

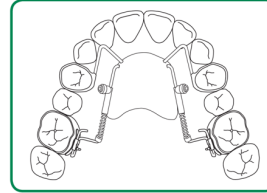
1. IDENTIFICATION OF THE COMPANY

Company Name
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER
(920) 457-5051
 Telephone for Information
(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Distal Jet
Product Description: A Lingual Molar Distalizing Appliance
Product Part Number: REF 855-500
Patent Number: #5,785,520
Material: 300 Series Stainless Steel



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



A Lingual Molar Distalizing Appliance
 Created by Dr. Aldo Carano and Sig. Mauro Testa

the distal JET™

*Patent # 5,785,520

3. KIT COMPONENTS

Part Name	Part #	Qty	Part Name	Part #	Qty
Bayonet Director	REF 855-502	10ea	Lingual Sheaths	REF 852-141	10ea
Bondable Connector	REF 855-503	10ea	Activation Lock	REF 855-608	10ea
Standard Bayonet	REF 855-504	10ea	Distal Stop	REF 855-510	10ea
Transpalatal Connector	REF 855-505	5ea	.050 Hex Wrench	REF 855-515	10ea
NiTi Springs – 240gms	REF 855-607	10ea			
NiTi Springs – 180gms	REF 855-607	10ea			

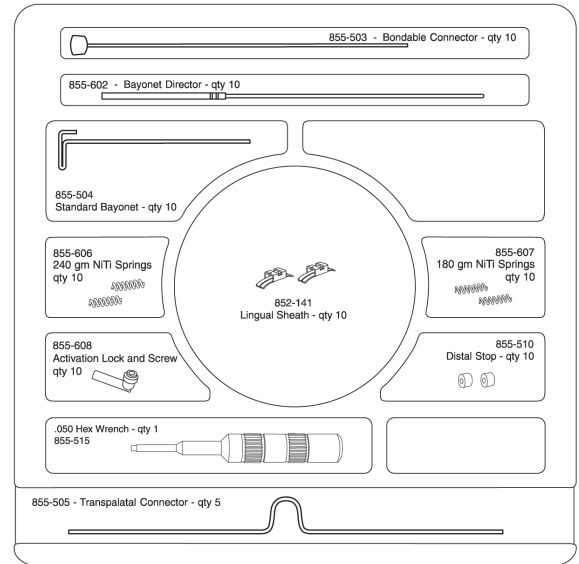
4. INTRODUCTION TO THE PRODUCT FAMILY

The Jet Family is a collection of user-friendly orthodontic appliances created to deliver consistent and reliable treatment results while requiring the minimum of patient cooperation. Constructed around a highly efficient piston and tube principle, coupled with controlled and defined force delivery, the Jet appliances are uniquely adapted in their bio-mechanic approach to maximize outcomes. Each one specifically addresses a common, yet challenging, clinical situation routinely confronted in daily practice.

5. OTHER PRODUCT FAMILY MEMBERS

SPRING JET 1 & 2 FOR ARCH EXPANSION KIT REF 855-520
 UPRIGHTER JET FOR TIPPED TEETH REF 855-513
 MESIAL JET FOR PROTRACTION KIT REF 855-522

For more information regarding other members of the Jet Family, contact your local representative, American Orthodontics' corporate Office, or visit www.americanortho.com



6. 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.

7. 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.

8. 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.

9. 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.

The Distal Jet's success, as with any laboratory appliance, is determined by the base it is built on: An accurate and detailed working model with correctly placed and sized bands is absolutely essential for proper fit and performance of the finished appliance.

10. KEY ELEMENTS

LINGUAL SHEATHS - Position with entry as close as possible to the center of resistance (CR).

TRANSPALATAL CONNECTOR - Extend anteriorly to contact the middle of the cuspid or slightly beyond - Maintain a 1mm clearance from the palate for acrylic.

BAYONET AND DIRECTORS - Parallel, as closely as possible, to the arch form at the level of the centers of resistance of the posterior teeth.

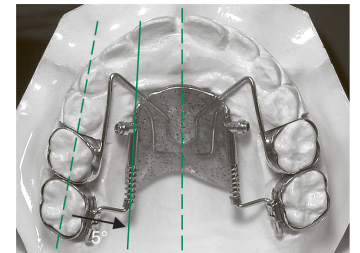
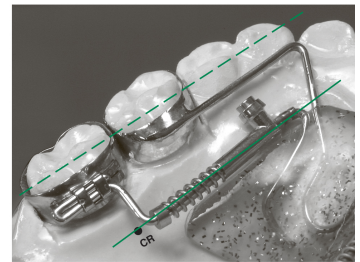
- *IMPORTANT: When viewed from the occlusal, the bayonet assembly – bayonets and bayonet directors – should be positioned with a 5° diversion away from the arch form and toward the palatal midline to avoid expansion of the molar during distalization.*

NANCE BUTTON - Extends anteriorly to the incisive papilla without impinging on it.

- Laterally extends to and parallels the bayonets and directors. The lateral border should prevent "rolling" of the activation lock for easy access to the activation screws.

- Ends at the distal of the second bicuspid or deciduous second molar teeth.

- Should be as smooth and thin as possible to provide maximum patient comfort.



11. STEP-BY-STEP INSTRUCTIONS

1. Form the transpalatal connector (check Key Elements). Wax in place.
2. Solder and polish. Reposition on model.
3. Paint separating medium on palate.
4. Bend bayonets, insert in sheaths (check Key Elements). Adjust and cut to length as necessary.
5. Place directors on bayonets, bend wire section, adjust and cut to length.
6. All cut ends of the bayonets and directors must be smooth and burr free. Check for free sliding movement without friction.
7. Salt and pepper acrylic Nance Button.
8. Trim and polish.
9. Add stops, springs and locks; tighten screws lightly. Lock and screws should be positioned for easy access in the mouth. Springs should NOT be compressed.
10. Tie elements together as one unit with ligature wire or floss from mesial of the lock to the vertical arm of the bayonet.

NOTES - All elements follow natural anatomical contours, connect together passively, and do not impinge soft tissues at any time.

- Anchorage options: 1st bicuspid, 2nd bicuspid, 2nd deciduous molars (mixed dentition case with 2nd deciduous molars shown).

12. APPLIANCE PLACEMENT AND ACTIVATION

1. Remove separators and clear any debris from the interproximal areas. Seat the appliance completely, checking the fit prior to cementation. Check passive fit of directors and bayonets – adjust as necessary.

- Mix cement, load bands and cement the appliance as a single unit, in the customary manner.
- After cement clean-up, remove stabilizing floss or wire prior to activation.
- The appliance is activated initially after cementation and at four week intervals by complete compression of coil spring with the activation lock (see special note below).
- After distalization is complete, convert the Distal Jet to a retainer.
- Peel the spring from the appliance with a Weingart plier.
- Slide the lock firmly against the stop and tighten the screw. (Fig.1)

NOTE: When activating appliance assemblies, it is recommended to turn the screw no more than 60° - 90° past initial contact with the Bayonet Director tube. When this is done, adequate positional retention of the tube in the Activation Lock will be achieved and no crushing of the tube will occur.

- Squeeze the end of the lock tightly onto the bayonet wire. Important: this prevents the appliance from becoming loose. (Fig.2)
- An alternative option is to tie the lock and bayonet wire/molar sheath together with a steel ligature or elastic chain or thread. (Figs.3 & 4)

SPECIAL NOTE Molar rotations must be corrected before they are distalized. This is easily accomplished in the lab by bending rotational compensation into the double-back sections of the bayonets. Seat and cement as above, do not activate, and recall in one month. Begin activation after molars are corrected.



13. 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.

14. 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.

15. 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.

16. REGULATORY INFORMATION

EC REP MT Promedt Consulting GmbH • Altenhofstrasse 80 • 66386 St. Ingbert • Germany

American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • (920)457-5051

 SINGLE USE ONLY

 SEE INSTRUCTIONS FOR USE

 NON STERILE

 WARNING CONTAINS CHROMIUM AND/OR NICKEL
FOR SYMBOL GLOSSARY VISIT WWW.AMERICANORTHO.COM

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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.**