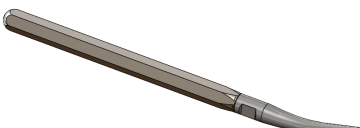
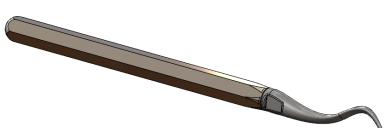


INSTRUCTIONS FOR USE

H4/PITTS21 TOOL & DIRECTOR TOOL

1. Product Family & Part Numbers

Product Family	Product Part Numbers
H4/Pitts21 Tool 	916.0100
Director Tool 	916.0101

2. Intended Use

The instruments are intended to be used to operate the ligating member of the H4 and Pitts21 passive self-ligating bracket systems.

Devices are supplied:

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

3. Indications for use

The Instruments are intended to be used in conjunction with the H4 and Pitts21 bracket systems.

4. Contraindications

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

5. Materials

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

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

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

	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.	
	The H4/P21 Tool and Director Tool are 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.	
	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.
Follow all regional and national standards regarding the use of orthodontic appliances.	
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.	
If, in relation to the use of the H4/Pitts21 Tool or Director Tool, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.	

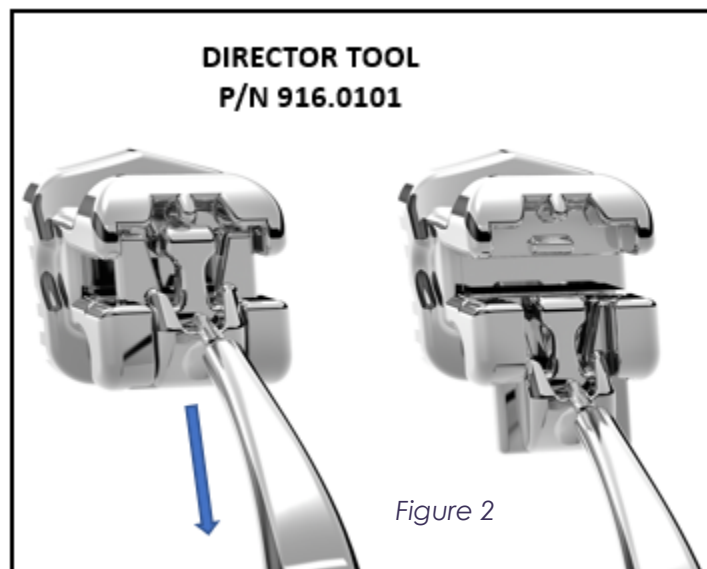
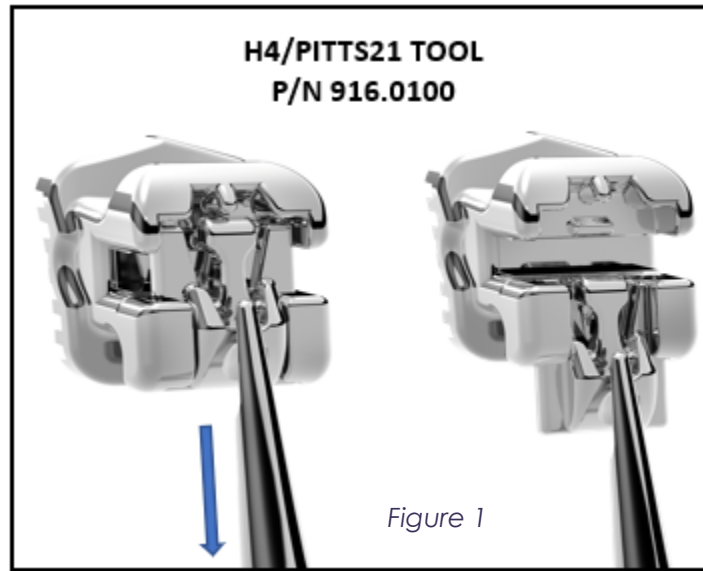
7. Patient Information

N/A

8. General Information for the Dentist/Orthodontist

- The Instruments are metal hand instruments comprised of an instrument handle and an instrument tip, designed to open the ligating member of the H4 and Pitts21 passive self-ligating bracket system.
- Repeated processing has minimal effect on the Instrument.
- End of Life is determined by visible and functional tests for wear, damage, corrosion, or breakage.
- The user is responsible for inspecting the instruments 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.
 - Gently pull the instrument to the occlusal side to open the ligating member.

Figure 1 & 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.

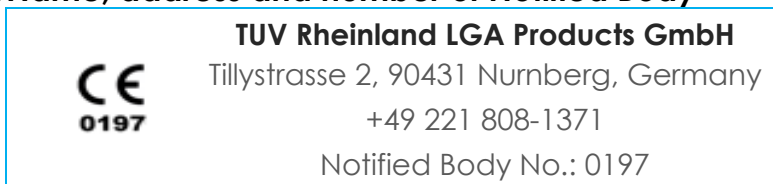
10. Storage and Handling for medical devices (if applicable)

- 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



12. Name, address and number of Notified Body



13. Name, address, and number of Authorized Representative



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.

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.
 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.
 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.

105-7300-24 (DOC-560) Ver. 1

Approved By:
[\(CO-108\) Update Symbols on IFUs](#)

Description
Updating Single Use, Non-Sterile, and Use By Date Symbols in Section 7. Added Single Use Symbol in Section 17. Please refer to change order in Evaluation Tab for change description for each document.

Justification
Wrong symbols on the IFU.

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

Version History:				
Author	Effective Date	CO#	Ver.	Status
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Yarely Jimenez	February 7, 2023 10:31 AM PST	CO-75	0	Superseded