INSTRUCTIONS FOR USE

OPEN COIL SPRING

1. Product Family & Part Numbers

Open Coil Springs — 21'' Spool			
Item Number	Inner Diameter	Wire Diameter	Force
60.40.212.00021	0.762mm (.030'')	0.228mm (.009'')	Extra Light
60.40.222.00021		0.254mm (.010'')	Light
60.40.232.00021		0.304mm (.012'')	Medium
60.40.242.00021		0.355mm (.014'')	Heavy
60.40.282.00021	0.914mm (.036'')	0.254mm (.010'')	Medium Light
60.40.272.00021		0.304mm (.012'')	Medium Heavy
60.40.252.00021		0.355mm (.014'')	Extra Heavy
60.40.262.00021	0.254mm (.010'')	0.254mm (.010'')	Facebow

Open Coil Springs — Three 7'' Length pack			
60.40.211.00007	0.762mm (.030'')	0.228mm (.009'')	Extra Light
60.40.221.00007		0.254mm (.010'')	Light
60.40.231.00007		0.304mm (.012'')	Medium
60.40.241.00007		0.355mm (.014'')	Heavy
60.40.281.00007	0.914mm (.036'')	0.254mm (.010'')	Medium Light
60.40.271.00007		0.304mm (.012'')	Medium Heavy
60.40.251.00007		0.355mm (.014'')	Extra Heavy
60.40.261.00007	0.254mm (.010'')	0.254mm (.010'')	Facebow

Open Coil Spring — 15mm Length 10 Pack		
Item Number	Inner Diameter	Force
60.40.223.00015	0.889mm (.035'')	100gm (Light)
60.40.233.00015		150gm (Medium)
60.40.243.00015		200gm (Heavy)

2. Description

Open Coil Springs (also known as Compression Springs) are available in lengths and forces as specified in section 1.

3. Intended Use

Open Coil Springs are intended to create spaces between teeth by exerting forces between 2 points.

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

Open Coil Springs work by being tied to a tooth via an orthodontic bracket system and then applying a load on opposing tooth though compression 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.

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

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 – Open 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 Open 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

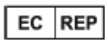
14. Name, address, and number of Authorized Representative

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.
 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.
 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.
 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.