OC WCT orthodontics
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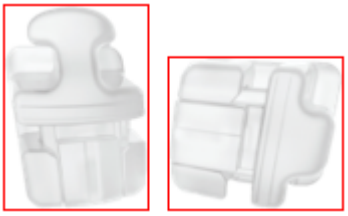
1300 NE ALPHA DR. MCMINNVILLE, OR 97128

INSTRUCTIONS FOR USE

CLEAR21

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Clear21™ aesthetic passive self-ligating bracket system. 	246.2XXX 256.2XXX

XXX = Multiple clear bracket part numbers

2. Description

The Clear21™ ceramic orthodontic bracket system is an aesthetic passive self-ligating bracket system for use in fixed appliance orthodontic treatment. The system consists of ceramic maxillary brackets that are bonded directly to the clinical crown of the patient's teeth. The Clear21™ brackets are sold non-sterile and designed for single use. Orthodontic adhesives and various hand instruments are required for bonding the Clear21™ brackets to the patient's teeth. Other ancillary orthodontic products generally available to the orthodontic industry, such as archwires, elastics, power chain, and extension/compression springs, may be used with the Clear21™ system to complement treatment. The Clear21 system is designed to use square finishing archwires with a normal cross-section of 0.020" x 0.020". Follow the manufacturer's instructions for all ancillary orthodontic products used with the Clear21™ bracket system.

3. Intended Use

The Clear21 bracket system is intended to be used in orthodontic treatment. The Clear21 brackets are intended to be temporarily affixed to the teeth in order to transmit force to the teeth to create movement of teeth during 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 Clear21™ orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.

5. Contraindications

- Patient's inability or unwillingness to cooperate/follow the treatment plan
- Patient with deficient oral hygiene
- Known allergies to any of the components or materials in the system.
- Any illness and/or underlying conditions that preclude orthodontic treatment.
- Any existing tooth root resorption
- Any existing decalcification of the tooth enamel.

6. Materials

Bracket Body & Ligating Door	Polycrystalline Alumina Al3O2
Spring Member	Nitinol per ASTM F2063 • Titanium balance • Nickel 54.58 to 57.0% wt.% • Carbon ≤ 0.04 wt.% • Cobalt ≤ 0.05 wt.% • Copper ≤ 0.01 wt.% • Chromium ≤ 0.01 wt.% • Hydrogen ≤ 0.005 wt.% • Iron ≤ 0.05 wt.% • Niobium ≤ 0.025 wt.% • Nitrogen ≤ 0.005 wt.% • Oxygen ≤ 0.04 wt.%,
	Coating • Zirconium Nitride (ZrN)
Assembly Adhesive	Typical Orthodontic Adhesive

7. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
	The Clear21™ system is designed for single 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.
 Contains Nickel and/or Chromium	This product contains 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.

Do not use on patients with known allergies to any of the materials in the Clear21™ system. Immediately remove the brackets in the event of an allergic reaction.
Only use the Quick-Turn Tool to operate the ligating door. The use of other instruments might result in damage to the Clear21 bracket. o The Quick-Turn Tool can generate very high forces, make sure that the tool is; ▪ Centered in the recess on the labial surface of the gingival side of the ligating door.
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.
Do not force any instrument into the bracket's archwire slot in either the open or closed condition as this may result in bracket damage.
Care should be taken to avoid contact with opposing teeth at occlusion.
Ensure the bracket door is completely closed and the wire seated properly in the archwire slot. If the door is not completely closed/ligated, this may allow the wire to escape.
MRI Safety Information – The Clear21™ system has 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 this product, 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 that 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 or bracket guards as recommended by the dental professional treating the patient.
- Always inform MRI or radiology staff that braces are in place before any procedure to ensure appropriate measures are taken for the procedure.

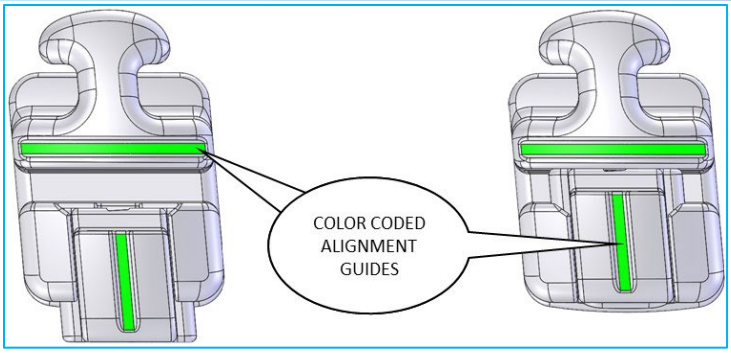
9. General Information for the Dentist/Orthodontist

- As part of developing an orthodontic 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 the adhesion of orthodontic bonding materials.
- 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.
- Proper removal of ceramic brackets is important to avoid any possible damage to tooth enamel. Carefully follow the bracket debonding instructions.
- Ceramic brackets may abrade the teeth in the opposing dental arch if they come in contact with the opposing teeth. Do not apply ceramic brackets to the teeth until the patient's bite has opened sufficiently to ensure there will be no contact between the ceramic brackets and the opposing teeth.
- The Clear21™ system is designed to use square finishing archwires with a "full-size cross-section of 0.020" x 0.020".
- It is recommended that the material of "full-size" archwires be limited to NiTi or Beta-Titanium to avoid excessive forces that may be caused by "full-size" stainless steel archwires and significant tooth discrepancies.
- Stainless steel archwires should be limited to a .019" x .019" cross-section and only used after tooth positional discrepancies have been well resolved with lighter force archwire materials like NiTi or beta titanium.
- The device is provided nonsterile, nor is it intended to be sterilized by the user. The industry standard of care for orthodontic devices is that the devices are provided to the orthodontist in protective packaging, they are removed from the packaging for use on the patient and the devices are not handled nor sterilized before their use.
- There is no information available that would preclude the use of commonly available oral healthcare products like toothbrush, toothpaste, water pick, mouth wash, etc.

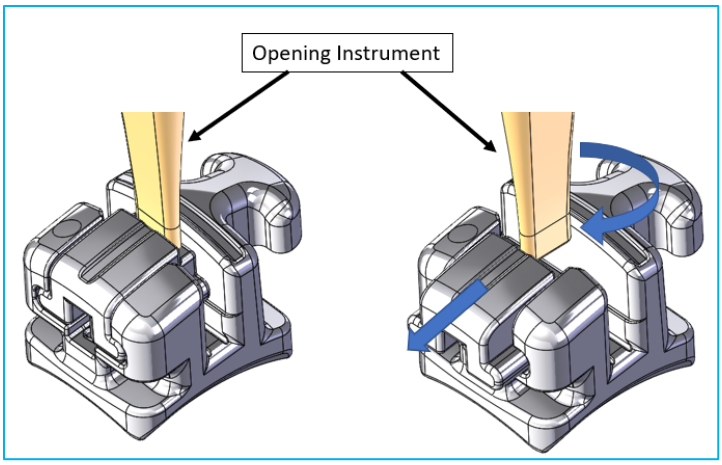
10. Handling Procedure on How to Use the Medical Device

- Bonding
  - Use conventional orthodontic adhesive, following the manufacturer's instructions to bond the brackets to the patient's teeth
  - Alignment guides are provided to assist in placement of the bracket on each tooth.



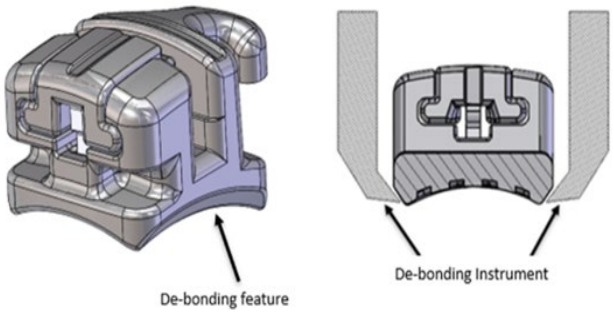
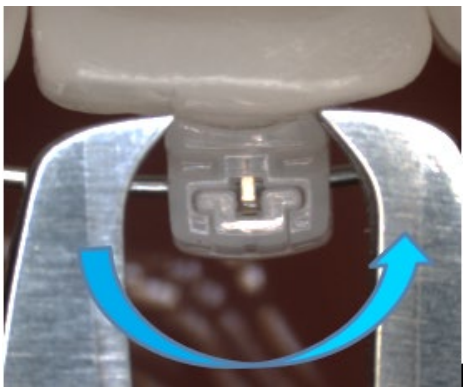
- Use an appropriate dental instrument to remove excessive adhesive "flash" around the perimeter of the bracket base, at the bracket-tooth interface, before adhesive cures. It is particularly essential to remove the excess adhesive flash from the mesial-distal edges of the bracket base. The mesial-distal sides of the bracket base contain features to aid in debonding the bracket at the end of treatment. Excess adhesive flash could obstruct the debonding features if it is not removed.

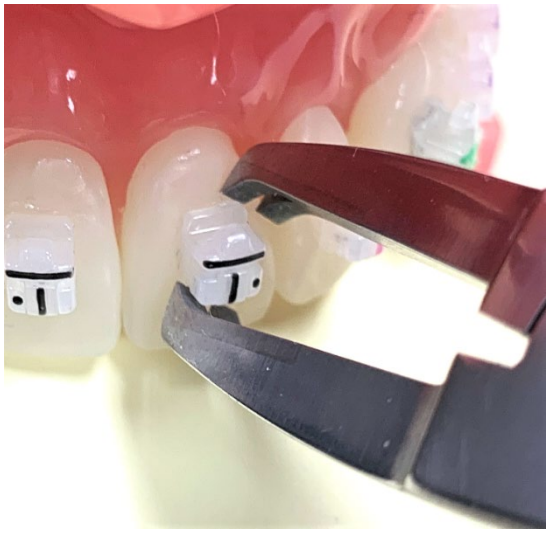
- Opening the ligating door
  - To open the ligating door, insert the Quick Turn Tool (Opening Instrument), centering it in the recess on the labial surface of the gingival side of the ligating door. Rotate the Quick Turn Tool 90 degrees in either the clockwise or counterclockwise direction. Only a 90-degree rotation is required to fully open the ligating door. Rotating the Quick Turn Tool more than 90 degrees will NOT open the ligating door any further and will NOT cause any damage. Only use the OC-Orthodontic Quick Turn Tool to operate the ligating door. The use of other instruments might result in damage to the Clear21 bracket.
  - Once the archwire has been inserted into the archwire slot and fully seated into the archwire slot; push the occlusal edge of the ligating door using the tip of the opening instrument or a gloved fingertip to close the ligating door. It may be necessary to hold the archwire down into the slot with P21/C21 Archwire Seating Tool or an appropriate instrument to ensure the archwire is fully seated before pushing the ligating door closed. Both an audible click and a light tactile snap will occur at the fully closed position.



11. Recommended De-bonding Procedure

Remove excess adhesive flash from the mesial and distal sides of the bracket with a Flame Carbide Bur or equivalent.	

The recommended debonding instrument is the OC-Orthodontics debonding instrument (P/N 533-0400). It is recommended, that the archwire remain ligated in the Clear21 brackets, to maintain control of the brackets when they are debonded from the patient's teeth. Place the wedge shape tips of the debonding instrument into the angled debonding feature, located on the mesial and distal sides of the bracket. The notches in the wedged tips of the OC Orthodontics debonding instrument are designed to straddle the archwire.	
Squeeze the handles of the debonding plier together, to wedge the tips of the debonding plier into the debonding features on the mesial and distal sides of the bracket base. While squeezing the handles together, pivot the handles either in the mesial or distal direction to de-bond the bracket from the tooth.	

In instances of crowding while debonding. The OC-Orthodontics debonding instrument (P/N 533-0400) can be placed at an angle on the upper and lower corners of the bonding base as shown	
Remove any adhesive residue remaining on the tooth surface with an appropriate adhesive removing instrument.	NO PICTURE

12. Disposal (if applicable)

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

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

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

14. Name and address of labeler

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

15. 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

16. 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

17. 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.
NON STERILE 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.
MD 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	
℞ 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.