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APII CLASS II APPLIANCE IFU

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ENGLISH

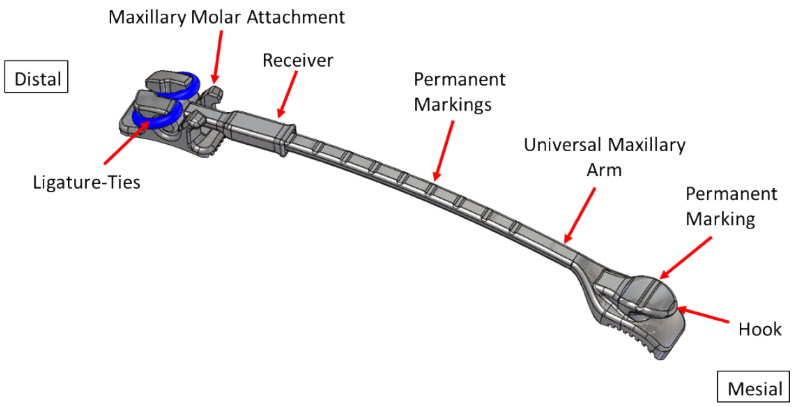
INSTRUCTIONS FOR USE

APII

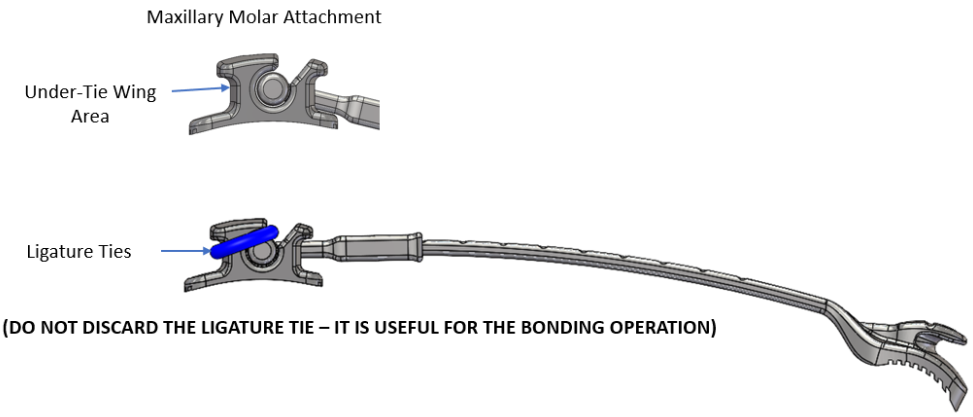
CLASS II APPLIANCE

1. Product Family & Part Numbers

Product Family	Product Part Numbers
APII Appliance	960.XXXX



XXX = Multiple part numbers



(DO NOT DISCARD THE LIGATURE TIE – IT IS USEFUL FOR THE BONDING OPERATION)

2. Description

APII is a right and left universal fixed class II correction appliance. The APII appliance comprises three stainless steel components, a maxillary first Molar Attachment, a Receiver, a universal Maxillary Arm that can be adjusted (cut) "in-office" to the appropriate length for the patient, and two ligature ties.

One side of the Maxillary Arm connects to the Receiver, which pivotally connects to the maxillary Molar Attachment and provides a stable connection to ensure an easy bonding procedure. The Molar Attachment is direct bonded to the 1st molar, using conventional light-cure orthodontic adhesive. The Maxillary Arm's opposite end is direct bonded to the maxillary cuspid or bicuspid using conventional light-cure orthodontic adhesive.

The Ligature Ties attached to the Maxillary Molar Attachment provide additional stability to the APII assembly and keep the Universal Maxillary Arm from swinging labially during the bonding operation.

An elastic rubber band with the desired force, selected and supplied by the doctor, is connected from the hook on the cuspid end of the Maxillary Arm to an appropriate anchor point chosen by the clinician, typically a mandibular 1st or 2nd molar tube. An APII appliance is placed on both sides of the patient's mouth.

The appliance is sold non-sterile and is designed for single use.

Orthodontic adhesives and various hand instruments are required for bonding the APII to the patient's teeth.

Other ancillary orthodontic products, generally available to the orthodontic industry, may be used with the APII to complement treatment. Follow the manufacturer's instructions for use for all ancillary orthodontic products used with the APII device.

3. Intended Use

The APII is intended for orthodontic treatment of children, teens, and adults. Other devices like elastomeric bands or similar force modules will be used with the APII device.

Devices are supplied:

- Non-sterile.
- Designed for single-use.
- For use by dentists and orthodontists only.

4. Intended User

The intended user of the APII devices are clinicians (professionally licensed orthodontists and dentists) and their trained personnel within orthodontic and dental offices. The APII devices are sold for professional use only.

5. Indications for use

The APII appliance is indicated to be used on both sides of the maxillary arch during the initial phase of therapy to treat Class II malocclusions without extractions and establish a Class I molar relationship by rotating and up-righting the maxillary first molar while distalizing the posterior segment of the maxillary arch (canine or premolar to molar).

6. Contraindications

- Patient's inability or unwillingness to cooperate/or 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.

7. Warnings and Precautionary Measures

- Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
- The APII appliance 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.
- 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 on patients with known allergies to any of the materials in the APII appliance. Immediately remove the appliance in the event of an allergic reaction.
- Devices are sold non-sterile.
- MRI (Magnetic Resonance Imaging) Safety Information
    - The APII Class II Appliance is MR unsafe. When scheduling an MRI or other radiology sevices while wearing orthodontic appliances, always inform MRI or other radiology staff prior to the procedure so that proper coordination of care can be arranged.
    - The APII Class II Appliance has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating migration, or image artifacts in the MR environment. Scanning a patient who has this device may result in patient injury, unintended appliance movement or detachment.
- Do not use any products that are damaged or do not comply with the labeling specifications.
- Ensure the APII Arm is completely inserted and attached to the APII Receiver and the APII Receiver is engaged to the APII Molar Attachment.
- Care should be taken to avoid contact with opposing teeth at occlusion.
- Follow all regional and national standards regarding the use of orthodontic appliances.
- If, in relation to the use of the APII device, 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 and/or bracket guards as recommended by the dental professional treating the patient.
- Always inform the MRI or radiology staff that braces are in place before any procedure to ensure appropriate measures are taken for the procedure.

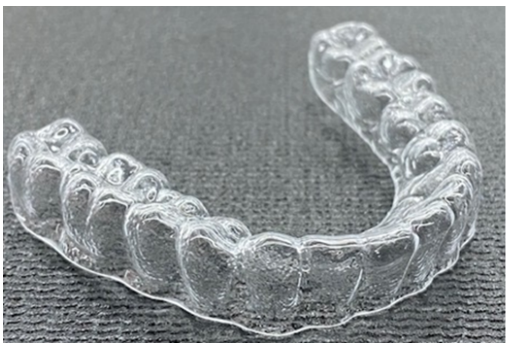
9. General Information for the Dentist/Orthodontist

- As part of developing a 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.

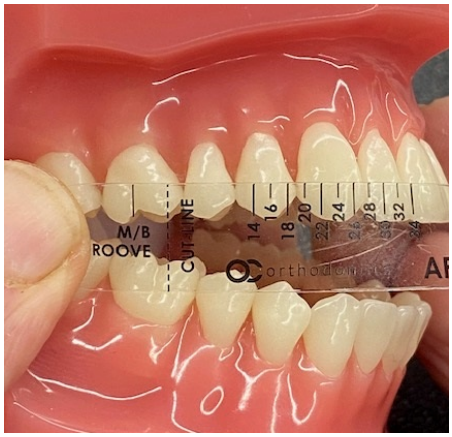
10. Handling Procedure on How to Use the Medical Device (Instructions for Use)

- **Required Instruments**
  - Hemostat, Forceps, Tweezers, etc
  - Orthodontic Hard Wire Cutter or Laboratory Cutter
  - Weingart Plier
  - Debonding Instrument

- **Mandibular Arch Anchorage**
  - Anchorage must be incorporated on the mandibular arch to avoid protrusion of the lower incisors.
  - Various types of anchorage can be utilized based on the orthodontist's preference. A mandibular thermoformed tray with direct bonded molar tubes is the recommended type of anchorage.
  - The recommended material for a thermoformed tray is GT Flex 1 mm thickness. If the lower 2nd molars (lower 7) have fully erupted, it is preferred to use them to stretch elastics from the cuspid/bicuspid.

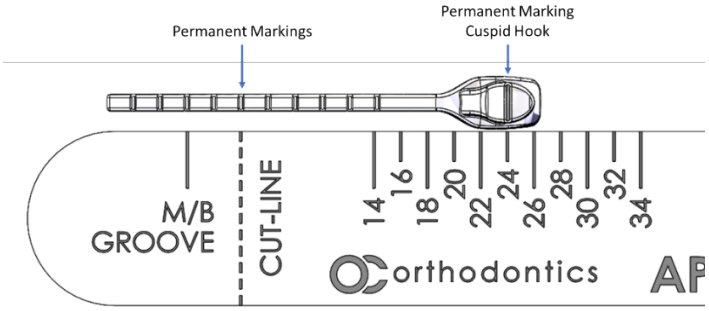


- **Maxillary Arm Adjustment**
  - The Maxillary Arm and Molar Attachment are universal and can be used on the right and left sides of the patient's maxillary arch.
  - The length of the Maxillary Arm is universal and must be adjusted to the specific length needed for the patient.
  - Using the APII Sizing Template, align the "M/B Groove" marking with the buccal groove on the maxillary first molar and determine the appropriate length to the height of the contour on the cuspid or bicuspid, depending on which tooth the mesial end of the Maxillary Arm will be bonded. The APII Sizing Template has a transparent protective film on its front surface. While it is not absolutely necessary, removing the transparent protective film can improve the clarity of the graduations and numbers on the Sizing Template.

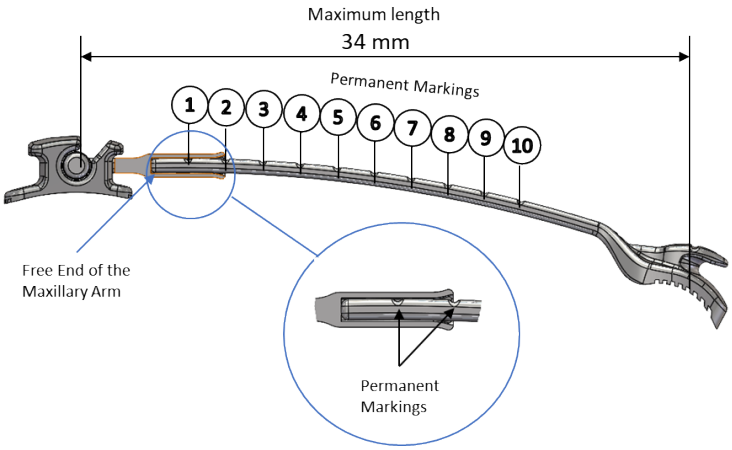


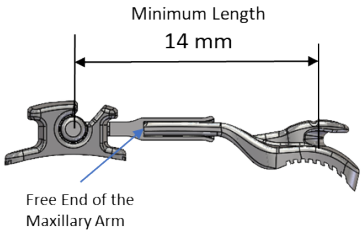
  - Use the APII Sizing Template to align the permanent marking of the cuspid hook with the desired length of the appliance. The "CUT-LINE" of the APII Sizing Template will indicate the approximate location of where to cut the free end of the maxillary arm using an Orthodontic Hard Wire or Laboratory Cutter.

The permanent markings along the length of the maxillary arm are in 2mm increments. A 1mm reduction in length can be accomplished by cutting the arm at the mid-point between two markings.



The following table provides the overall length of the receiver/Maxillary Arm assembly when the Maxillary Arm is cut at each permanent marking.





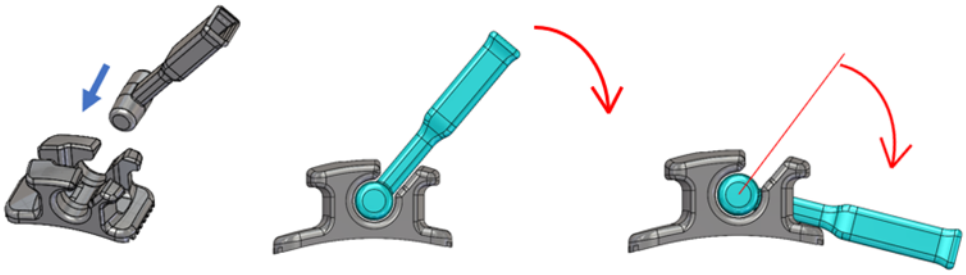
Permanent Marking	Overall Length in mm
As provided	34
1	32
2	30
3	28
4	26
5	24
6	22
7	20
8	18
9	16
10	14

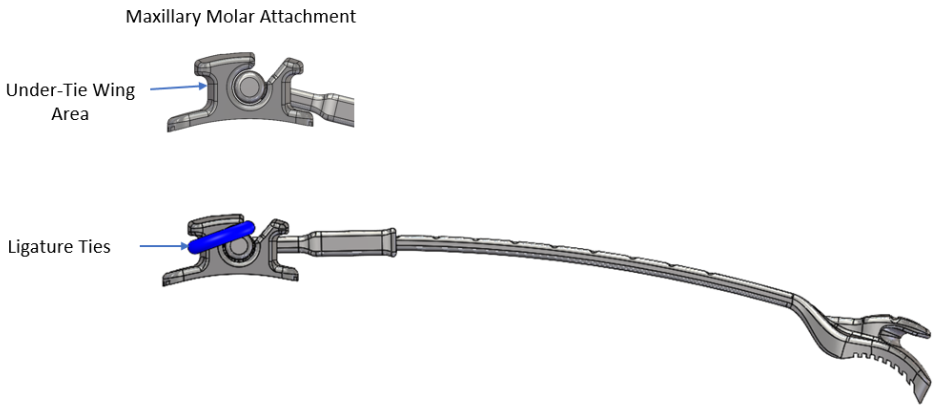
- Insert the free end of the Maxillary Arm into the Receiver after the Maxillary Arm is cut to the appropriate length.
- With the Maxillary Arm fully seated in the Receiver, use an Orthodontic Hard Wire Cutter or similar instrument to squeeze down the occlusal gingival surfaces of the Receiver in two areas (near the funnel entry of the Receiver & the mid-point of the Receiver) to secure the Maxillary Arm in the Receiver.

- To adjust the Maxillary Arm to the torque or rotation of the cuspid, follow these steps:
  - To properly adjust the cuspid pad, use two Weingart Pliers or similar instruments to hold the free end of the Maxillary Arm. With one Weingart plier, hold the arm at the free end of the arm just past the last visual marking near the cuspid/bicuspid pad. Place a second Weingard Plier next to the hook and apply a gentle force to adjust the torque, rotation, or both of the cuspid pad as necessary.

- **General Bonding**
  - Use conventional orthodontic adhesive, following the manufacturer's instructions to bond the APII appliance to the patient's teeth.

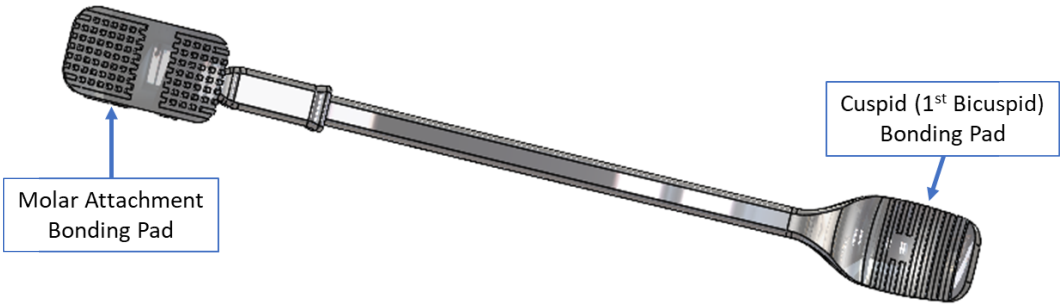
- **Bonding the APII Appliance**
  - The factory-installed Ligature Ties are attached to the tie wings of the Maxillary Molar Attachment. The Ligature Ties will keep the Maxillary Arm from swinging labially and accidentally disengaging from the Maxillary Molar Attachment and improve the overall stability of the APII assembly during the bonding operation.
  - If the Receiver was removed from the Molar Attachment during the Maxillary Arm Adjustment, engage the Receiver/Maxillary Arm assembly into the Molar Attachment as illustrated in the following figure. The Receiver can be engaged in the Molar Attachment from the gingival or occlusal side of the Molar Attachment. Rotate the Receiver as shown to lock it into the Molar Attachment. Finally, re-install the Ligature Ties on the Molar Attachment tie wings to stabilize the APII assembly.





  - Use an appropriate instrument (hemostat, forceps, tweezers, etc.) to handle the APII appliance.

- Apply a generous amount of adhesive to the Molar Button bonding pad and the cuspid (1st Bicuspid) bonding pad.



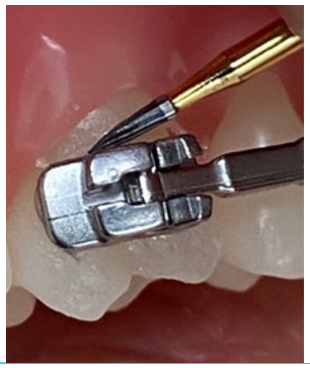
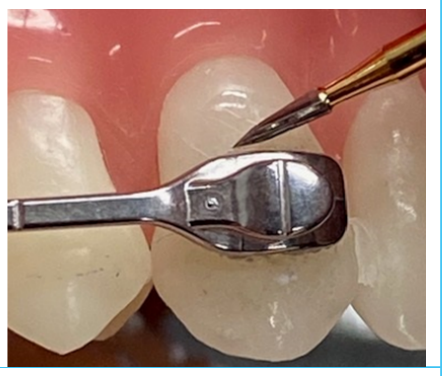
- First, position the molar attachment bonding pad on the 1st molar and align with the buccal groove on the 1st molar. Next, position the cuspid pad onto the mesial 3rd of the cuspid or 1st bicuspid.
- Make any necessary fine adjustments to position the APII appliance properly.
- Remove excessive adhesive while maintaining the alignment of the APII appliance.
- First, fully light cure the molar pad. Next, fully light cure the cuspid or 1st bicuspid pad.
- **REMOVE THE FACTORY-INSTALLED LIGATURE TIES!**

11. Activation of the APII appliance

- With the lower mandibular thermoformed tray in place or other appropriate anchorage, attach an elastic on the lower 1st or 2nd molar tube and connect the other end of the elastic to the hook on the cuspid/1st bicuspid pad.
- The orthodontic professional should select the appropriate elastic product to treat the individual case and establish appropriate, timely follow-up appointments.

12. Debonding Procedure

- **Removal of the Maxillary Arm**

Remove excess adhesive flash around the cuspid (1st bicuspid) bonding pad and the Molar Attachment bonding pad using a Flame Carbide Bur or equivalent.	 
To minimize patient discomfort, place a cotton roll perpendicular to the cuspid (1st bicuspid) and have the patient bite down on it.	
The following instruments are useful for debonding the Maxillary Arm and the Molar Attachment. • Bracket Debonding Pliers • Angled Bracket Debonding Pliers • Mini Pin & Ligature Cutter	
Debond the Universal Maxillary Arm from the cuspid/bicuspid.	
Remove the Receiver/Universal Maxillary Arm assembly from the Molar Attachment by swinging it out labially and disengage it from the Molar Attachment by sliding it occlusally.	
Debond the Molar Attachment after removing the Receiver/Universal Maxillary Arm assembly.	
Remove any adhesive residue remaining on the tooth surface with an appropriate adhesive-removing instrument.	

13. Cleaning and sterilization instructions

- The device is provided non-sterile and is not intended to be sterilized by the user. The industry standard of care for orthodontic devices is that they are provided to the orthodontist in protective packaging, removed from the packaging for use on the patient, and not handled or sterilized before use.
- There is no information available that would preclude the use of commonly available oral healthcare products like toothbrushes, toothpaste, water picks, mouthwashes, etc.

14. Disposal (if applicable)

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

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

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

16. Name and address of labeler

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

17. Other Information – Supplementary Documents

- 105-7310-01 – Symbols Glossary
  - Explanation of symbols on product labeling.
- 105-7320-01 – 17-4 Stainless Steel Orthodontic Devices Material and Chemical Characterization
  - Materials used in APII Class II Appliance

18. Request for IFU and/or Supplementary Documents in Paper Form

- Identical IFU and Supplementary Documents in paper form can be requested by phone: (866)752-0065 / International: 1 (503) 472-8320 or by email info@oc-orthodontics.com
  - Provide the product name, REF number (part number), and address you would like to receive the paper copy. The paper copy will be delivered to the indicated address within seven calendar days with no additional cost.

105-7300-25 (DOC-422) Ver. 8

Approved By:

(CO-1040) MR Unsafe - APII, Buttons, Stops, Hooks, Coil Springs, & Preformed Lig Ties

Description

Activating MR Unsafe symbol on labels for APII, Buttons, Stops, Hooks, & Coil Springs.

Justification

MR Unsafe needed on labels. There is an updated MRI warning

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

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	August 5, 2026 4:13 PM PDT	CO-1040	8	Published
Maureen Janssen	March 13, 2025 7:22 AM PDT	CO-643	7	Superseded
Maureen Janssen	January 27, 2025 8:44 AM PST	CO-599	6	Superseded
Maureen Janssen	May 29, 2024 8:10 AM PDT	CO-445	5	Superseded
Juergen Bathen	April 16, 2024 8:46 AM PDT	CO-376	4	Superseded
Maureen Janssen	March 13, 2024 2:27 PM PDT	CO-333	3	Superseded
Juergen Bathen	February 27, 2024 8:15 AM PST	CO-317	2	Superseded
Juergen Bathen	January 10, 2024 9:46 AM PST	CO-297	1	Superseded
Maureen Janssen	December 7, 2022 6:44 AM PST	CO-53	0	Superseded