

INSTRUCTIONS FOR USE

LATEX-FREE LIGATURE TIES

1. Product Family & Part Numbers

Product Family

Latex Free Ligature Ties



Product Part Numbers

Color Code	Item Number
Assorted Colors	60.63.510.31200
 BLACK	60.63.510.01200
 BLUE	60.63.510.02200
 BURGUNDY	60.63.510.03200
 CAROLINA BLUE	60.63.510.04200
 CLEAR	60.63.510.05200
 DARK BLUE	60.63.510.06200
 GRAPE	60.63.510.10200
 GRAY	60.63.510.11200
 GREEN	60.63.510.12200
 LIGHT GREEN	60.63.510.13200

Product Part Numbers	
Color Code	Item Number
 LIGHT PINK	60.63.510.14200
 METALLIC BLUE	60.63.510.15200
 NEON BLUE	60.63.510.18200
 NEON GREEN	60.63.510.19200
 NEON PINK	60.63.510.20200
 ORANGE	60.63.510.21200
 PERIWINKLE	60.63.510.22200
 PURPLE	60.63.510.23200
 RASPBERRY	60.63.510.24200
 RED	60.63.510.25200
 SILVER	60.63.510.26200
 TEAL	60.63.510.27200
 WHITE	60.63.510.29200
 YELLOW	60.63.510.30200

2. Description

The Latex-Free Ligature Ties are medical-grade polymer rings. They have a 0.052" inner diameter, 0.120" outer diameter and, 0.0325" thickness. They are provided in an assortment of colors as listed in section 1.

3. Intended Use

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

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-Free Power Ligature Ties are indicated for use in retaining archwires on orthodontic brackets that do not have a self-ligating mechanism.




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 Ligature Ties 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

	<p>Federal law restricts this device to the sale by or on the order of a licensed orthodontist.</p>
	<p>Latex-Free Ligature Ties are designed for single use patient use only, by a professional or on the order of an orthodontist or a dentist.</p> <p>There is a risk of cross-contamination between patients if re-used.</p>
	<p>The product is shelf life sensitive and must be used by date on label/packaging.</p>
<p>Before use, counsel patients on the materials contained in this device. Also, counsel patient of the potential for allergy/hypersensitivity to these materials.</p>	
<p>Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction.</p>	
<p>Follow all regional and national standards regarding the use of orthodontic appliances.</p>	
<p>Do not use any products which are damaged, or do not comply with the labeling specifications.</p>	
<p>MRI Safety Information – Latex-Free Ligature Ties 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.</p>	
<p>If, in relation to the use of Latex-Free Ligature Ties, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.</p>	

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 Ligature Ties are placed over bracket and archwire as prescribed by the orthodontist using a ligature placement instrument.
- Latex-Free Ligature Ties 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 product has a shelf life of 2 years. Refer to product label and packaging for use by date.

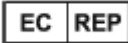
12. Name and address of labeler

	World Class Technology 1300 NE Alpha Dr. McMinnville, OR 97128 USA
---	--

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
---	--

14. Name, address, and number of Authorized Representative

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

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.
 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>

105-7300-17 (DOC-553) Ver. 4

Approved By:

[\(CO-450\) Update Shelf Life in Lig Ties IFU](#)

Description

Changed Shelf Life from 3 years to 2 years. Please refer to change order form in Evaluation tab for more information.

Justification

Incorrect shelf life noted in IFU. Ligature Ties did have correct shelf life of two years, and labels did reflect an expiration date of 2 years from manufacture date. The error was in the IFU, and there is no risk of expired product in the field.

Assigned To:	Initiated By:	Priority:	Impact:
Maureen Janssen	Maureen Janssen	Medium	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	June 19, 2024 8:50 AM PDT	CO-450	4	Published
Maureen Janssen	March 13, 2024 4:03 PM PDT	CO-324	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