"	.050" ± .015"	70 ± 35 *gf*	

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60.63.974.00035	NLE 3/8" 9mm 3.5 Medium (50 PK)		.050" ± .015"	100 ± 35 *gf*	
60.63.975.00045	NLE 3/8" 9mm 4.5 Heavy (50 PK)		.060" ± .015"	130 ± 35 *gf*	
60.63.976.00060	NLE 3/8" 9mm 6.0 X-Heavy (50 PK)		.075" ± .015"	170 ± 35 *gf*	

3. Description

The Latex and Latex-Free Elastics come in a variety of inside diameters, cross section thickness, initial extension force and 24-hour residual force as listed in section 2. Latex Elastics are available in mixed colors (orange, green, blue, purple, pink, yellow and in natural). Latex-Free Elastics are only available in clear.

4. Intended use

The Latex and Latex-Free Elastics are intended for use in orthodontic and dental treatment in conjunction with other orthodontic appliances and accessories.

5. Indications for Use

The Latex and Latex-Free Elastics are indicated for exerting pressure on teeth via intra-oral and extra-oral attachment to orthodontic devices.

6. Contraindications

- Patient's inability or unwillingness to cooperate/follow the treatment plan
- Patient with deficient oral hygiene
- Known allergies to any of the components or materials in the system.
- Any illness and/or underlying conditions that preclude orthodontic treatment.
- Any existing tooth root resorption

7. Warning and Precautions

- For professional/orthodontist use only.
- The product is shelf life sensitive and must be used by date on label/packaging.
- Before use, counsel patients on the materials contained in this device. Also, counsel the patient of the potential for allergy/hypersensitivity to these materials.
- Follow all regional and national standards regarding the use of orthodontic medical devices.
- Do not use any products which are damaged or do not comply with the labeling specifications.

8. General Information for the Dentist/Orthodontist

- Orthodontic training in standard procedures will determine the appropriate instruments to use with Latex and Latex-Free Elastics.
- Disposal of all orthodontic appliances and instruments must follow regional and national regulations.

9. Handling Procedure on how to use the medical device (Instructions for use)

Latex and Latex-Free Elastics are placed over hooks in the bracket system or as prescribed by the orthodontist using an Elastics placing instrument.

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10. Materials

The Latex Elastics are composed of Kent Elastomer Product's natural rubber latex tubing K-100™. The Latex-Free Elastics are composed of PolyOne's Versaflex™ D2104 N polymer.

11. Cleaning and sterilization instructions

Latex and Latex-Free Elastics are provided clean but non-sterile.

12. Disposal (if applicable)

- Disposal of all orthodontic medical devices must follow regional and national regulations.

13. Name and address of labeler

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14. Storage and Handling for medical devices

- The device should be stored in a dark, dry environment. Optimum storage temperature is 42.8ºF to 77ºF (6º C - 25º C).
- The product has a shelf life of 2 years. See product label and packaging for use by date.

15. Explanation of Symbols on label and packaging

The following are per ISO 15223-1 (*References as indicated*).

Symbol; Standard Reference	SYMBOL TITLE – Explanatory Text
 Ref. 5.1.1	**Manufacturer**: Indicates the medical device manufacturer.
 Ref. 5.1.2	**Authorized Representative:** Indicates the Authorized representative in the European Community.
 Ref. 5.1.4	**Use by:** Indicates the date after which the medical device is not to be used.
 Ref. 5.1.5	**Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
 Ref. 5.1.6	**Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
 Ref. 5.2.7	**Non-sterile:** Indicates a medical device that has not been subjected to a sterilization process.
 Ref. 5.3.2	**Keep away from sunlight:** Indicates a medical device that needs protection from light sources.

Ref. 5.3.7	**Temperature Limit:** Indicates the temperature limits to which the medical device can be safely exposed.
Single Use Ref. 5.4.2	**Do not re-use/single patient use:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
LATEX Ref. 5.4.5	**Contains or presence of natural rubber latex:** Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
Symbols Not Derived from Standards	
CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	**European conformity:** European conformity (CE) mark with Notified Body identification number.

16. Name, address and number of Notified Body

CE 0197

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