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INSTRUCTIONS FOR USE

ARCHWIRE SEATING INSTRUMENT

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Archwire Seating Instrument 	246.1002

2. Intended Use

The Archwire Seating Instrument is an orthodontic hand instrument. It incorporates a handle for manipulating the device and a working end. The working end is angled with an opening designed to straddle the mesial-distal width of the Pitts 21 and Clear21 brackets. There are two projections on either side of the opening on the working end of the instrument. Each of the projections contains a notch for engaging the archwire.

The Archwire Seating Instrument is designed for use with the Pitts 21 and Clear21 self-ligating orthodontic brackets. The two projections on the working end of the device contain notches for engaging the archwire. Once the device is engaged on the archwire, the operator can de-torque the archwire to align it with the archwire slot, and then permit the operator to fully seat the archwire to the bottom of the archwire slot. The ligating door on the Pitts 21 or Clear21 brackets are easily closed once the archwire is fully seated into the archwire slot. The Archwire Seating Instrument is of particular benefit when installing full-size cross-section archwires made of stiffer material.

Devices are supplied:

- Non-sterile
- For use by dentists and orthodontists only.

3. Indications for use

The primary intended use for the Archwire Seating Instrument is for installing archwires made of beta titanium or stainless steel with a .019" x .019" or .020" x .020" cross-section. The tool also simplifies the installation of archwires with smaller cross-sections and more resilient materials like NiTi (Nickel-Titanium).

4. Contraindications

- This product may contain Nickel and/or Chromium, so do not use on individuals with known allergic sensitivity to these metals.
- Any illness and/or underlying conditions that preclude orthodontic treatment.

5. Materials

The Archwire Seating Instrument is a single-piece tool made from 17-4PH Stainless Steel per the requirements of Table 1.

Table 1

Stainless Steel 17-4PH per ASTM B883-19		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Iron (Fe)	Balance	Balance
Nickel (Ni)	3	5
Chromium (Cr)	15.5	17.5
Carbon (C)	--	0.07
Copper (Cu)	3	5
Silicon (Si)	--	1.0
Manganese (Mn)	--	1.0
Niobium; Tantalum (Nb+Ta)	0.15	0.45
Other	--	1.0

6. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
Ni Cr Contains Nickel and/or Chromium	Before use, counsel patients on the materials contained in this device. Also, counsel the patient on the potential for allergy/hypersensitivity to these materials.
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.	
Ensure the archwire is fully seated in the archwire slot before closing the ligating door.	
If, in relation to the use of the Archwire Seating Instrument, 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

- Not Applicable

8. General Information for the Dentist/Orthodontist

- Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement, removal, and operation of the ligating mechanism.
- Disposal of all orthodontic appliances and instruments must follow regional and national regulations.

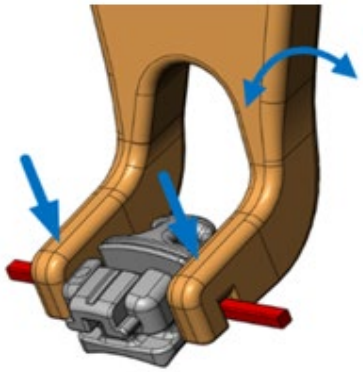
9. Handling Procedure on How to Use the Medical Device (Instructions for Use)

1. Hold the tool in one hand.
2. Straddle the Mesial and Distal width of the bracket with the tool handle angled away from the ligating door , see Fig. 1.

Fig 1

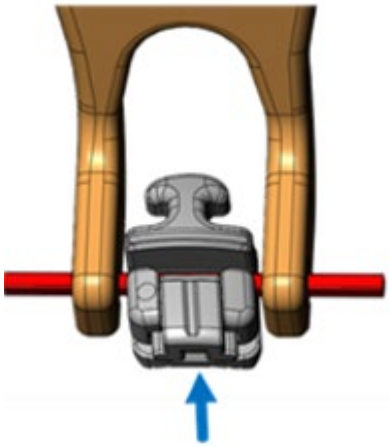
3. Engage the notches at the working end of the tool over the labial surface of the archwire, see Fig 2.
4. De-torque the archwires, as necessary, by rotating the handle in the occlusal-gingival direction to align it with the bracket's archwire slot. Refer to Fig. 2.
5. Once aligned with the archwire slot, push the archwire into the archwire slot to fully seat it into the bracket. Refer to Fig 2.

Fig 2



6. Keep the archwire seated, and use your gloved finger on other hand to push the ligating door closed. Refer to Fig 3.

Fig 3



10. Cleaning and Sterilization Instructions

- The Archwire Seating Instrument is to be cleaned and sterilized per the recommendations of WCT's 105-7300-00 Instrument Cleaning & Sterilization IFU.

11. Disposal (if applicable)

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

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

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

13. Name and address of labeler

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

14. 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

15. 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

16. 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.
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	
 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.