

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 through 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.
- 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. Warnings and Precautionary Measures

- Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
- Open 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.
- Do not use on patients with known allergies to any of the materials in the system.
- 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 (Magnetic Resonance Imaging) Safety Information
 - Open Coil Springs are MR Unsafe. When scheduling an MRI or other radiology services while wearing orthodontic appliances, always inform MRI or other radiology staff prior to the procedure so that proper coordination of care can be arranged.

- Open Coil Springs have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifacts in the MR environment. Scanning a patient who has this device may result in patient injury, unintended appliance movement or detachment.
- 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.

7. 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.

8. 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.

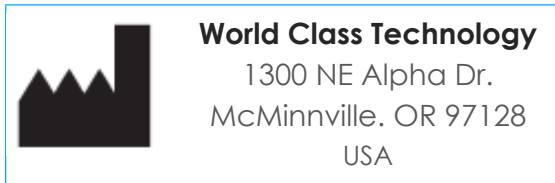
9. Disposal (if applicable)

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

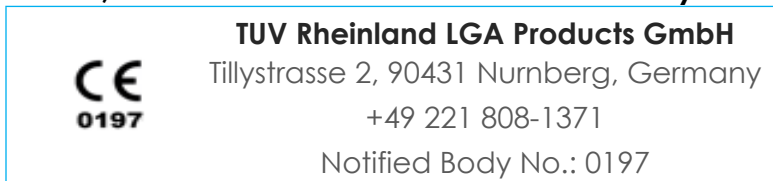
10. Storage and Handling for medical devices (if applicable)

- The device should be stored in a dry environment under ambient conditions.

11. Name and address of labeler



12. Name, address and number of Notified Body



13. Name, address, and number of Authorized Representative



14. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
 - Explanation of symbols on product labeling.
- 105-7320-02 – Coil Springs Material and Chemical Characterization
 - Materials used in Coil Springs.

15. Request for IFU and/or Supplementary Documents in Paper Form

- Identical IFU and Supplementary Documents in paper form can be requested by phone: (866)752-0065 / International: 1 (503)472-8320 or by email info@oc-orthodontics.com
 - Provide the product name, REF number (part number), and address you would like to receive the paper copy. The paper copy will be delivered to the indicated address within seven calendar days with no additional cost.

Approved By:
[\(CO-1040\) MR Unsafe - APII, Buttons, Stops, Hooks, Coil Springs, & Preformed Lig Ties](#)

Description
Activating MR Unsafe symbol on labels for APII, Buttons, Stops, Hooks, & Coil Springs.

Justification
MR Unsafe needed on labels. There is an updated MRI warning

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

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Maureen Janssen	February 23, 2023 7:22 PM PST	CO-108	1	Superseded	
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