INSTRUCTIONS FOR USE

METAL BANDS

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Duraband 	33.30.XXX.XXXXX
Fierro Bands 	34.30.XXX.XXXXX

**XXXXX = Multiple part numbers in product family*

2. Intended Use

WCT Orthodontic bands wrap around the molar teeth of the maxillary or mandibular dental arch, and function in conjunction with a variety of orthodontic appliances supporting orthodontic treatment. Bands are pressed and bonded to bicuspid and molar teeth, to serve as a sturdy anchorage point for supporting auxiliary devices in 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 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

Bands are pressed and bonded to bicuspid and molar teeth, to serve as a sturdy anchorage point for supporting auxiliary devices. Weld or solder the required attachments in accordance to treatment plan.

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.

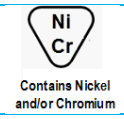
5. Materials

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

Table 1

305 Stainless Steel per AMS5514H		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Carbon (C)	-	0.12
Manganese (Mn)	-	2.00
Silicon (Si)	-	1.00
Phosphorus (P)	•	0.040
Sulfur (S)	-	0.030
Chromium (Cr)	17.00	19.00
Nickel (Ni)	10.00	13.00
Molybdenum (Mo)	-	0.75
Copper (Cu)	-	0.75

6. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
	Metal Bands 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 (see Table 1).
Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction.	
When using a band pusher, exercise caution to prevent the instrument from slipping form the band, thus injuring the patient's mucous membrane.	
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 bands have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the metal bands 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 Bands, 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.
- Use conventional orthodontic band cement following manufacturer's instructions.
    - Place it using the instrument of our choice.
    - Remove excess cement from around the band and from the occlusal of the tooth.
- 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

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

12. 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

13. 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

14. 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	
 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.
 MDR 2017/745 Annex 1 23.2(q)	**Medical Device:** Indicates that the device is a medical device.
 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.