

Revision History		
Rev	Description of Changes	Release Date
A	CO#20054: Initial Release	2020-06-22

CAUTION: Federal law restricts this device to the sale by or on the order of a licensed orthodontist.

1. Product Family

Instruments

2. Product Part Number & Description

- 916.0100 - H4/Pitts21 Tool
- 916.0101 - Director Tool
- 246.1000 - Clear21 Quick-Turn, Opening Instrument
- 246.1002 - Archwire Seating Instrument
- 946.1001 - H4/Pitts21 Opening Plier

3. Indications for use

An orthodontic hand instrument is a hand-held device intended to perform various tasks in general orthodontic procedures during the treatment of malocclusions. A malocclusion is imperfect positioning of the teeth when the jaws are closed.

4. Contraindications

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

5. Precautions

- Adequate reprocessing of reusable medical devices is a critically important step in protecting patient safety.
- Refer to 'Section 4. Contraindications.'

6. Adverse Reactions

Possible allergic reaction to materials in the instrument.

7. Warnings

- Clean and sterilize instruments before and between patient uses to prevent cross-contamination.
- Handle used and contaminated instruments with protective gloves in accordance with local policies and procedures.
- Cold sterilization solutions are not suggested.
- A pH neutral cleaner should be used to prevent corrosion and staining. Enzymatic detergents are preferable.
- Only clean instruments should be sterilized.
- Long, narrow cannulations and blind holes require particular attention during cleaning.
- Do not use mineral oil to lubricate instruments.
- Do not use a sterilized instrument if the sterilization packaging has been compromised.
- Instruments should not be used for anything other than their intended use.

8. Limitations on Reprocessing

Repeated processing has minimal effect on these instruments. End of life is determined by visible and functional tests for wear, damage, corrosion, breakage, loose or tight joints, misaligned joints or nicked blades. The user is responsible for the inspection instrument before each use.

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9. Instructions

9.1. Point of use

Remove excess soil with disposable cloth/paper wipe. Avoid allowing soil and debris to dry on the instrument.

9.2. Containment and Transportation

Move instruments to, clearly marked, decontamination area.

9.3. Preparation

- Remove coarse impurities on the devices immediately after application with a soft brush (within a maximum of 2 hours).
- For hinged instruments, open and close the hinge at least 5 times with the instrument submerged in an enzymatic cleaner.
- For instruments with blind holes (holes that don't go completely through the instrument), flush holes with a syringe and enzymatic cleaner.

9.4. Cleaning and Disinfection (3 Methods)

9.4.1. Method 1: Manual (Ultrasonic) and Disinfection

- Hold instrument under warm running potable water 85°F - 104°F (30°C - 40°C), use an instrument brush to mechanically clean instrument until all visible soil has been removed. Ensure that any hinges and/or joints are soil-free. Do not use metal or wire wool brushes.
- Rinse under running warm running potable water 85°F - 104°F (30°C - 40°C) for 1 minute.
- Place instrument with jaws open in an ultrasonic cleaner filled with pH neutral enzymatic detergent solution for the time suggested by the manufacturer of the enzymatic detergent solution (Empower™ from Metrex Research is recommended).
- Upon completion of the cycle, remove instruments immediately and rinse thoroughly with distilled or deionized water to remove residual detergent from the instrument for at least 30 seconds.
- Submerge instrument in disinfectant solution for the suggested soaking time of the disinfectant (CaviCide™ from Metrex Research is recommended). There should be no contact between devices.
- Rinse instrument thoroughly with distilled or deionized water to remove residual disinfectant for at least 30 seconds.
- Dry instrument and any hinges or joints thoroughly with filtered compressed air or a clean dry towel before sterilization.

9.4.2. Method 2: Manual and Disinfection

- Hold instrument under warm running potable water 85°F - 104°F (30°C - 40°C), use an instrument brush to mechanically clean instrument until all visible soil has been removed. Ensure that any hinges or joints are free of soil. Do not use metal or wire wool brushes.
- Rinse under warm running potable water 85°F - 104°F (30°C - 40°C) for 1 minute.
- Place the instrument in a tray for manual cleaning with the jaws open.
- Soak instrument in a pH neutral, enzymatic cleaning solution for the time suggested by the manufacturer of the enzymatic cleaning solution.
- Allow instruments to remain covered with the cleaning solution. Use an instrument brush for mechanical cleaning under the solution level to remove all remaining visible debris. Ensure that any joints or hinges are free of debris. Do not use metal or wire wool brushes.

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- Remove instruments immediately and rinse thoroughly with distilled or deionized water to remove residual detergent from the instrument for at least 30 seconds.
- Submerge instrument in disinfectant solution for the suggested soaking time of the disinfectant (CaviCide™ from Metrex Research is recommended). There should be no contact between devices.
- Rinse instrument thoroughly with distilled or deionized water to remove residual disinfectant for at least 30 seconds.
- Dry instrument and any hinges or joints thoroughly with filtered compressed air or a clean dry towel.

9.4.3. Method 3: Automatic and Disinfection

- Equipment: Thermal Disinfection Unit (Washer-Disinfector).
- Recommended Detergent: Empower™ from Metrex Research.
- Recommended Disinfectant: CaviCide™ from Metrex Research.
- Place the instruments in the thermal disinfectant unit, ensuring no contact between the instruments.
- Initiate the cycle.
- Remove the devices from the thermal disinfectant unit after the end of the cycle.

9.5. Maintenance

Spray instrument with a lubricant per manufacturer suggested instructions. MetriLube™ Spray from Metrex Research is recommended.

9.6. Inspection and Function Testing

Visually inspect the instrument for damage and wear. Open and close handles to check for joint stiffness or play. Discontinue use of any instrument showing signs of misalignment, loose or tight joints, nicked blades, broken tips, or corrosion.

9.7. Sterilization (2 Methods)

9.7.1. Method 1: Autoclave Sterilization

Place the instrument in a suitable pouch for steam sterilization and sterilize using either Fractionated Vacuum or Gravity Displacement and one of the following exposure temperatures and times:

- Fractionated Vacuum Autoclave
 - 132°C - 134°C (270°F - 273°F) for 4 minutes and at least 20 minutes dry time.
 - 121°C (270°F) for 20 minutes and at least 20 minutes of dry time.
- Gravity Displacement Autoclave
 - 132°C - 134°C (270°F - 273°F) for 5 minutes and at least 20 minutes dry time.
 - 121°C (270°F) for 20 minutes and at least 20 minutes of dry time.

9.7.2. Method 2: Dry Heat Sterilization

Place instrument flat on a rack with jaws open (do not place the instrument in pouch). Avoid instrument to instrument contact and sterilize per the following exposure temperature and time:

- Dry Heat
 - 190°C (375°F) for 20 minutes.

9.8. Storage

Sterilized, pouched instruments should be stored in a clean, dry, and dust-free environment. Sterilization can only be maintained if the instruments remain pouched.