




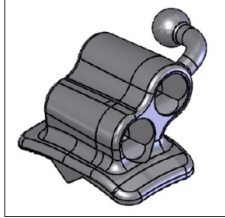
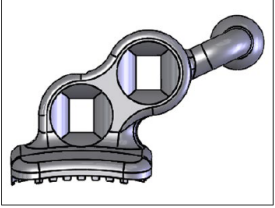




INSTRUCTIONS FOR USE METAL BUCCAL TUBES

1. Product Family & Part Numbers

Product Family	Product Part Numbers
<p>BioMIM Single, Double, Triple (Convertible & Non-convertible), BioMINI, H4 and Pitts21 Buccal Tubes</p> <p>Convertible</p> <div style="display: flex; justify-content: space-around;">   </div> <div style="text-align: center; margin-top: 10px;">  </div> <p>Non-Convertible</p> <div style="display: grid; grid-template-columns: 1fr 1fr; gap: 10px;">       </div>	<p>*907.XXXX, 908.XXXX and 947.XXXX</p>

*XXXXX = Multiple part numbers in product family

2. Description

World Class Technology (WCT) Corporation market buccal tubes as the BioMIM® Buccal Tubes, BioMINI® Buccal Tubes, Pitts21® Buccal Tubes, and H4™ Buccal Tubes. These buccal tubes are available in a variety of geometries for a given prescription. Each prescription has a distinct torque angle or offset angle per tooth position. The mesial-distal width for each buccal tube also varies by tube. Right and left buccal tubes are available in two distinct slot sizes, 0.018" or 0.022". The buccal tube base includes a "dimple" designed to fit the anatomy of the molar teeth. The buccal tubes may include color coding, which is a visual identification for the clinician/orthodontist.

WCT's buccal tubes are offered as a single slot double slot, or triple slot for the use with the headgear, lip bumpers, and other orthodontic auxiliary devices.

WCT's buccal tubes come in convertible and non-convertible. A non-convertible buccal tube is a one-piece appliance. Single non-convertible buccal tubes are available with the option of a reduced dimple. The convertible buccal tubes consist of a tube body and a ligating member/cap that is fastened through a coining operation to the body. WCT's Convertible Buccal Tube ligating member/cap is branded as the EZCAP™. Clinicians can remove the ligating member/cap during the treatment to allow vertical and/or torque bends to be placed between the first and second molar region of the archwire.

3. Intended Use

The WCT Metal Buccal Tubes are devices intended for use in orthodontic treatment. The WCT Buccal Tubes are intended to be temporarily affixed directly to the surface of a molar tooth or to the facial (buccal) surface of an orthodontic molar band during the orthodontic treatment.

4. Intended Patient Target Groups

WCT Metal Buccal Tubes is intended to be used for general orthodontic treatment of children, teens, and adults with malocclusion.

5. Indications for use

The WCT Buccal Tubes are indicated for use on the first and/or second molar of the maxillary or mandibular dental arch in conjunction with a variety of orthodontic appliances for movement of natural teeth in patients with malocclusion. BioMINI Buccal Tubes are specifically indicated for use on the second molars. The devices are for professional use only. The buccal tubes are single use devices that are provided non-sterile, and not intended to be sterilized by the end user/orthodontist per standard industry practice.

6. Contraindications

- Patient's inability or unwillingness to cooperate/or follow the treatment plan.
- Patient with deficient oral hygiene.
- 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.

7. Warnings and Precautionary Measures

- Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
- WCT Buccal Tubes 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 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 WCT Buccal Tubes. Immediately remove the brackets in the event of an allergic reaction.
- Devices are sold Non-Sterile.
- MRI (Magnetic Resonance Imaging) Safety Information
 - WCT Buccal Tubes 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.
 - WCT Buccal Tubes have not been evaluated for safety and compatibility in the MR environment. The devices 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 WCT Buccal Tubes, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.

8. 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 WCT Buccal Tube removal, are taken for the procedure.

9. 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 of orthodontic bonding materials.
- 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.

10. Cleaning and Sterilization Instructions

- The device is provided non-sterile, nor is it 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, they are removed from the packaging for use on the patient and the devices are not handled nor sterilized before their use.
- This is no information available that would preclude the use of commonly available oral healthcare products like toothbrushes, toothpaste, water pick, mouth wash, etc.

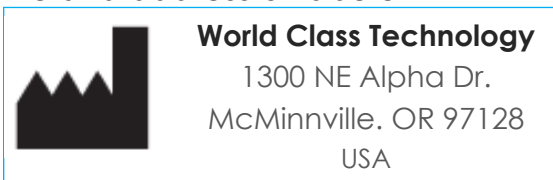
11. Disposal (if applicable)

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


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

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


13. Name and address of labeler



14. 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
---	--

15. Name, address, and number of Authorized Representative

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

16. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
 - Explanation of symbols on product labeling
- 105-7320-01 – Material and Chemical Characterization
 - Materials use in WCT’s Orthodontic Metal Buccal Tubes

17. 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.

105-7300-10 (DOC-541) Ver. 2

Approved By:

[\(CO-952\) Buccal Tubes IFU - MR Unsafe](#)

Description

Updating MRI verbiage to note that BTs are MR Unsafe. Removed the Symbols section.

Justification

Adding the MR Unsafe symbol to labels per ASTM F2503.

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

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	March 27, 2026 7:24 AM PDT	CO-952	2	Published
Maureen Janssen	February 23, 2023 7:22 PM PST	CO-108	1	Superseded
Yarely Jimenez	February 7, 2023 10:31 AM PST	CO-75	0	Superseded