

1. IDENTIFICATION OF THE COMPANY

Company Name
 American Orthodontics
 3524 Washington Avenue
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24 HR EMERGENCY TELEPHONE NUMBER
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 Telephone for Information
(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Jones Jig
Product Description: Molar Distalizing Assembly
Part Numbers:

H.G. Occlusal .018	REF	855-400
H.G. Occlusal .022	REF	855-401
	REF	855-402
	REF	855-403



H.G. Gingival .018 **H.G. Gingival .022**

Patent Number: #5,064,370
Material: 300 Series Stainless Steel

CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

3. KIT COMPONENTS

<u>Part Name</u>	<u>Part #</u>	<u>Qty</u>	<u>Part Name</u>	<u>Part #</u>	<u>Qty</u>
H.G. Occlusal - .018	REF 855-400	Kit of 20	H.G. Occlusal - .022	REF 855-401	Kit of 20
H.G. Gingival - .018	REF 855-402	Kit of 20	H.G. Gingival - .022	REF 855-403	Kit of 20
H.G. Occlusal - .018	REF 855-404	1 Mainframe	H.G. Occlusal - .022	REF 855-405	1 Mainframe
H.G. Gingival - .018	REF 855-412	1 Mainframe	H.G. Gingival - .022	REF 855-413	1 Mainframe
Spring	REF 855-410	1ea	Sliding Eyelet Tube	REF 855-411	1ea
12 Minute Video	REF 400-400	1ea			

4. SUMMARY OF PRODUCT

This appliance distalizes maxillary molars within the maxillary arch. Force is obtained by compressing the open portion of a superelastic nickel-titanium coil spring against an achnor mechanism that is banded to the second bicuspid. The forces are low and continuous. Patient cooperation is eliminated. Although the appliance may be used anytime throughout orthodontic treatment, it has been particularly effective at the beginning - the patient does not require anterior brackets until the molar correction is achieved.

5. INDICATIONS FOR USE, DOMAIN OF USAGE

American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

6. CONTRAINDICATIONS

American Orthodontics sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as working sequence of the medical devices. This will include any sterilization procedures.

7. SIDE EFFECTS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury and/or contraindications that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly. During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

8. PRE-STARTING PROCEDURES

Read all instructions and study photo details carefully before proceeding. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as working sequence of the medical devices. This will include any sterilization procedures.

9. STEP-BY-STEP INSTRUCTIONS

1. Fit maxillary second bicuspids with bands.
2. Take maxillary impression.
3. Wax maxillary second bicuspid bands in impression and pour.
4. Construct modified Nance:
 - a. Contour .036" to palate and solder to lingual of maxillary second bicuspid bands.
 - b. Salt/pepper acrylic on palate; the button should resemble a modified "butterfly," i.e. from mesial of 5 | 5 to middle of 3 | 3 anteroposterior and laterally within 3.5 mm of 43 | 34. The acrylic must be trimmed away to relieve the incisive papilla (Fig. 1).
 - c. Trim and polish the appliance.
5. Cement the maxillary first molars and second bicuspids.
6. Contour buccal arch form into the .036" jig mainframe, placing it close to the cuspid to avoid lip irritation. Assemble appliance by placing the spring followed by the sliding eyelet tube. The last 5 mm of the .036" frame has been annealed to bend easily; roll this over into a comfortable loop/stop (Fig. 2). The mesial of the loop should end at the middle 1/3 to distal 1/3 of the cuspid.
7. Twist an .010 ligature around the mesial tie wing of the second bicuspid and secure. Do not clip excess wire.
8. Place the assembly into the headgear and arch wire slots. Ligate securely as illustrated (Fig. 3). The mainframe should be parallel to the occlusal plane.
9. Thread one end of the ligature wire, which was previously wrapped around the 2nd bicuspid, through the sliding eyelet tube and compress the coil spring until closed end sections just touch. Twist to secure. **DO NOT OVER COMPRESS THE SPRING.** Tuck the cut ligature under the appliance arm.
10. Schedule patient return for four to five weeks. IF THERE IS NO TIP in either molars or bicuspids, compress open coil in spring. IF THERE IS TIP, check the tightness of the molar tieback and dismiss. The tip should be eliminated by next appointment. Make sure the spring has not been over-compressed.

Fig. 1

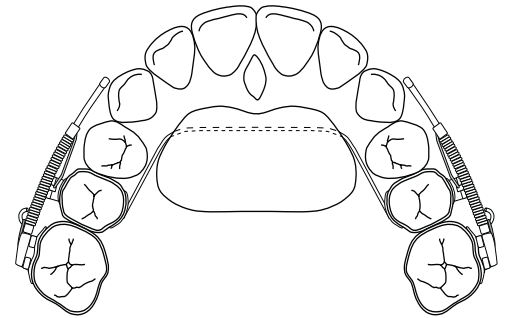


Fig. 2 (headgear gingival illustrated)

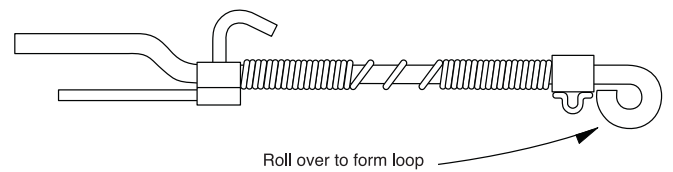
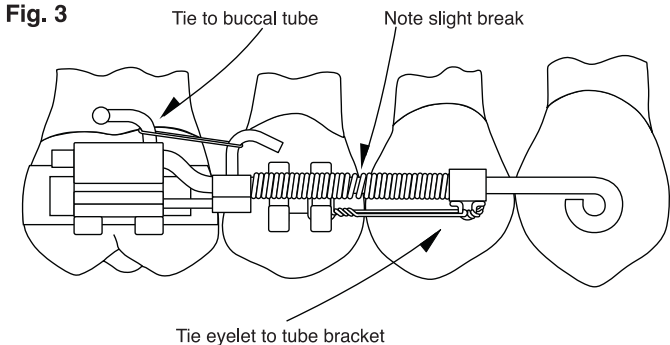


Fig. 3



10. DISCUSSION AND SUGGESTIONS

1. Maxillary anterior teeth normally are not bonded/banded until the molar correction is achieved. This is done so as not to "round trip" these teeth.
2. The design of the modified Nance is important. The Nance must be designed to rest the hard palate only. It is approximately 2 x 1½ centimeters and generally oval in shape. It is designed to avoid contact with the incisors, canines, bicuspid teeth and the incisive papilla.
3. When placing buccal arch contour into the jig frame, note rotation of maxillary first molars. If insertion of the stabilizing wire into the arch slot is difficult, or requires a severe first order bend, insert the .036 leg into headgear tube and let the stabilizing wire lay buccal to the arch slot. Ligate securely with .014 ligature wire to prevent rolling of the appliance. In 2-3 appointments, the molar should rotate disto-buccal such that easy insertion of the stabilizing wire into the arch slot is possible.
4. The treatment that is chosen to be accomplished in the lower arch is dictated by that arch independent of the maxillary molar treatment. If the overjet/overbite relationship allows for treatment to proceed in the lower arch, treatment is started along with the upper molar correction with the Jones Jig. We do not recommend the Nance be built up to make a bite block to "unlock the occlusion," as palatal irritation will surely follow along with loss of palatal anchorage.
5. To maintain the molar correction, several options can be used:
 - a. Korn maxillary lip bumper
 - b. Bond anterior teeth and place a stopped arch wire mesial to molars

- c. A maxillary Hawley-type appliance, with wire stops mesial to molars
- d. Transpalatal bar
- e. An inactive Jasper Jumper may be used
- 6. The means used to retract the bicuspid and cuspids is dictated by your own mechano-therapy, as long as the molars are maintained in their corrected position. You can use Class II mechanics as your diagnosis of facial type and growth dictate.
- 7. You can determine within reasonable accuracy when the molar correction will be accomplished without depending on patient cooperation to achieve the desired results. A typical Class II should be corrected in four to six months. Class II, Division 2 and true Class II malocclusions, where the mesial lingual cusp is mesial also, will take from eight to fourteen months.
- 8. One of the benefits of this appliance is there is no vertical component to the force system, thereby eliminating the deleterious effects that are found in Class II elastics or cervical headgear therapy. This appliance exerts a true Class I force delivery.
- 9. Another benefit of the Jig is that it may be used unilaterally.
- 10. A video tape is available from American Orthodontics for further information.

11. STORAGE AND TRANSPORT CONDITIONS

There are no storage and transport conditions that will negatively affect the product/medical device outside of harsh or rough handling; which could cause mechanical damage.

12. DISPOSAL CONSIDERATIONS

American Orthodontics' products are designed and manufactured for single use and, once removed from the patient's mouth, must be disposed of properly. American Orthodontics expressly disclaims any liability for the spread of disease or personal injury caused by reuse. It is the primary responsibility of the dental professional and/or orthodontist to follow applicable laws relating to the disposal of used orthodontic medical devices.


13. WARRANTY LIABILITY

Buyer's remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller's option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

14. REGULATORY INFORMATION



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The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. **Reasonable safety precautions must always be observed.**