

INSTRUCTIONS FOR USE LATEX-FREE POWER CHAINS

1. Product Family & Part Numbers













Product Family


Latex Free Power Chains



Elastomeric Power Chain Part Numbers

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

Elastomeric Power Chain Part Numbers			
Color Code	Short	Long	Continuous
 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 Chain Elastics Part Numbers			
Color Code	Short	Long	Continuous
 CLEAR	60.62.200.31100	60.62.300.31100	60.62.400.31120

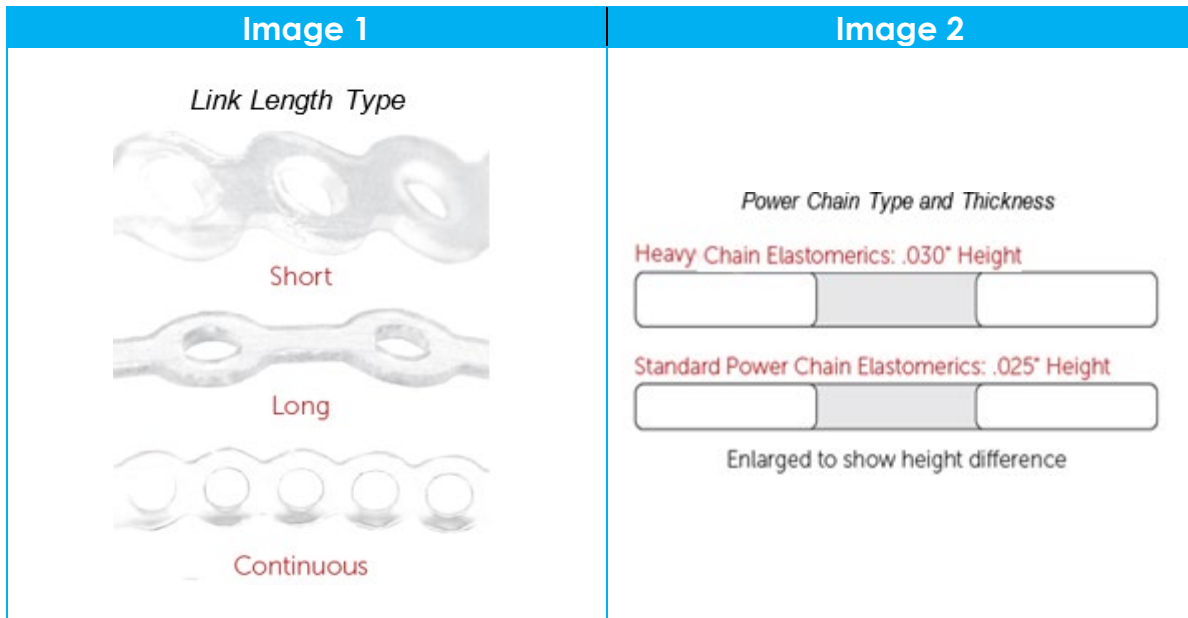
2. Description

The Latex-Free Power Chains are "interconnected elastomeric rings or multi-perforated elastomeric bands" manufactured from a medical-grade polymer. The device is used to apply forces to orthodontic devices.

They are provided in 15-foot spools in a variety of colors as listed in Section 1. Power Chain is available in Short, Long, and Continuous link lengths as well as standard and Heavy thicknesses as shown in image 1 and 2. See Tables 1 and 2 for applicable Power Chain size and force.

Table 1

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



Intended Use

Elastomeric Chains are intended to be used in conjunction with orthodontic brackets, buccal tubes, or similar orthodontic devices, for orthodontic treatment of children, teens, and adults. Power Chains are used to aid in the movement of natural teeth in patients with malocclusion during orthodontic treatment. The appliance is sold non-sterile and designed for single use.

Devices are supplied:

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

3. Intended User

The intended users of Elastomeric Chains are clinicians (professional licensed orthodontists and dentists) and their trained personnel within orthodontic and dental offices. Elastomeric Chains are sold for professional use only.

4. Indications for use

The Latex-Free Power Chains are used to consolidate space between teeth or apply a force to correct misaligned teeth.




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-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 1.

7. Warnings and Precautionary Measures

	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
	Latex-Free Power Chains are 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 – Latex-Free Power Chains have 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 Latex-Free Power Chains, 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 appropriate instruments for use with Latex-Free Power Chains.
- Disposal of all orthodontic appliances and instruments must follow regional and national regulations.
- Latex-Free Power Chains are provided clean, but non-sterile.
- Latex-Free Power Chains are commonly stretched between brackets, where each loop is placed around a different bracket's tie wing.
 - Clinicians can prescribe the Heavy or Standard Power Chain.

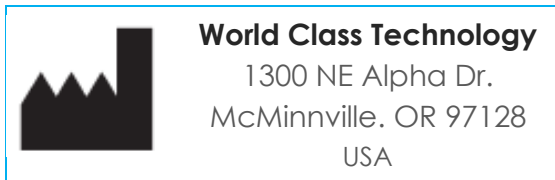
10. Disposal (if applicable)

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

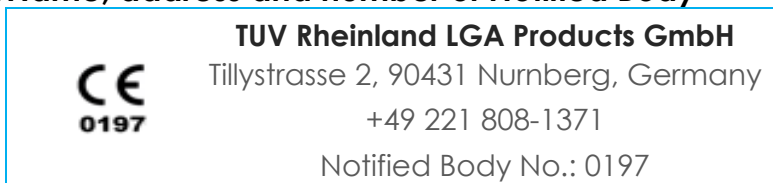
11. Storage and Handling for medical devices (if applicable)

- The device should be stored in a clean, dry, and dust-free environment under ambient conditions.
- The product has a shelf life of 2 years. Refer to product label and packaging for use by date.

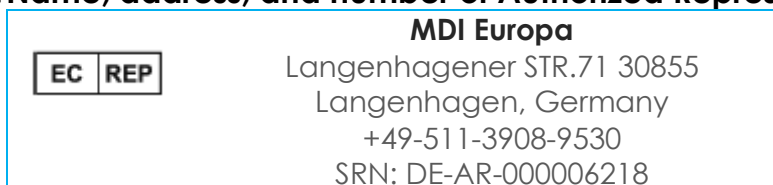
12. Name and address of labeler



13. Name, address and number of Notified Body











14. Name, address, and number of Authorized Representative



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. 5.1.4	Use by: Indicates the date after which the medical device is not to be used.
 Ref. 5.1.2	Authorized Representative: Indicates the Authorized representative in the European Community.
 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.
 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>

105-7300-16 (DOC-550) Ver. 4

Approved By:

[\(CO-472\) Power Chain IFU](#)

Description

Updating Power Chain IFU. Please refer to change order in evaluation tab for more information.

Justification

Design change was cancelled. Updating IFU to align with old dimensions.

Assigned To:	Initiated By:	Priority:	Impact:
Josh Otto	Josh Otto	Urgent	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Josh Otto	June 19, 2024 8:43 AM PDT	CO-472	4	Published
Josh Otto	May 1, 2024 2:38 PM PDT	CO-402	3	Superseded
Maureen Janssen	August 7, 2023 1:16 PM PDT	CO-217	2	Superseded
Maureen Janssen	February 23, 2023 7:22 PM PST	CO-108	1	Superseded
Yarely Jimenez	February 7, 2023 10:31 AM PST	CO-75	0	Superseded