Revision History

Rev	Description of Changes	Release Date
A	CO#20030: Initial Release	2020-05-22
B	CO#20048: Updated product part numbers sequence in Sec. 1	2020-06-15
C	CO#20084: Updated section 12 and 13.	2020-08-20

1. Product Family & Part Numbers

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

**XXXX = Multiple part numbers in product family*

2. Intended Use

WCT Orthodontic bands wrap around the molar and bicuspid (premolar) 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.

3. Instructions 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 with your treatment plan. Use conventional orthodontic band cement following manufacturer's instructions. Place it using the instrument of your choice. Remove excess cement from around the band and from the occlusal surface of the tooth.

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		
Element Name	**Min. (% by weight)**	**Max. (% by 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	--	0.75
Copper (Cu)	--	0.75

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6. Warnings and Precautionary Measures

- When using a band pusher, exercise caution to prevent the instrument from slipping from the band thus injuring the patient's mucous membrane.
- 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.
- 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.

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 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 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. 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.
 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.
 Ref. 5.1.5	**Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
 Ref. 5.1.6	**Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
 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. 5.4.4	**Caution:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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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.
MD MDR 2017/745 Annex 1 23.2(q)	**Medical Device:** Indicates that the device is a medical device.
	**Product contains Nickel.** FDA 21 Part 184 Sec. 184.1537 Nickel.
	**Product contains Nickel and/or Chromium** FDA 21 Part 872 Sec. 872.3710 Base metal alloy.
CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	**European conformity:** European conformity (CE) mark with Notified Body identification number.

13. Name, address and number of Notified Body

CE 0197

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