

INSTRUCTIONS FOR USE

CRIMPABLE BALL HOOK

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Crimpable Ball Hooks 	906.0004 (20 Pack)
Premium Crimpable Ball Hook 	906.0007-20 (20 Pack)

2. Description

The Crimpable Ball Hooks are one-piece metal auxiliary devices designed to be fixated (crimped) to Beta Titanium and Stainless-Steel orthodontic archwires. The crimping feature provides a strong, non-sliding lock onto the archwire to facilitate elastic treatment. Force modules like elastics, springs, and similar force modules can be attached to the Crimpable Ball Hooks for general, orthodontic treatment. The device is designed to fit the following cross-section archwires: .018"X.018", .019"X.019", .020"X.020", .018"X.025", .019"X.025", .021"X.025".

3. Intended Use

The Crimpable Ball Hooks are intended for general orthodontic treatment. This device will be used with conventional treatment mechanics, along with other devices like elastomeric bands or similar force modules. 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 Ball Hooks are clinicians (professionally licensed orthodontists and dentists) and their trained personnel within orthodontic and dental offices. The Crimpable Ball Hooks 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 Ball Hooks are indicated for use in orthodontic treatment of the maxillary and mandibular arches. They are used to attach auxiliary appliances like elastics and other force modules to the maxillary and/or mandibular archwire to facilitate the application of force necessary for tooth movement. The Crimpable Ball Hooks 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 Crimpable Ball Hooks 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 Ball Hooks 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 Ball Hooks 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 appliance 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 Ball Hooks, 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. Handling Procedures

- The Crimpable Ball Hook includes a crimpable member for receiving an orthodontic archwire and a ball hook extending from the crimpable member. Crimpable Ball Hooks will be fastened (crimped) to the orthodontic archwire using an appropriate crimping plier.
 - Place Crimpable Ball Hook at the desired location on archwire as shown in Fig.1

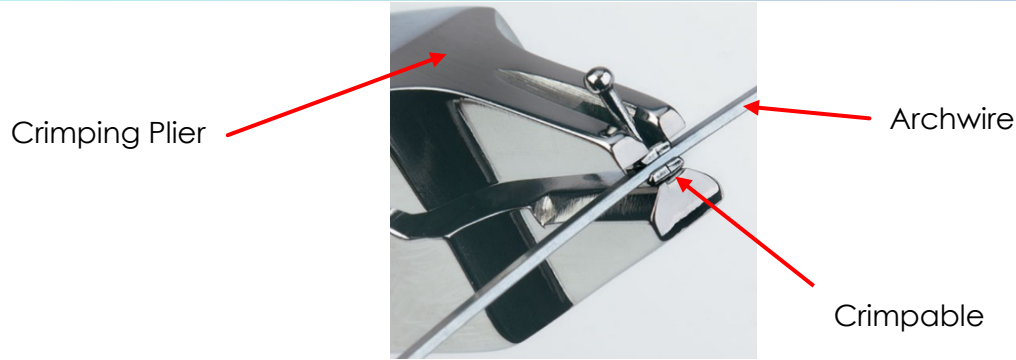


Fig.1

- 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.

12. 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.

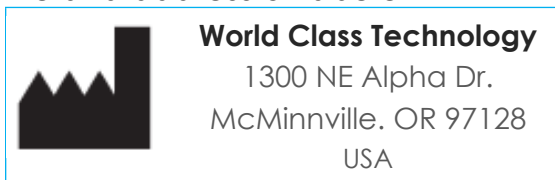
13. Disposal (if applicable)

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

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

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

15. Name and address of labeler



16. 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

17. Name, address, and number of Authorized Representative



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

18. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
 - Explanation of symbols on product labeling.
- 105-7320-03 – Crimpable Stops and Ball Hooks Material and Chemical Characterization.
 - Materials used in Crimpable Ball Hooks.

19. 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

Version History:					
Author	Effective Date	CO#	Ver.	Status	
Maureen Janssen	August 5, 2026 4:13 PM PDT	CO-1040	3	Published	
Josh Otto	April 29, 2026 7:24 AM PDT	CO-973	2	Superseded	
Juergen Bathen	March 26, 2026 10:57 AM PDT	CO-920	1	Superseded	
Yarely Jimenez	February 22, 2023 8:59 AM PST	CO-74	0	Superseded	