

INSTRUCTIONS FOR USE

METAL LINGUAL BUTTONS

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Direct Bond / Weldable Lingual Buttons	*906.XXXX
*XXXXX = Multiple part numbers in product family	



2. Intended Use

WCT Metal Direct Bond / Weldable Lingual Buttons are medical devices 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

The WCT orthodontic attachments are indicated for use on the lingual maxillary or mandibular arch, in conjunction with a variety of orthodontic appliances for the movement of teeth in patients with malocclusion.

The WCT Lingual Buttons are indicated for direct bonding to the lingual surface of the cuspid, bicuspid or molar teeth and/or welded to molar bands to retain elastomeric auxiliaries or other orthodontic force modules.

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.
- Metal Lingual Buttons 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.
- Do not use on patients with known allergies to any of the materials in the system.
- 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 (Magnetic Resonance Imaging) Safety Information
 - Metal Lingual Buttons 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.
 - Metal Lingual Buttons 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 this device may result in patient injury, unintended appliance movement or detachment.
- If, in relation to the use of Metal Lingual Buttons, 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 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.

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.

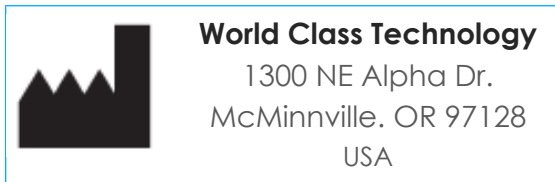
8. Disposal (if applicable)

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

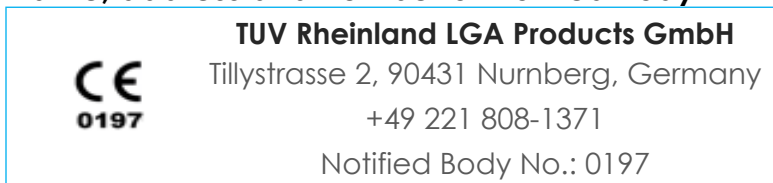
9. Storage and Handling for medical devices (if applicable)

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

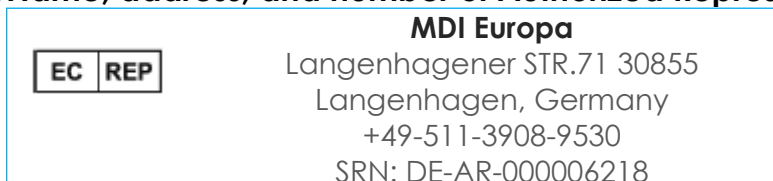
10. Name and address of labeler



11. Name, address and number of Notified Body



12. Name, address, and number of Authorized Representative



13. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
 - Explanation of symbols on product labeling.
- 105-7320-01 – 17-4 Stainless Steel Orthodontic Devices Material and Chemical Characterization.
 - Materials used in Metal Lingual Buttons.

14. Request for IFU and/of 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	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	