

## INSTRUCTIONS FOR USE METAL LINGUAL SHEATH

### 1. Product Family & Part Numbers

| Product Family | Product Part Numbers |
|----------------|----------------------|
| Lingual Sheath | 60.30.236.XXXXX      |



\*XXXXX = Multiple part numbers in product family

### 2. Intended Use

The WCT Lingual Sheaths are indicated for welding onto molar bands to provide an opening to accept palatal bars, quad helix, and other maxillary and mandibular removable appliances incorporating the 0.036" X 0.072" distal engagement end.

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

Weld the lingual sheath to an orthodontic band and affix to the tooth. Use conventional orthodontic band cement following manufacturer's instructions. Remove excess cement from around the band and the occlusal surface of the tooth. Palatal bars, quad helix and other auxiliary equipment can be inserted into the sheath after bonding.

### 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 (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.

## 5. Materials

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

**Table 1**

| 305 Stainless Steel per AMS 5514 |                 |                 |
|----------------------------------|-----------------|-----------------|
| Chemical Name                    | Min. (weight %) | Max. (weight %) |
| Carbon                           | --              | 0.12            |
| Manganese                        | --              | 2.00            |
| Silicon                          | --              | 1.0             |
| Phosphorus                       | --              | 0.040           |
| Sulfur                           | --              | 0.030           |
| Chromium                         | 17.00           | 19.00           |
| Nickel                           | 10.00           | 13.00           |
| Molybdenum                       | --              | 0.75            |
| Copper                           | --              | 0.75            |

## 6. Warnings and Precautionary Measures

|                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                   | Federal law restricts this device to the sale by or on the order of a licensed orthodontist.                                                                                                                    |
|                                                                                                                                                                                                                                                                                 | Metal Lingual Sheath is 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. |
| <br>Contains Nickel and/or Chromium                                                                                                                                                                                                                                             | Do not use on patients with known allergies to any of the materials in the system (see Table 1).                                                                                                                |
| Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction.                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                 |
| Do not apply excess force on the lingual sheath as this may lead to detachment from tooth or band.                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                 |
| 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 – Metal Lingual Sheaths 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 Metal Lingual Sheaths, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.                                                                                                                                                             |                                                                                                                                                                                                                 |

## 7. 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.

## 8. 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.

## 9. Disposal (if applicable)

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

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

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

## 11. Name and address of labeler

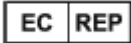


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## 12. Name, address and number of Notified Body

|                                                                                   |                                                                                                                                  |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
|  | <b>TUV Rheinland LGA Products GmbH</b><br>Tillystrasse 2, 90431 Nurnberg, Germany<br>+49 221 808-1371<br>Notified Body No.: 0197 |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|

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

|                                                                                   |                                                                                                                      |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
|  | <b>MDI Europa</b><br>Langenhagener STR.71 30855<br>Langenhagen, Germany<br>+49-511-3908-9530<br>SRN: DE-AR-000006218 |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|

## 14. Explanation of Symbols

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

| Symbol<br>Standard<br>Reference                                                                                 | SYMBOL TITLE – Explanatory Text                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br>Ref. 5.1.1                | <b>Manufacturer:</b><br>Indicates the medical device manufacturer.                                                                                             |
| <br>Ref. 5.1.2               | <b>Authorized Representative:</b><br>Indicates the Authorized representative in the European Community.                                                        |
| <br>Ref. 5.1.3               | <b>Date of manufacture:</b><br>Indicates the date when the medical device was manufactured.                                                                    |
| <br>Ref. 5.1.5               | <b>Batch Code:</b><br>Indicates the manufacturer's batch code so that the batch or lot can be identified.                                                      |
| <br>Ref. 5.1.6               | <b>Catalogue or model number:</b><br>Indicates the manufacturer's catalogue number so that the medical device can be identified.                               |
| <br>Ref. 5.2.7               | <b>Non-sterile:</b><br>Indicates a medical device that has not been subjected to a sterilization process.                                                      |
| <br>Single Use<br>Ref. 5.4.2 | <b>Do not re-use/single patient use:</b><br>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
| <br>Ref. 5.4.3               | <b>Consult instructions for use:</b><br>Indicates the need for the user to consult the instructions for use.                                                   |

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

| Symbol<br>Standard<br>Reference                                                                                                          | SYMBOL TITLE – Explanatory Text                                          |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <br>Ref. 5.7.7<br>MDR<br>2017/745<br>Annex 1<br>23.2(q) | <b>Medical Device:</b><br>Indicates that the device is a medical device. |

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

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**Approved By:**  
[\(CO-108\) Update Symbols on IFUs](#)

**Description**  
Updating Single Use, Non-Sterile, and Use By Date Symbols in Section 7. Added Single Use Symbol in Section 17. Please refer to change order in Evaluation Tab for change description for each document.

**Justification**  
Wrong symbols on the IFU.

|                     |                      |                  |                |
|---------------------|----------------------|------------------|----------------|
| <b>Assigned To:</b> | <b>Initiated By:</b> | <b>Priority:</b> | <b>Impact:</b> |
| Maureen Janssen     | Maureen Janssen      | High             | Major          |

**Version History:**

| Author          | Effective Date                | CO#                    | Ver. | Status     |
|-----------------|-------------------------------|------------------------|------|------------|
| Maureen Janssen | February 23, 2023 7:22 PM PST | <a href="#">CO-108</a> | 1    | Published  |
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