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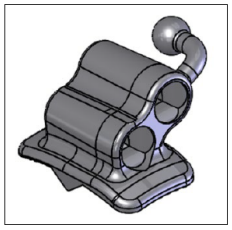
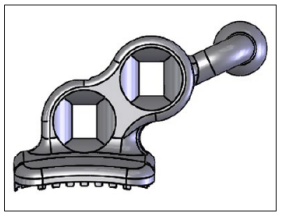
# INSTRUCTIONS FOR USE

# METAL BUCCAL TUBES

## 1. Product Family & Part Numbers

| Product Family | Product Part Numbers |
|---|---|
| BioMIM Single, Double, Triple (Convertible & Non-convertible), BioMINI, H4 and Pitts21 Buccal Tubes<br><br>Convertible<br>    <br><br>Non-Convertible<br>       | *907.XXXX, 908.XXXX and 947.XXXX |

*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.

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.

## 4. 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.

## 5. 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 (see Table1).
- 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.

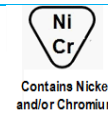
## 6. Materials

All part numbers referenced on sec. 1 are manufactured using materials per Table 1

**Table 1**

| Stainless Steel 17-4PH per ASTM B883-19 | | |
|---|---|---|
| **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 |

## 7. Warnings and Precautionary Measures

| | |
|---|---|
| ℞ ONLY | Federal law restricts this device to the sale by or on the order of a licensed orthodontist. |
|  | Metal Buccal Tubes are designed for single use patient use only, by a professional or on the order of an orthodontist or a dentist.<br><br>There is a risk of cross-contamination between patients if re-used. |
|   | Do not use on patients with known allergies to any of the materials in the system (see Section 5). |
| Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction. | |
| Follow all regional and national standards regarding the use of orthodontic appliances. | |
| Do not use any products which are damaged, or do not comply with the labeling specifications. | |

| |
|---|
| MRI Safety Information – The buccal tubes have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ceramic bracket system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. |
| If, in relation to the use of 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 be damaged.
- 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.

## 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.
- 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. Disposal (if applicable)

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

## 11. Storage and Handling for medical devices (if applicable)

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

## 12. Name and address of labeler

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

## 13. Name, address and number of Notified Body

CE 0197

**TUV Rheinland LGA Products GmbH**
Tillystrasse 2, 90431 Nurnberg, Germany
+49 221 808-1371
Notified Body No.: 0197

## 14. Name, address, and number of Authorized Representative

EC REP

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

## 15. Explanation of Symbols

**The following are per ISO 15223-1** (*References as indicated*).

| Symbol Standard Reference | SYMBOL TITLE – Explanatory Text |
|---|---|
| Ref. 5.1.1 | **Manufacturer**: Indicates the medical device manufacturer. |
| EC REP Ref. 5.1.2 | **Authorized Representative:** Indicates the Authorized representative in the European Community. |
| Ref. 5.1.3 | **Date of manufacture:** Indicates the date when the medical device was manufactured. |
| LOT Ref. 5.1.5 | **Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| REF Ref. 5.1.6 | **Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified. |

**The following are per ISO 15223-1** (*References as indicated*).

| Symbol Standard Reference | SYMBOL TITLE – Explanatory Text |
|---|---|
|   Ref. 5.2.7 | **Non-sterile:** Indicates a medical device that has not been subjected to a sterilization process. |
|  Single Use Ref. 5.4.2 | **Do not re-use/single patient use:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
|  Ref. 5.4.3 | **Consult instructions for use:** Indicates the need for the user to consult the instructions for use. |
|   Ref. 5.7.7 MDR 2017/745 Annex 1 23.2(q) | **Medical Device:** Indicates that the device is a medical device. |

| Symbols Not Derived from Standards | |
|---|---|
| ℞ ONLY 21 CFR 801.109 | **Prescription Only:** CAUTION: U.S. Federal law restricts this device for sale by or on order of a licensed dentist or physician. |
|   Contains Nickel and/or Chromium | **Product contains Nickel and/or Chromium** FDA 21 Part 872 Sec. 872.3710 Base metal alloy. |
|  MDD 93/42/EEC Annex II; MDR 2017/745 Annex V | **European conformity:** European conformity (CE) mark with Notified Body identification number. |