INSTRUCTIONS FOR USE

OPENING INSTRUMENT

1. Product Family & Part Numbers

Product Family	Product Part Numbers
Opening Instrument (Tool) NOTE: Also marketed as Quick-Turn (Tool) 	246.1000

2. Intended Use

The instrument is intended to be used to operate the ligating member of the Clear21 and Pitts21 Pro passive self-ligating bracket system.

Devices are supplied:

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

3. Indications for use

The Opening Instrument is intended to be used in conjunction with the Clear21 and Pitts21 Pro bracket system.

4. Contraindications

This product contains nickel and chromium and should not be used for individuals with known allergic sensitivity to these components. It an allergic reaction occurs, direct the patient to consult a physician.

5. Materials

- Instrument Tip Materials per Table 1 and Table 2
- Instrument Handle Material per Table 3

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(s)	-	1.0

Table 2

Titanium Nitride per ASTM B265-95 Grade 2		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Titanium	98.905	-
Carbon (C)	-	0.10
Oxygen (O)	-	0.25
Nitrogen (N)	-	0.03
Hydrogen (H)	-	0.015
Iron (Fe)	-	0.30
Other	-	0.4

Table 3

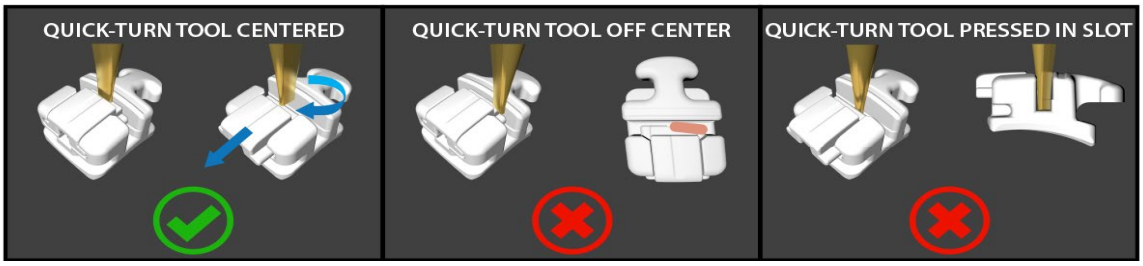
Stainless Steel UNS S30400		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Iron (Fe)	Balance	Balance
Nickel (Ni)	8	10.5
Chromium (Cr)	18	20
Carbon (C)	-	0.08
Sulfur (S)	-	0.03
Silicon (Si)	-	1.0
Manganese (Mn)	-	2.0
Other	-	-

6. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
Adequate reprocessing of reusable medical devices is a critically important step in protecting patient safety.	
Clean and sterilize instruments prior to and between patient use to prevent cross-contamination.	
NON STERILE	The Opening Instrument is provided non-sterile and designed to be re-used only, by a professional or on the order of an orthodontist or a dentist.
Handle used and contaminated instruments with protective gloves in accordance with local policies and procedures.	
Cold sterilization is not suggested.	
A pH neutral cleaner should be used to prevent corrosion and staining. Enzymatic detergents are preferable.	
Only clean instruments should be sterilized.	
Do not use mineral oil to lubricate instrument.	

Do not use a sterilized instrument if the sterilization packaging has been compromised. The instrument should not be used for anything other than the intended use.	
 Contains Nickel and/or Chromium	This product contains nickel and chromium 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 this product on patients with known allergies to any of the materials used in this device. Immediately remove the device in the event of an allergic reaction.	
Do not use any products which are damaged, or do not comply with the labeling specifications.	
The Quick-Turn Tool can generate very high forces, make sure that the tool is: o Centered in the recess on the labial surface of the gingival side of the ligating door. o Not pressed into the bracket slot, see Figure 1 for examples of correct and incorrect placement of the Quick-Turn Tool.	
If, in relation to the use of the Opening Instrument, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.	

Figure 1



7. Patient Information

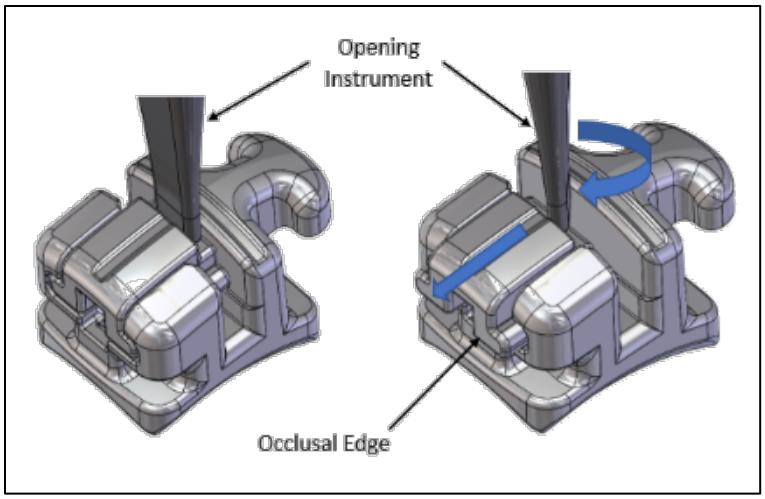
N/A

8. General Information for the Dentist/Orthodontist

- The Opening Instrument is a metal hand instrument comprised of an instrument handle and an instrument tip, designed to open the ligating member of the Clear21 and Pitts21 Pro passive self-ligating bracket system.
- Repeated processing has minimal effect on the Instrument.
- End Life is determined by visible and functional tests for wear, damage, corrosion, or breakage.
- The user is responsible for inspecting the instrument prior to each use.
- Handling Procedure on how to use the medical device.

- Insert the Instrument into the recess on the labial surface of the ligating door, between the ligating door and bracket body (Figure 2).
- Rotate the Instrument 90 degrees either in a clockwise or counterclockwise direction to fully open the ligating door (Reference Figure 1 for proper alignment of tip to bracket).

Figure 2



- For Cleaning and sterilization instructions, refer to World Class Technology Instrument Cleaning & Sterilization document 105-7300-00.

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 sterilized, pouched device should be stored in a clean, dry and dust-free environment under ambient conditions. Sterilization can only be maintained if the instruments remain pouched.

11. Name and address of labeler

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

12. 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

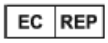
13. Name, address, and number of Authorized Representative

EC REP

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

14. 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. 5.1.5	**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. 5.4.3	**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.

The following are per ISO 15223-1 (*References as indicated*).

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
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	
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.