Revision History

Rev	Description of Changes	Release Date
A	CO#20030: Initial Release	2020-05-22
B	CO#20084: Updated section 12 and 13	2020-08-20

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Beta Titanium Archwire Forms	646.XXXX 61.40.170.XXXXX 61.40.270.XXXXX
Stainless Steel Archwire Forms	651.XXXX 61.40.180.XXXXX 61.40.280.XXXXX
Super Elastic Archwire Forms	625.XXXX 627.XXXX 41.40.120.XXXXX 41.40.220.XXXXX 41.40.320.XXXXX 41.40.420.XXXXX 41.40.520.XXXXX 61.40.120.XXXXX 61.40.125.XXXXX 61.40.130.XXXXX 61.40.135.XXXXX 61.40.220.XXXXX 61.40.225.XXXXX 61.40.230.XXXXX 61.40.235.XXXXX 61.40.420.XXXXX 61.40.425.XXXXX 61.40.520.XXXXX 61.40.525.XXXXX 61.40.150.11622 61.40.156.01622 61.40.250.11622 61.40.256.01622 61.40.150.11725 61.40.156.01725 61.40.250.11725 61.40.256.01725
Thermal Activated Archwire Forms	320.XXXX 620.XXXX 621.XXXX 41.40.110.XXXXX 41.40.210.XXXXX 41.40.310.XXXXX

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	41.40.410.XXXXX 41.40.510.XXXXX 41.40.610.XXXXX 61.40.110.XXXXX 61.40.115.XXXXX 61.40.210.XXXXX 61.40.415.XXXXX 61.40.510.XXXXX 61.40.515.XXXXX 61.40.710.XXXXX
Thermal Activated Ultra-Soft Archwire Form	600.0492
Beta Titanium Straight Wire	40.40.870.XXXXX
Stainless Steel Straight Wire	40.40.880.XXXXX

**XXXXX = Multiple part numbers in product family*

2. Intended Use

WCT Archwires & Straight Wires are used to apply forces and aid in the movement of natural teeth in patients with malocclusion during orthodontic treatment.

Devices are supplied:

- Non-sterile
- Designed for single-use
- For use by dentists and orthodontists only.

3. Instructions for use

Insert the archwire in the slot of the brackets and buccal tubes and fix it with an elastomeric or wire ligature. When using self-ligating brackets, close according to manufacturer's instructions

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

Materials List	
Stainless Steel Archwires and Straight Wires	304V per ASTM A313
Beta Titanium Archwires and Straight Wires	Ti Beta 3 (Ti 11.5Mo-6Zr-4.5Sn)
Super Elastic Archwires	Nickel Titanium #1 per ASTM F2063
Thermal Activated Archwires	Nickel Titanium #1 per ASTM F2063

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Thermal Activated Ultra-Soft Archwires	Nickel Titanium #8 per ASTM F2063

6. Warnings and Precautionary Measures

- When gripping and/or holding archwire or straight wires, only use instruments without sharp edges or serrated surface. Scratches and scuffing of the wire caused by such instruments can lead to the wire breaking in the mouth.
- Excessive force and/or repeated bending of the archwire and straight wire can lead to breakage.
- 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 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.
- 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.

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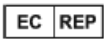
11. Name and address of labeler

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

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.
 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.

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.

Ni Contains Nickel	**Product contains Nickel.** FDA 21 Part 184 Sec. 184.1537 Nickel.
Ni Cr Contains Nickel and/or Chromium	**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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