

Revision History		
Rev	Description of Changes	Release Date
A	CO#20068: Initial Release	2020-07-14

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

1. Product Family

Latex-Free Power Chains



2. Product Part Number(s)

ELASTOMERIC POWER CHAIN			
COLOR CODE*	○○○○○○ SHORT	○○○○○○○ LONG	○○○○○○○ CONTINUOUS
BLACK	60.62.200.01100	60.62.300.01110	60.62.400.01120
BLUE	60.62.200.02100	60.62.300.02110	60.62.400.02120
BURGUNDY	60.62.200.03100	60.62.300.03110	60.62.400.03120
CAROLINA BLUE	60.62.200.04100	60.62.300.04110	60.62.400.04120
CLEAR	60.62.200.05100	60.62.300.05110	60.62.400.05120
DARK BLUE	60.62.200.06100	60.62.300.06110	60.62.400.06120
GRAPE	60.62.200.10100	60.62.300.10110	60.62.400.10120
GRAY	60.62.200.11100	60.62.300.11100	60.62.400.11120
GREEN	60.62.200.12100	60.62.300.12110	60.62.400.12120
LIGHT GREEN	60.62.200.13100	60.62.300.13110	60.62.400.13120
LIGHT PINK	60.62.200.14100	60.62.300.14110	60.62.400.14120
METALLIC BLUE	60.62.200.15100	60.62.300.15110	60.62.400.15120
NEON BLUE	60.62.200.18100	60.62.300.18110	60.62.400.18120
NEON GREEN	60.62.200.19100	60.62.300.19110	60.62.400.19120
NEON PINK	60.62.200.20100	60.62.300.20110	60.62.400.20120
ORANGE	60.62.200.21100	60.62.300.21110	60.62.400.21120
PERIWINKLE	60.62.200.22100	60.62.300.22110	60.62.400.22120
PURPLE	60.62.200.23100	60.62.300.23110	60.62.400.23120
RASPBERRY	60.62.200.24100	60.62.300.24110	60.62.400.24120
RED	60.62.200.25100	60.62.300.25110	60.62.400.25120
SILVER	60.62.200.26100	60.62.300.26110	60.62.400.26120
TEAL	60.62.200.27100	60.62.300.27110	60.62.400.27120
WHITE	60.62.200.29100	60.62.300.29110	60.62.400.29120
YELLOW	60.62.200.30100	60.62.300.30110	60.62.400.30120

HEAVY DUTY CHAIN ELASTICS			
COLOR CODE	○○○○○○○ SHORT	○○○○○○○ LONG	○○○○○○○ CONTINUOUS
Clear	60.62.200.31100	60.62.300.31100	60.62.400.31120

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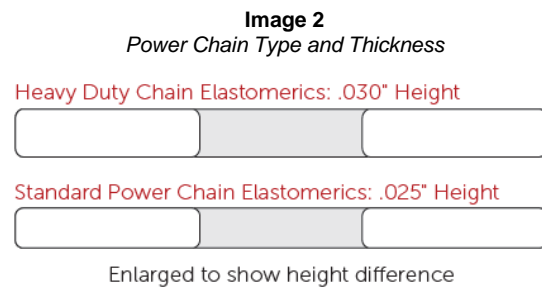
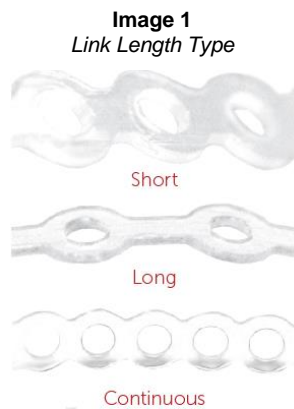
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3. Description

The Latex-Free Power Chains are medical-grade polymer ribbons made of, elastic ligature like rings linked together forming a continuous band. They are provided in 15-foot spools in a variety of colors as listed in section 2. Available in Short, Long, and Continuous link lengths (distance between the centers of the holes of adjacent links, see Image 1), see Table 1 for applicable Power Chain size. Latex-Free Power Chains are also available in Heavy Duty type, see image 2 for a description of Chain Type and Thickness.

Table 1

Chain Style	Inner Diameter	Outer Diameter	Link Length
Short	0.047"	0.112"	0.120"
Long	0.037"	0.108"	0.159"
Continuous	0.053"	0.118"	0.098"



4. Intended use

The Latex-Free Power Chains are used to retain wires to orthodontic devices, most commonly on brackets that do not have a self-ligating mechanism.

5. Indications for Use

The Latex-Free Power Chains are indicated for retaining archwires on brackets and/or exerting additional force upon orthodontic bracket and wire systems to assist in pulling teeth into alignment and maintaining the position of teeth.

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.

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- 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-Free Power Chains.
- 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-Free Power Chains are commonly stretched between brackets, where each loop is placed around a different bracket’s tie wing. Clinician can prescribe the Heavy Duty or Standard Power Chain.

10. Materials

The Latex-Free Power Chains are composed of polyester-based thermoplastic polyurethane (TPU) using Covestro’s Texin® 285. When specified, Texin® 285, can be colored using World Class Technology approved colorant as described in section 2.

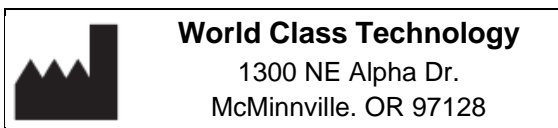
11. Cleaning and sterilization instructions

Latex-Free Power Chains 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











14. Storage and Handling for medical devices

- The device should be stored in a clean, dry, and dust-free environment under ambient conditions.
- 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.
 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.
Symbols Not Derived from Standards	
 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



TUV Rheinland LGA Products GmbH
 Tillystrasse 2, 90431 Nurnberg, Germany
 +49 221 808-1371
 Notified Body No.: 0197