
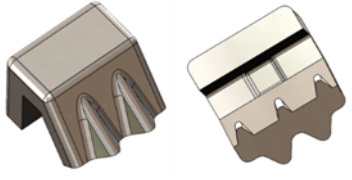


INSTRUCTIONS FOR USE

CRIMPABLE STOP

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Crimpable Stop 	906.0005 (10 Pack)
Premium Crimpable Stop 	906.0008-20 (20 Pack)

2. Description

The Crimpable Stops are one-piece metal auxiliary devices designed to be fixated (crimped) to NiTi, Beta Titanium, and Stainless Steel orthodontic archwires. The crimping feature provides a strong, non-sliding lock onto the archwire to prevent archwires from sliding through the bracket. Additionally, the Crimpable Stops enable the activation of force modules for finishing wires. The device is designed to be used with round, square, and rectangular cross-section Nickel -Titanium, Beta Titanium, and Stainless-Steel wires.

3. Intended Use

The Crimpable Stops are intended for general, orthodontic treatment. This device will use conventional treatment mechanics. No new or unique treatment mechanics will be required for this device. The appliance is sold non-sterile and is designed for single use only.

4. Intended User

The intended users of the Crimpable Stops are clinicians (professionally licensed orthodontists and dentists) and their trained personnel within orthodontic and dental offices. The Crimpable Stops are sold for professional use.

5. Intended Patient Target Groups

The Crimpable Ball Hooks are intended to be used for general orthodontic treatment of children, teens, and adults with malocclusion.

6. Indications for use

The Crimpable Stops are indicated for use in orthodontic treatment of the maxillary and mandibular arches. They are used to prevent the archwire from sliding through the bracket, limit tooth movement, or activate force modules to facilitate the application of force necessary for tooth movement. The Crimpable Stops are intended to aid in the movement of natural teeth in patients with malocclusion.

7. 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.

8. Warnings and Precautionary Measures

- Federal law restricts this device to the sale by or on the order of a licensed Orthodontist.
- The Stops 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.
- This product contains nickel and chromium and should not be used for individuals with known allergic sensitivity to these metals. Prior to use, patients should be counseled on the materials contained in the device, as well as the potential for allergy/hypersensitivity to these materials.
- Do not use on patients with known allergies to any of the materials in the Crimpable Ball Hooks. Immediately remove the device in the event of an allergic reaction.
- Devices are sold non-sterile.
- MRI (Magnetic Resonance Imaging) Safety Information
 - The Crimpable Stops 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.
 - The Crimpable Stops have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. Scanning a patient who has this device may result in patient injury, unintended bracket movement, or detachment.
- Do not use any products that are damaged or do not comply with the labeling specification.
- Follow all regional and national standards regarding the use of orthodontic appliances.
- If, in relation to the use of the Crimpable Stops, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.

9. 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 loosen or come off.
- 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.

10. 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 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 immune compromised patients. Closely monitor oral hygiene in immunocompromised patients.
- Assess whether further orthodontic treatment is advisable in the presence of root resorption.

11. Materials

- 906.0005 Crimpable Stops are manufactured from 17-4 PH Stainless Steel per ASTM B883. Material Composition per Table 1 below.

Table 1

Stainless Steel MIM-17-4PH composition per ASTM B883-24		
Chemical Name	Min. (weight %)	Max. (weight %)
Iron (Fe)	Balance	Balance
Nickel (Ni)	3	5
Chromium (Cr)	15.5	17.5
Carbon (C)	-	0.07
Copper (Cu)	3	5
Silicon (Si)	-	1.0
Manganese (Mn)	-	1.0
Niobium; Tantalum (Nb+TA)	0.15	0.45
Other(s)	-	1.0

- 906.0008-20 Premium Crimpable Ball Hooks are manufactured from 304L Stainless Steel. Material Composition per Table 2 below.

Table 2

Stainless Steel 304L		
Chemical Name	Min. (weight %)	Max. (weight %)
Iron (Fe)	Balance	Balance
Nickel (Ni)	9.0	13.0
Chromium (Cr)	18.0	20.0
Carbon (C)	-	0.03
Silicon (Si)	-	1.0
Manganese (Mn)	-	2.0
Phosphorus (P)	-	0.045
Sulfur (S)	-	0.03

12. Handling Procedures

- The Crimpable Stops include a crimpable member for receiving an orthodontic archwire. Crimpable Stops will be fastened (crimped) to the orthodontic archwire using an appropriate crimping plier.
 - Place Crimpable Stop at the desired location on archwire as shown in Fig.1

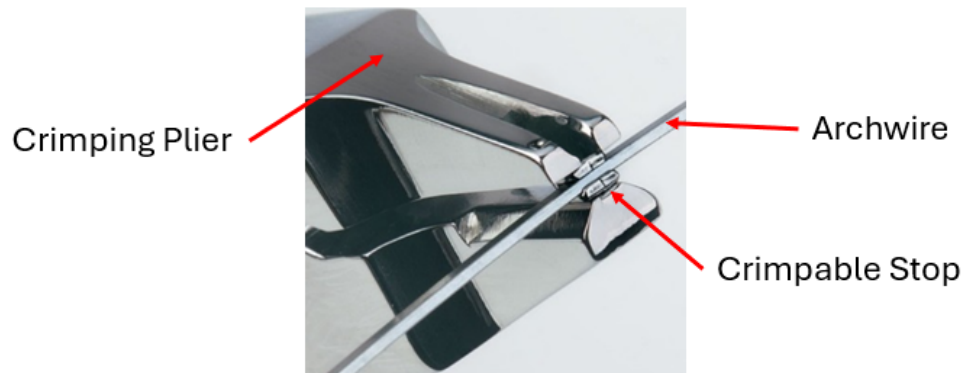


Fig.1

- Use appropriate crimping plier and apply sufficient force to the crimpable member until the appliance is firmly fixated.
- The device is provided nonsterile and is not intended to be sterilized by the user. The industry standard of care for orthodontic devices is that the devices are provided to the orthodontist in protective packaging, then removed from the packaging for use on the patient. The devices are not sterilized prior to use.

13. Cleaning and sterilization Instructions

- The device is provided nonsterile and is not intended to be sterilized by the user. The industry standard of care for orthodontic devices is that the devices are provided to the orthodontist in protective packaging, the devices are removed from the packaging for use on the patient, and the devices are not handled or sterilized before their use.
- There is no information available that would preclude the use of commonly available oral healthcare products like toothbrushes, toothpaste, water pick, mouthwash, etc.


14. Disposal (if applicable)

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

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


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

16. Name and address of labeler



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

17. 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

18. Name, address, and number of Authorized Representative



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

19. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary of Explanation of symbols on product labeling.

20. 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.

105-7300-04 (DOC-520) Ver. 1

Approved By:

[\(CO-920\) Premium Crimpable IFUs](#)

Description

Revising Crimpable Hooks and Stops IFUs to include Premium Crimpable Attachments. Do not publish online or in Greenlight until design Transfer.

Justification

IFU Updates to include new product.

Assigned To:	Initiated By:	Priority:	Impact:
Josh Otto	Josh Otto	Medium	Critical

Version History:

Author	Effective Date	CO#	Ver.	Status
Juergen Bathen	March 26, 2026 10:57 AM PDT	CO-920	1	Published
Yarely Jimenez	February 22, 2023 8:59 AM PST	CO-74	0	Superseded