INSTRUCTIONS FOR USE

CLOSED COIL SPRING

1. Product Family & Part Numbers

Closed Coil Spring — 10 Pack					
Item Number	Force	Unloaded Length	Total Length	Inner Diameter	Outer Diameter
60.40.110.09075	75gm (Extra Light)	9mm (0.3'')	9.02mm - 10.49mm (0.35'' - 0.41'')	0.76mm (.03'')	1.22mm (.048'')
60.40.110.12075		12mm (0.47'')			
60.40.120.09150	150gm (Light)	9mm (0.3'')			1.27mm (.050'')
60.40.120.12150		12mm (0.47'')			
60.40.130.09200	200gm (Medium)	9mm (0.3'')			1.32mm (.052'')
60.40.130.12200		12mm (0.47'')			
60.40.140.09250	250gm (Heavy)	9mm (0.3'')			1.37mm (.054'')
60.40.140.12250		12mm (0.47'')			

Closed Coil Spring — 21" Spool			
Item Number	Force	Length	Inner Diameter
60.40.112.21075	75gm (Extra Light)	533.4mm (21'')	0.76mm (.03'')
60.40.122.21150	150gm (Light)		
60.40.132.21200	200gm (Medium)		
60.40.142.21250	250gm (Heavy)		

2. Description

Closed Coil (also known as Extension) Springs are available lengths and forces as specified in section 1. The 9mm and 12mm are available with Eyelets manufactured with smooth edges and a round hole for easy attachment to Temporary Anchorage Devices, hooks, or brackets.

3. Intended Use

Closed Coil Springs are intended to deliver, compressive forces for tooth movement.

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

Closed Coil Springs work by being tied to a tooth via an orthodontic bracket system and then applying a load on opposing tooth though extension of the spring. This force moves the tooth in a desired direction to align teeth as prescribed by a trained orthodontist.

5. Contraindications

- Patient's inability or unwillingness to cooperate/or follow the treatment plan.
- Known allergies to any of the components or materials in the system (see Section 6).
- Any illness and/or underlying conditions that preclude orthodontic treatment.
- Any existing tooth root resorption.
- Any existing decalcification of the tooth enamel.
- Patients with deficient oral hygiene.

6. Materials

All part numbers referenced on sec. 1 are manufactured using materials per Table 1 and Table 2 shows the materials used for Eyelets.

Table 1

Nickel Titanium Springs per ASTM F2063 – 18	
Element	**%(mass/mass)**
Nickel	54.5 to 57.0
Carbon, maximum	0.040
Cobalt, maximum	0.050
Copper, maximum	0.010
Chromium, maximum	0.010
Hydrogen, maximum	0.005
Iron, maximum	0.050
Niobium, maximum	0.025
Nitrogen, maximum	0.005
Oxygen, maximum	0.040
Titanium	Balance

Table 2

Stainless Steel 302 Grade	
Element	**%(mass/mass)**
Carbon, maximum	0.015
Manganese, maximum	2.000
Phosphorus, maximum	0.045
Sulfur, maximum	0.030
Silicon, maximum	1.00
Chromium	17.00 -19.00
Nickel	8.00 -10.00
Nitrogen, maximum	0.10
Copper	-

7. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
	Closed Coil Springs 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.
 Contains Nickel and/or Chromium	Do not use on patients with known allergies to any of the materials in the system (see Table 1).
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 – Closed Coil Springs 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 of Closed Coil Springs, 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

- There is no information available which would preclude the use of commonly available oral healthcare products.
- Chewing hard foods can cause appliances to be damaged.
- Some sports may cause damage to orthodontic appliances, and their presence may increase the risk of harm in the event of certain sports-related injuries.
- When participating in sports, always wear appropriate mouth and/or bracket guards as recommended by the dental professional treating the patient.
- Always inform the MRI or radiology staff that braces are in place before any procedure to ensure appropriate measures are taken for the procedure.

9. General Information for the Dentist/Orthodontist

- As part of developing a treatment plan, and before appliance placement, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.
- Follow the manufacturer's instructions for any orthodontic bonding agents, instruments or other materials used in the orthodontic treatment.
- Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement and removal.
- Oral hygiene is of particular importance for immunocompromised patients. Closely monitor oral hygiene on immunocompromised patients.
- Assess whether further orthodontic treatment is advisable in the presence of root resorption.

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 dry environment under ambient conditions.

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

CE 0197

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

EC REP

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.
EC REP Ref. 5.1.2	**Authorized Representative:** Indicates the Authorized representative in the European Community.
LOT Ref. 5.1.5	**Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF Ref. 5.1.6	**Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
NON STERILE 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. 5.4.3	**Consult instructions for use:** Indicates the need for the user to consult the instructions for use.

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

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
MD 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	
℞ ONLY 21 CFR 801.109	**Prescription Only:** CAUTION: U.S. Federal law restricts this device for sale by or on order of a licensed dentist or physician.
Ni Cr Contains Nickel and/or Chromium	**Product contains Nickel and/or Chromium** FDA 21 Part 872 Sec. 872.3710 Base metal alloy.
CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	**European conformity:** European conformity (CE) mark with Notified Body identification number.