

INSTRUCTIONS FOR USE

LATEX & LATEX-FREE ELASTICS

1. Product Family & Part Numbers

Product Family

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



High-Grade Latex Elastics Product Numbers

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	
60.63.855.31045	CLE 1/4" 6mm 4.5 Heavy (50 PK)				

High-Grade Latex Elastics Product Numbers					
Catalog Number	Catalog Description	Inner Diameter	Cross section thickness	Initial extension force	24-hour residual force
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)			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)			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)			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"	
60.63.874.00035	LE 3/8" 9mm 3.5 Medium (50 PK)			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)			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)			170 ± 35 gf	
60.63.876.31060	CLE 3/8" 9mm 6.0 X-Heavy (50 PK)				

Latex-Free Elastics Product Numbers					
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)			100 ± 35 gf	
60.63.935.00045	NLE 1/8" 3mm 4.5 Heavy (50 PK)			130 ± 35 gf	
60.63.936.00060	NLE 1/8" 3mm 6.0 X-Heavy (50 PK)			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)			100 ± 35 gf	
60.63.945.00045	NLE 3/16" 5mm 4.5 Heavy (50 PK)			130 ± 35 gf	
60.63.946.00060	NLE 3/16" 5mm 6.0 X-Heavy (50 PK)			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)			100 ± 35 gf	

Latex-Free Elastics Product Numbers					
Catalog Number	Catalog Description	Inner Diameter	Cross section thickness	Initial extension force	24-hour residual force
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)		.050" ± .015"	70 ± 35 gf	
60.63.974.00035	NLE 3/8" 9mm 3.5 Medium (50 PK)	.375" ± .010"	.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	

2. 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 1. Latex Elastics are available in mixed colors (orange, green, blue, purple, pink, yellow and in natural). Latex-Free Elastics are only available in clear.

3. 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.

Devices are supplied:

- Non-sterile
- Designed for single-use
- For use by dentists and orthodontists only.

WCT devices are intended to be used in conjunction with other orthodontic devices. WCT orthodontic appliances are used to aid in the movement of natural teeth in patients with malocclusion during orthodontic treatment.

4. 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.




5. 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.

6. 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.

7. Warnings and Precautionary Measures

	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
	Product is designed for single use patient use only, by a professional or on the order of an orthodontist or a dentist. There is a risk of cross-contamination between patients if re-used.
	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 patient of the potential for allergy/hypersensitivity to these materials.	
Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction.	
Follow all regional and national standards regarding the use of orthodontic appliances.	
Do not use any products which are damaged, or do not comply with the labeling specifications.	
MRI Safety Information – The product has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ceramic bracket system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.	
If, in relation to the use of this product, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.	

8. Patient Information

- Not Applicable

9. 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.
- Latex and Latex-Free Elastics are placed over hooks in the bracket system or as prescribed by the orthodontist using an Elastics placing instrument.
- Latex and Latex-Free Elastics are provided clean but non-sterile.


10. Disposal (if applicable)

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


11. Storage and Handling for medical devices (if applicable)

- The device should be stored in a dark, dry environment. Optimum storage temperature is 42.8°F to 77°F (6° C - 25° C).
- The product has a shelf life of 3 years. Refer to product label and packaging for use by date.

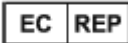
12. Name and address of labeler

	World Class Technology 1300 NE Alpha Dr. McMinnville, OR 97128 USA
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13. Name, address and number of Notified Body












	TUV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nurnberg, Germany +49 221 808-1371 Notified Body No.: 0197
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14. Name, address, and number of Authorized Representative

	MDI Europa Langenhagener STR.71 30855 Langenhagen, Germany +49-511-3908-9530 SRN: DE-AR-000006218
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15. Explanation of Symbols

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.
 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.
 Ref. 5.7.7 MDR 2017/745 Annex 1 23.2(q)	Medical Device: Indicates that the device is a medical device.

Symbols Not Derived from Standards	
<p>R_X ONLY 21 CFR 801.109</p>	<p>Prescription Only: CAUTION: U.S. Federal law restricts this device for sale by or on order of a licensed dentist or physician.</p>
<p>CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V</p>	<p>European conformity: European conformity (CE) mark with Notified Body identification number.</p>