

INSTRUCTIONS FOR USE

METAL BRACKETS

1. Product Family & Part Numbers

Product Family	Product Part Numbers
BioMIM Mini-Twin Brackets	901.XXXX and 905.XXXX
H4 Self-ligating Bracket System	916.XXXX
Pitts21™ Self-ligating Bracket System	946.XXXX
Phase 1 Eyelets	500.0001; 500.0002; 500.0003; 500.0004

*XXXXX = Multiple part numbers in product family

2. Intended Use

WCT Metal Brackets and Phase 1 Eyelets are intended to be used in orthodontic treatment. The devices are intended to be temporarily affixed to the teeth in order to transmit force to the teeth to create movement of teeth during treatment. The devices are for Professional Use Only by dental professionals in the recommended indications.

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.

3. Indications for use

WCT Metal Brackets are intended to aid in the movement of teeth during orthodontic treatment.

4. 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.

5. Warnings and Precautionary Measures

- Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
- WCT Metal Brackets are designed for single 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 nitinol – an alloy of nickel and titanium – and chromium and should not be used for individual 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 WCT Metal Brackets. Immediately remove the brackets in the event of an allergic reaction.
- Devices are sold Non-Sterile.
- MRI (Magnetic Resonance Imaging) Safety Information
 - WCT Metal Brackets 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 the proper coordination of care can be arranged.
 - WCT's Metal Brackets 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 these devices may result in patient injury, unintended bracket movement or detachment.
- Do not use any products which are damaged, or do not comply with the labeling specifications.
- Care should be taken to avoid contact with opposing teeth at occlusion.
- Follow all regional and national standards regarding the use of orthodontic appliances.
- If, in relation to the use of Metal Brackets, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.

6. 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, such as bracket removal, are taken for the procedure.

7. 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.
- Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.
- 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.
- Brackets should be removed per recommended de-bonding procedure.


8. Disposal (if applicable)

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


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

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


10. Name and address of labeler

	World Class Technology 1300 NE Alpha Dr. McMinnville, OR 97128 USA
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11. 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
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12. Name, address, and number of Authorized Representative

	MDI Europa Langenhagener STR.71 30855 Langenhagen, Germany +49-511-3908-9530 SRN: DE-AR-000006218
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13. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
 - Explanation of symbols on product labeling.
- 105-7320-01 – Material and Chemical Characterization
 - Materials used in WCT's Metal Brackets

14. 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.

105-7300-09 (DOC-399) Ver. 2

Approved By:

[\(CO-967\) MR Unsafe - Brackets IFU](#)

Description

105-7300-09: Removed references to Table 1 Materials, Section 5 Materials, and Section 13 Explanation of Symbols. Changed the Warnings and Precautionary Measures table to bulleted list and updated verbiage. Updated the AR symbol to "EU REP". Added Section 13 Other Information – Supplementary Documents and Section 14 Request for IFU anmd/or Supplementary Documents in Paper Form. 105-7320-01: Added P21 brackets, H4 brackets, BioMIM brackets, and Phase 1 Eyelets to section 1.1.

Justification

MR Unsafe symbol is needed on labels for H4, P21, BioMIM, and eyelets. There is an updated MRI warning for metal brackets. Please refer to CO-931.

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

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