OC WCT orthodontics
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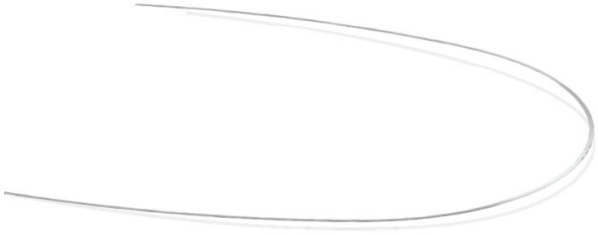
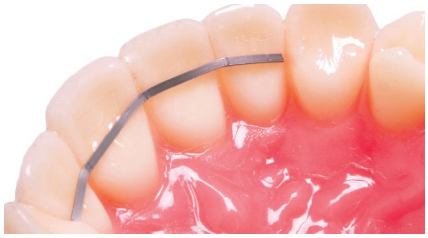
INSTRUCTIONS FOR USE

METAL ARCHWIRE AND STRAIGHT WIRE

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Beta Titanium Archwire Forms 	646.XXXX 61.40.170.XXXXX 61.40.270.XXXXX 61.40.470.XXXXX 61.40.570.XXXXX
Stainless Steel Archwire Forms 	651.XXXX 61.40.180.XXXXX 61.40.280.XXXXX 61.40.480.XXXXX 61.40.580.XXXXX

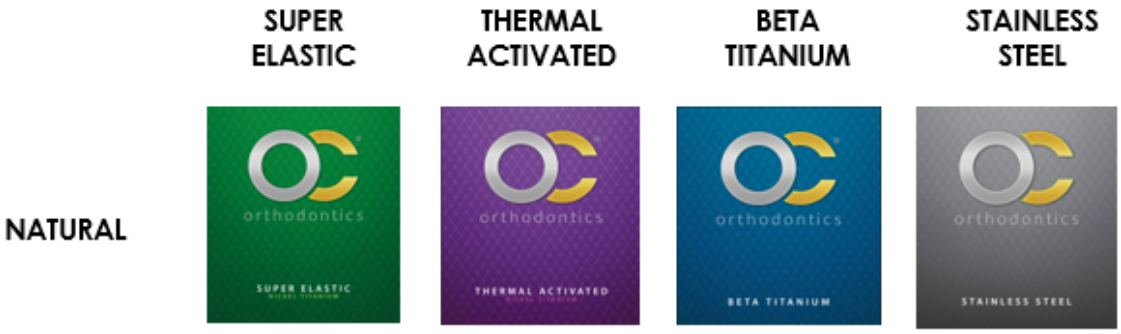
Product Family	Product Part Numbers
Super Elastic Archwire Forms 	625.XXXX 627.XXXX 41.40.120.XXXXX 41.40.220.XXXXX 41.40.320.XXXXX 41.40.420.XXXXX 41.40.520.XXXXX 41.40.620.XXXXX 61.40.120.XXXXX 61.40.125.XXXXX 61.40.130.XXXXX 61.40.220.XXXXX 61.40.225.XXXXX 61.40.230.XXXXX 61.40.420.XXXXX 61.40.425.XXXXX 61.40.520.XXXXX 61.40.525.XXXXX 61.40.720.XXXXX 61.40.725.XXXXX
Thermal Activated Archwire Forms 	320.XXXX 620.XXXX 621.XXXX 41.40.110.XXXXX 41.40.210.XXXXX 41.40.310.XXXXX 41.40.410.XXXXX 41.40.510.XXXXX 41.40.610.XXXXX 61.40.110.XXXXX 61.40.115.XXXXX 61.40.210.XXXXX 61.40.215.XXXXX 61.40.410.XXXXX 61.40.415.XXXXX 61.40.510.XXXXX 61.40.515.XXXXX 61.40.710.XXXXX

Product Family	Product Part Numbers
Thermal Activated Ultra-Soft Archwire Form 	600.XXXX 300.XXXX
Beta Titanium Straight Wire 	40.40.870.XXXXX
Super Elastic Straight Wire 	40.40.850.01622
Dead Soft Retention Wire 	40.40.700.01027

Product Family	Product Part Numbers
Stranded Retention Wire (SRW) 	40.42.111.00195 40.42.111.00215

**XXXXX = Multiple sizes in product family*

Colored Archwire Boxes



2. Description

World Class Technology's (WCT) wires and accessories are used in a variety of fixed and removable orthodontic appliances to correct and retain the alignment and position of teeth. WCT wires include preformed orthodontic archwires, straight wires, and retention wires. The wires are available in a variety of materials, configurations, arch forms and dimensions that are comparable to orthodontic wires offered throughout the industry.

Archwires are ligated in the slots of orthodontic brackets and apply forces to the teeth. Archwires manufactured at WCT are available in a variety of performed arch forms (arch shapes), materials, and cross-sectional dimensions, which allow orthodontists to select the archwire that best meets the treatment plan for each patient. WCT preformed arch forms are available in common industry arch forma and also manufactured-specific arch forms. WCT arch forms are available for both the upper/maxillary and low/mandibular arches, and in varying sizes and arch forms.

Straight wires may be used by orthodontists to fabricate orthodontic appliances that apply forces to aid in teeth movement or maintain teeth position. Orthodontist can shape straight wires into archwires to be used in conjunction with orthodontic

brackets or shaped into various forms to aid in the movement of teeth. Straight wires may also be fabricated into removable retainers or bonded directly to teeth to maintain alignment and position.

Retention wires are used maintain teeth alignment and position, preventing relapse or teeth shifting. Retention wires are bonded directly to teeth. WCT's retention wires are available in stainless steel and Titanium materials.

3. 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.

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.

4. Indications for use

The WCT wires are indicated for use in orthodontic treatment of the maxillary and mandibular arches.

1. The WCT performed archwires are indicated for use as orthodontic archwires to apply force to the teeth to effect movement of natural teeth in patients with malocclusion. Archwires are used in conjunction with orthodontic brackets that are temporarily affixed to the teeth.
2. The WCT straight wires are indicated for use in the fabrication of appliances that apply tooth movement forces in patients with malocclusion. Straight wires are also indicated for maintaining teeth position. Straight wires may be formed into archwires, bonded to teeth or used in the fabrication of space maintainers and removeable retainer appliances.
3. The WCT retention wires are indicated for maintaining teeth position. Retention wires are bonded directly to the surfaces of the teeth.

All of the WCT wires are for professional use only. The wires are single use devices that are provided non-sterile per standard industry practice.

5. 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.

6. Materials

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

Table 1

Materials List	
Stainless Steel Archwires, Straight Wires, and Stranded Retention Wire	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 Nickel Titanium #4 per ASTM F2063
Thermal Activated Archwires	Nickel Titanium #1 per ASTM F2063 Nickel Titanium #4 per ASTM F2063
Thermal Activated Ultra-Soft Archwires	Nickel Titanium #8 per ASTM F2063
Dead Soft Retention Wire	Grade 1 Titanium

Table 2

304V per ASTM A313		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Carbon (C)	-	0.08
Manganese (Mn)	-	2
Phosphorus (P)	-	0.045
Sulfur (S)	-	0.030
Silicon (Si)	-	1
Chromium (Cr)	18	20
Nickel (Ni)	8	10.5
Molybdenum (Mo)	…	…
Nitrogen (N)	-	0.10
Iron (FE)	-	Balance
Other(s)	…	…

Ti Beta 3 (Ti 11.5Mo-6Zr-4.5Sn)		
Chemical Name	**Min. (weight%)**	**Max (weight%)**
Molybdenum (MO)	10.00	13.00
Zirconium (Zr)	4.50	7.50
Tin (Sn)	3.75	5.25
Nitrogen (N)	---	0.050
Carbon (C)	---	0.10
Hydrogen (H)	---	0.05
Iron (Fe)	---	0.35
Oxygen (O)	---	0.18
Cobalt (Co)	---	---
Other Elements, Total	---	0.40
Titanium (Ti)	---	Balance

Table 4

Nickel Titanium #1 per ASTM F2063		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Nickel (Ni)	54.5	57.0
Carbon (C)	-	0.040
Cobalt (Co)	-	0.050
Copper (Cu)	-	0.010
Chromium (Cr)	-	0.010
Hydrogen (H)	-	0.005
Iron (Fe)	-	0.050
Niobium (Nb)	-	0.025
Nitrogen (N)	-	0.005
Oxygen (O)	-	0.040
Titanium (Ti)	-	Balance

Table 5

Nickel Titanium #4 per ASTM F2063		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Nickel (Ni)	54.5	57.0
Carbon (C)	-	0.040
Cobalt (Co)	-	0.050
Copper (Cu)	-	0.010
Chromium (Cr)	-	0.010
Hydrogen (H)	-	0.005
Iron (Fe)	-	0.050
Niobium (Nb)	-	0.025
Nitrogen (N)	-	0.005
Oxygen (O)	-	0.040
Titanium (Ti)	-	Balance

Table 6

Nickel Titanium #8 per ASTM F2063		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Nickel (Ni)	54.5	57.0
Carbon (C)	-	0.040
Cobalt (Co)	-	0.050
Copper (Cu)	-	0.010
Chromium (Cr)	-	0.010
Hydrogen (H)	-	0.005
Iron (Fe)	-	0.050
Niobium (Nb)	-	0.025
Nitrogen (N)	-	0.005
Oxygen (O)	-	0.040
Titanium (Ti)	-	Balance

Table 7

CP Titanium Gr1	
Chemical Name	**Max Weight %**
Nitrogen (N)	0.03
Carbon (C)	0.08
Hydrogen (H)	0.015
Iron (Fe)	0.20
Oxygen (O)	0.18
Titanium (Ti)	Balance

7. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
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 breakage during treatment.	
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).	
Ni Cr Contains Nickel and/or Chromium	Super Elastic, Thermal Activated and Thermal Activated Ultra-Soft Archwires contain nitinol, an alloy of nickel and titanium and should not be used for individuals with known allergic sensitivity to these metals. Prior to use, patients should be counseled on the materials contained in the device, as well as the potential for allergy/hypersensitivity to these materials. (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.	
MRI Safety Information – WCT's Metal Archwire and Straight Wire 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 archwires and/or straight wires, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.	

8. 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.

9. 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.
- 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
- 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.

10. Disposal (if applicable)

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

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

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

12. Name and address of labeler

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

13. 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

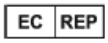
14. Name, address, and number of Authorized Representative

EC REP

MDI Europa
Langenhagener STR.71 30855
Langenhagen, Germany
+49-511-3908-9530
SRN: DE-AR-000006218

15. 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.
 Ref. 5.7.7 MDR 2017/745	**Medical Device:** Indicates that the device is a medical device.

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.
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.

105-7300-07 (DOC-525) Ver. 4

Approved By:

(CO-534) Archwire and Straight Wire IFU Ver 4

Description

Updating the Ti-Beta 3 Material Composition table. Please refer to change order form in Evaluation tab for more information.

Justification

Received Ti-Beta 3 material composition from Fort Wayne Metals.

Assigned To:	Initiated By:	Priority:	Impact:
Maureen Janssen	Maureen Janssen	Medium	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	September 11, 2024 9:42 AM PDT	CO-534	4	Published
Maureen Janssen	March 13, 2024 3:21 PM PDT	CO-236	3	Superseded
Maureen Janssen	June 22, 2023 9:48 AM PDT	CO-148	2	Superseded
Maureen Janssen	April 18, 2023 1:56 PM PDT	CO-126	1	Superseded
Yarely Jimenez	February 22, 2023 8:59 AM PST	CO-74	0	Superseded