

1. Company Identification

 J&J ORTHODONTICS
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2. Product Identification

Product Name: Orthodontic NiTi Closed Coil Spring with Eyelet, NiTi Closed Coil Spring Spool, Stainless Steel Closed Coil Spring Spool; NiTi Open Coil Spring Pack, NiTi Open Coil Spring Spool, Stainless Steel Open Coil Spring Spool; NiTi Distalizing Open & Closed Spring

Spring Wire Diameter	Spring Force Level	Unloaded Length	Inner Diameter	Outer Diameter
NiTi Closed Coil Spring with Eyelets				
0.010"	Light Force 150 gm	3 mm	0.91 mm (0.036")	1.42 mm (0.056")
		6 mm		
		9 mm		
		12 mm		
		15 mm		
0.012"	Heavy Force 200 gm	3 mm	0.91 mm (0.036")	1.52 mm (0.060")
		6 mm		
		9 mm		
		12 mm		
		15 mm		
NiTi Closed Coil Spring Spool				
0.010"	Light Force 150 gm	910mm (36")	0.91 mm (0.036")	1.42 mm (0.056")
0.012"	HeavyForce 200 gm	910mm (36")	0.91 mm (0.036")	1.52 mm (0.060")

Spring Wire Diameter	Spring Force Level	Unloaded Length	Inner Diameter	Outer Diameter
NiTi Open Coil Spring Spool				
0.008"	Extra Light Force	910mm (36")	0.91 mm (0.036")	1.32 mm (0.052")
0.010"	Light Force	910mm (36")	0.91 mm (0.036")	1.42 mm (0.056")
0.012"	Medium Force	910mm (36")	0.91 mm (0.036")	1.52 mm (0.060")
0.014"	Heavy Force	910mm (36")	0.91 mm (0.036")	1.62 mm (0.064")

3. Device Description

Closed Coil Springs and Open Coil Springs are orthodontic components available in multiple lengths and force configurations, as specified in Section 2.

NiTi Closed Coil Spring variants are available with Eyelets, which are manufactured with smooth edges and circular holes to facilitate attachment to Temporary Anchorage Devices (TADs), hooks, or brackets. Standard eyelets and TAD eyelets are available in single pack and assorted kit.

Closed Coil Spring Spool and Open Coil Spring Spool are available in NiTi and Stainless Steel material.

4. . Intended Use

Closed Coil Springs are intended for the application of controlled compressive forces to achieve orthodontic tooth movement.

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

These springs are:

- 1) Supplied non-sterile
- 2) Designed for single use only
- 3) Intended for professional use by licensed dentists or orthodontists
- 4) To be used in conjunction with other orthodontic devices to aid in the movement of natural teeth in patients for malocclusion correction

5. Indications for Use

Closed Coil Springs are indicated for use in the application of force between teeth using an orthodontic bracket system. When secured to a tooth and extended toward an opposing tooth.

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. The spring applies a biomechanical load which results in movement of the tooth into a desired position as prescribed by a trained orthodontist.

6. Contraindications

Use of Coil Springs is contraindicated in the following cases:

- 1) Patients who are unable or unwilling to comply with the treatment plan
- 2) Patients with known hypersensitivity or allergies to any of the component materials (refer to Section 7)
- 3) Presence of systemic or local conditions that contraindicate orthodontic treatment
- 4) Evidence of existing tooth root resorption
- 5) Presence of enamel decalcification
- 6) Patients with inadequate oral hygiene

7. Materials

- 1) NiTi Coil Spring Composition (Table 1)
- 2) Stainless Steel Coil Spring and Eyelet Composition (Table 2)

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 1

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	-

Table 2

8. Warnings and Precautions

- 1) This device is restricted to sale by or on the order of a licensed dentist or orthodontist by federal law of the United States.
- 2) This device is for single-patient use only. Reuse may result in cross-contamination or reduced mechanical performance.
- 3) Do not use in patients with known allergies to any of the materials listed in Section 7.
- 4) Discontinue use immediately in the event of an allergic reaction.
- 5) Comply with all applicable regional and national standards for orthodontic treatment.
- 6) Do not use damaged or non-conforming products.
- 7) **MRI Safety Information:** The Coil Spring has not been evaluated for use in the MR (Magnetic Resonance) environment. The device has not been tested for MRI-related heating, migration, or image artifacts. Scanning a patient with this device may pose serious safety risks.
- 8) In the event of death or serious health deterioration related to the use of this product, notify the manufacturer and the competent regulatory authority immediately.

9. Patient Information

- 1) Use of standard over-the-counter oral hygiene products is not contraindicated.
- 2) Avoid chewing hard foods, which may damage the orthodontic appliances.
- 3) Certain sports may increase the risk of appliance-related injuries. Use of mouthguards or bracket guards is recommended.
- 4) Always inform MRI or radiology personnel of the presence of orthodontic appliances prior to imaging procedures.

10. Professional Use Guidelines

- 1) Prior to appliance placement, assess the case for the need for interdisciplinary collaboration with other health professionals (e.g., physicians, ENT specialists, speech pathologists).
- 2) Use only manufacturer-approved orthodontic bonding agents, instruments, and accessories.

- 3) Orthodontic appliances should be placed and removed using appropriate instruments and techniques, as determined by professional training.
- 4) Special attention should be paid to the oral hygiene of immunocompromised patients.
- 5) Carefully evaluate the presence of root resorption before initiating or continuing orthodontic treatment.

11. Disposal Instructions

Dispose of used or damaged devices in accordance with local, regional, and national regulations for medical waste.

12. Storage and Handling

- 1) Store the device in a dry environment under ambient temperature conditions.
- 2) Avoid exposure to moisture or extreme temperatures during storage and transportation.

13. Regularly Information

The following symbols might appear on the label:

PICTOGRAMS

	MANUFACTURER		AUTHORIZED REPRESENTATIVE
	DATE OF MANUFACTURE		KEEP AWAY FROM SUNLIGHT
	DO NOT REUSE		CONSULT INSTRUCTIONS
	LOT NUMBER		CATALOG NUMBER
	NON STERILE		CAUTION
	SHELF LIFE		CE MARKING

INSTRUCTIONS FOR USE

ORTHODONTIC COIL SPRING

