INSTRUCTIONS FOR USE

H4 & PITTS21 OPENING PLIER

1. Product Family & Part Numbers

Product Family	Product Part Numbers
H4 & Pitts21 Opening Plier	946.1001

2. Intended Use

The H4 & Pitts21 Opening Plier is an orthodontic hand instrument. Each of the plier handles has a unique tip, which is designed to engage specific features on the ligating door and bracket body to aid in opening the ligating door.

The H4 & Pitts21 Opening Plier is designed to open the ligating door of the H4 & Pitts21 passive self-ligating bracket systems. It is common for plaque to form on the teeth and orthodontic brackets, so higher than normal forces can be required to open when excessive plaque forms on bracket. When used as instructed, the H4 & Pitts21 Opening Plier applies a reciprocal force on the ligating door and bracket body, which is sufficient to open brackets with excessive plaque formation without causing discomfort for the patient.

Devices are supplied:

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

3. Indications for use

The primary intended use for the Opening Plier is to open the ligating door on H4 and Pitts21 brackets.

4. Contraindications

- This product may contain Nickel and/or Chromium, so do not use on individuals with known allergic sensitivity to these metals.

5. Materials

- Plier handles are made of MIM-17-4PH Stainless Steel, H900 Condition per ASTM B883-19 (see Table 1).
- Hinge pin is made of 17-4PH Stainless Steel, H1150 Condition per AMS5643V and Passivation per ASTM A967/A967M-17 (see Table 2).
- Hinge Wave Washer is made of 17-7PH Stainless Steel, CH900 Condition (see Table 3).

Table 1

Stainless Steel 17-4PH per ASTM B883-19, H900 Condition		
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

Table 2

Stainless Steel 17-4PH per AMS5643V, H1150 Condition		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Carbon (C)	--	0.07
Manganese (Mn)	--	1.00
Silicon (Si)	--	1.00
Phosphorus (P)	--	0.040
Sulfur (S)	--	0.030
Chromium (Cr)	15.00	17.50
Nickel (Ni)	3.00	5.00
Columbium (Niobium (Nb))	5xC	0.45
Copper (Cu)	3.00	5.00
Molybdenum (Mo)	--	0.50

Table 3

Stainless Steel 17-7PH, CH900 Condition		
Chemical Name	**Min. (weight %)**	**Max. (weight %)**
Carbon (C)	--	0.090
Manganese (Mn)	--	1.000
Silicon (Si)	--	1.000
Phosphorus (P)	--	0.040
Sulfur (S)	--	0.030
Chromium (Cr)	16.00	18.00
Nickel (Ni)	6.500	7.750
Aluminum (Al)	0.750	1.500
Molybdenum (Mo)	--	0.750
Copper (Cu)	--	0.500

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 Plier 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.	
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.
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 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.

7. Patient Information

- Not Applicable

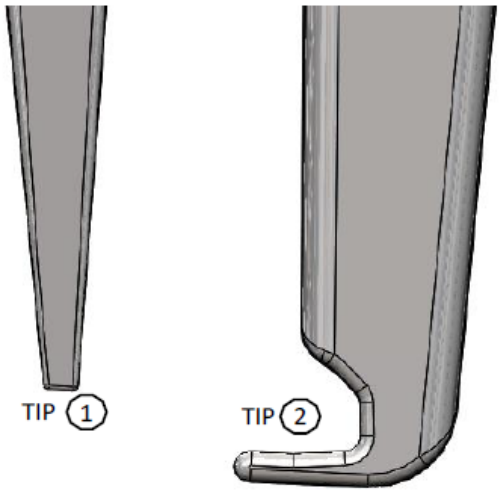
8. General Information for the Dentist/Orthodontist

- 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)

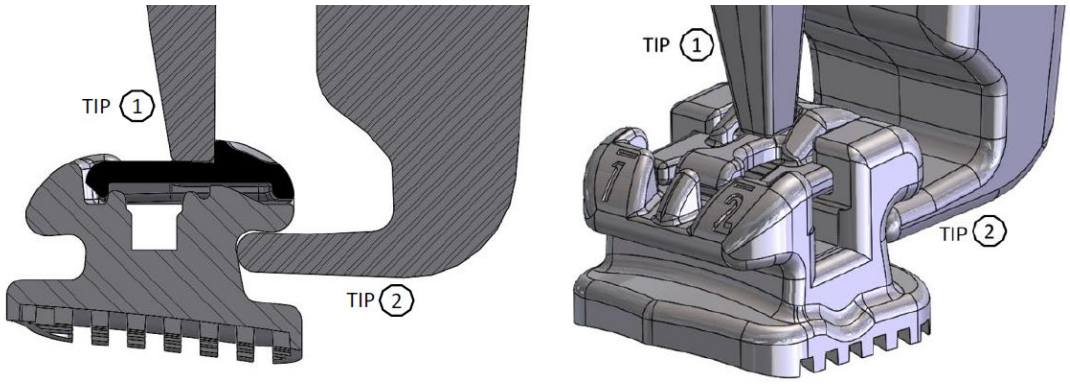
1. The H4 & Pitts21 Opening Plier has two tips, a pointed tip (Tip 1) and a blade tip (Tip 2), see Fig. 1.

Fig 1



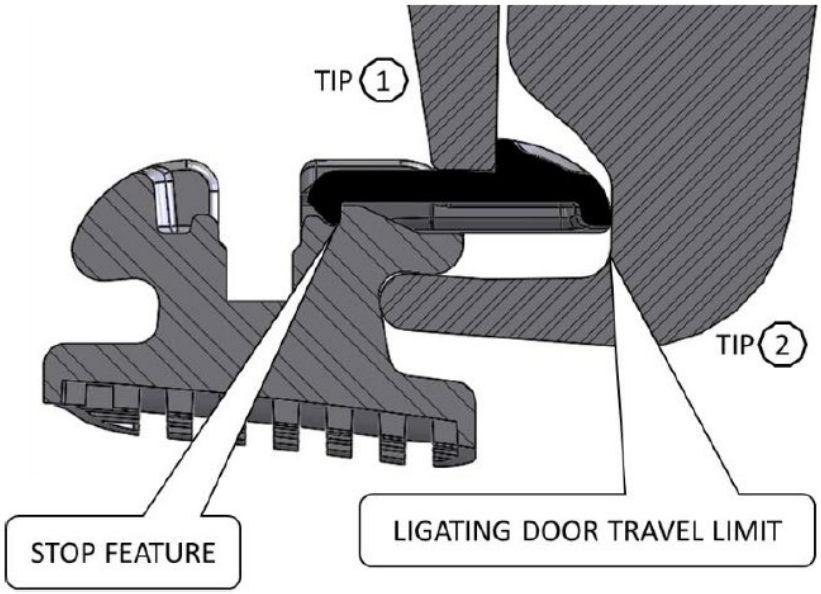
2. Open the jaws of the H4 & Pitts21 Opening Plier and place Tip 2 (blade tip) under the occlusal tie-wing of the bracket.
3. While holding the Tip 2 under the occlusal tie-wing, and with the jaws still open, place Tip 1 (pointed tip) in the opening feature of the ligating door. It may be necessary to slightly tilt the plier in the gingival direction, and slightly close the jaws by squeezing the handles together until Tip 1 registers into the opening feature in the ligating door. Refer to Fig. 2.

Fig 2



4. Once both Tip 1 and Tip 2 are located correctly in the opening feature of the ligating door and under the occlusal tie-wing, squeeze the plier handles together to open the ligating door. Tip 1 and Tip 2 will apply a reciprocal force on the ligating door and bracket, and move the ligating door towards the occlusal side to expose the archwire slot.
5. The Opening Plier limits how far the ligating door can travel in the open direction, which minimizes the likelihood of the ligating door moving beyond the stop feature incorporated in the bracket body. Refer to Fig. 3.

Fig 3



10. Cleaning and Sterilization Instructions

- The Opening Plier 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.

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

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
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.

Symbols Not Derived from Standards	
CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	**European conformity:** European conformity (CE) mark with Notified Body identification number.