

**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  
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**2. IDENTIFICATION OF THE PRODUCT**

**Product Name:** Jasper Jumper™  
**Product Description:** Fixed Functional Appliance  
**Product Part Number:** REF 852-900  
**Patent Number:** #4,708,646  
**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**

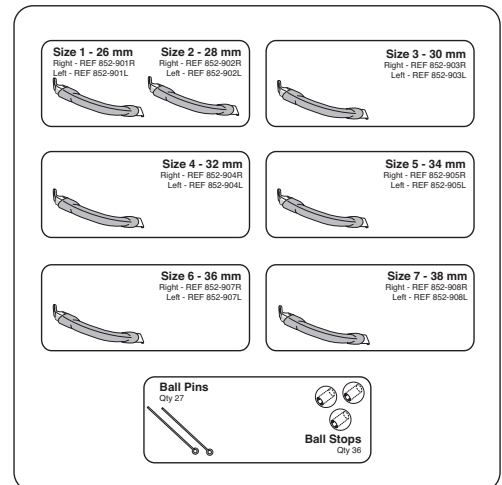
Part Name	Part #	Qty	Part Name	Part #	Qty
Jasper Jumper Right Sz1	REF 852-901R	1ea	Jasper Jumper Left Sz1	REF 852-901L	1ea
Jasper Jumper Right Sz2	REF 852-902R	1ea	Jasper Jumper Left Sz2	REF 852-902L	1ea
Jasper Jumper Right Sz3	REF 852-903R	2ea	Jasper Jumper Left Sz3	REF 852-903L	2ea
Jasper Jumper Right Sz4	REF 852-904R	2ea	Jasper Jumper Left Sz4	REF 852-904L	2ea
Jasper Jumper Right Sz5	REF 852-905R	2ea	Jasper Jumper Left Sz5	REF 852-905L	2ea
Jasper Jumper Right Sz6	REF 852-907R	1ea	Jasper Jumper Left Sz6	REF 852-907L	1ea
Jasper Jumper Right Sz7	REF 852-908R	1ea	Jasper Jumper Left Sz7	REF 852-908L	1ea
Ball Pins		27ea	Ball Stops		36ea

**4. THE JUMPER**

As an adjunct to fixed appliance therapy, the Jasper Jumper presents an opportunity to minimize extractions and to reduce or eliminate headgear. When activated 4 mm, the Jasper Jumper will exert 360 grams of force. The Jumper is the first of a new category of orthodontic appliances that can produce rapid intermaxillary changes because it is fixed. It delivers a gentle, continuous force that can move teeth singly or in large groups to produce significant dental alveolar and pro le changes. This process “jumps the bite” and achieves a correct anterior/posterior relationship in much less time than more traditional approaches. Depending on the case, the Jumper can apply “headgear like” forces, “activator like” forces, or a mixture of both.

The Jasper Jumper provides the following:

1. It is fixed so patient cooperation is assured.
2. It works along the growth or Y axis, thus properly advances the mandible rather than retracting the maxilla.
3. Because of the ball joint, the Jumpers swivel allowing normal functions such as eating and tooth brushing.
4. It is safe. No extra-oral traction is involved.
5. It is cosmetic
6. It can be used for Class II or Class III corrections and can be used to apply different forces on each side of the jaw for cross bites.
7. Forces are adjustable and measurable.



**5. DESIGN**

The primary design goal was to create a fixed appliance. Orthodontists have seen the benefits of fixed appliances in individual arches. Very little progress, however, has been made toward linking these two separate tooth alignment mechanisms together to produce occlusal improvements. Extraoral appliances were not considered as they are all removable. Extraoral forces also have safety problems and poor patient acceptance. Therefore, a method of intraoral/intermaxillary linkage was seen as the only logical approach to the problem. There are only four possible ways to physically link the upper and lower jaws together. The jaws may be fixed together either rigidly or flexibly and they can either be pulled together or pushed apart. This gives us four possible categories of appliances.

## **6. HEADGEAR AND ACTIVATOR TYPE EFFECT**

Fixed forces allow the orthodontist to apply a gentle, continuous force that can affect the growth of the face and jaws 24 hours a day. The orthodontist can then program how the Jumper will impact the upper or lower arch to produce primarily a headgear effect or primarily a lower advancement and development effect - or a mixture of both. To produce a headgear effect, first prepare the lower arch as a "solid anchor". This can be done by using a large rectangular archwire with anterior lingual crown torque and molar tip backs. The second molars should be banded and the arch tied back. It can be anchored even further with the use of a lingual arch and/or a lip bumper. The upper arch is not tied back, so the upper molars are allowed to slide distally along the archwire into Class I. Once they are back, you can then slide the other teeth back singly, or in small groups, using the Jumpers to retain your upper molars distally in Class I. This program pits the entire solid, lower arch against two upper teeth and thus produces maximal upper distalization. To produce an activator effect, make both the upper and lower arches into "solid anchors" with large, rectangular wires and appropriate torques. When the Jumpers are in place, instruct the patient not to resist the push of the Jumper and to posture forward into Class I. Thus, very little force is placed on the teeth and the developing facial matrix will have an opportunity to normalize its growth. The Jumper holds the jaws and/or teeth in the preferred position and allows the natural growth and remodeling characteristics of bones and muscles to develop in ways which support that preferred position. There is considerable controversy over whether or not it is possible to "create" growth in this manner. To normalize the facial environment by posturing into Class I simply gives the face an opportunity or a potential to grow. Whether or not this occurs is then controlled by heredity, age, or other factors beyond our control. The Jumper gives the orthodontist a tool to do either or both of these techniques. The Jumper is not limited to a single effect, like headgear, and is more analogous to the braces themselves that produce varied responses. To be able to use and control "braces" to produce a full range of responses requires skill and patience. The brackets and wires simply produce a fixed force. The orthodontist must then apply and direct this force to achieve treatment goals. The same is true of the Jumpers. Skill and experience will allow you to make full use of this important tool in your armamentarium.

## **7. FORCES**

**Pulling Forces:** One of the unfortunate side effects of pulling mechanics is that extrusive forces are placed on the teeth. Extrusion of the upper incisors is very undesirable and lower molar extrusion can open the bite by rotating the mandible downward and backward which negatively effects the profile and occlusion. These forces also tend to narrow and constrict arch development and have a lingual force vector on the crowns.

**Pushing Forces:** On the other hand, pushing mechanics all have intrusive force vectors as a side effect and this is generally beneficial. Intrusion of the lower incisors is usually necessary during the correction of a Class II malocclusion. Furthermore, upward pressure on the maxillary molars prevents their extrusion. Intrusive forces have an expansive effect. Another beneficial side effect of pushing mechanics is that the forces parallel the natural growth vector of the face. The face grows downward and forward roughly along the Y-axis. Pushing forces act along this axis to encourage development as opposed to pulling forces which act 90° out of phase to facial growth. Another unique advantage of pushing forces is that the appliance can be pushed away from the teeth during eating and brushing. This is the key side effect that allows for a comfortable, hygienic fixed appliance. When chewing, the Jumper curves away from the occlusion into a "C" shape. Patients can actually eat, brush and function with this appliance in place. In addition, since they are intraoral, they are nearly invisible.

## **8. 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.

## **9. MEASURING FOR CORRECT SIZE**

To get the right length, have patient bite in their retruded or centric bite and measure from the mesial of the headgear tube to the distal of the lower ball stop, then add 12 mm (4 mm for the tube, 4 mm of free play, 4 mm of built-in activation). Some patients may require a different length Jumper on their left or right side.

## **10. 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.

## 11. 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.

## 12. 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.

## 13. CASE SELECTION

Any Class II patient with a deep bite – either extraction or non-extraction. Or an adult or Class I case to increase your anchorage during anterior retraction. Lower jaw advancement can relieve pressure on the T.M.J. and improve function. However, joint function should be evaluated prior to Jumper installation and monitored throughout treatment.

## 14. ARCH WIRES

The largest rectangular wire possible.

**1. Upper Arch:** The action of the Jumper tends to intrude, tip, distalized and expand the upper molars. Your upper rectangular arch therefore should be narrowed slightly and have palatal crown torque on the molars. If a palatal arch is used to control the upper molars, then any size upper arch wire may be used. The upper anteriors should have labial crown torque.

**2. Lower Arch:** It is necessary to have 6-8mm space distal to the lower arch ball stops. In an extraction case, use the Jumpers to correct the bite prior to complete retraction of the lower cuspids or remove the 5|5 brackets. In a non-extraction case it will be necessary to remove the first bicuspid brackets during the Jumper phase. Ideally, lower second molars should be banded. Place lingual crown torque in the lower incisor area to prevent anterior tipping, or use  $-10^\circ$  torqued lower incisor brackets.

## 15. INSTALLATION

1. At a prior appointment, remove the lower 1<sup>st</sup> bicuspid brackets, if necessary, and fabricate your lower rectangular arch wire. Make your anterior bends first, then make a sharp, 2mm. bayonet bend just distal to the cuspids to act as a stop for the lower ball stop. Slide the balls onto the arch wire. Then add any other necessary bends distal to the balls.

2. Then schedule the patient for a lower arch adjustment for the following month. At that time, remove the lower arch and make necessary adjustments. You are now ready to install the Jumpers. They will be available in different lengths (see chart on last page).

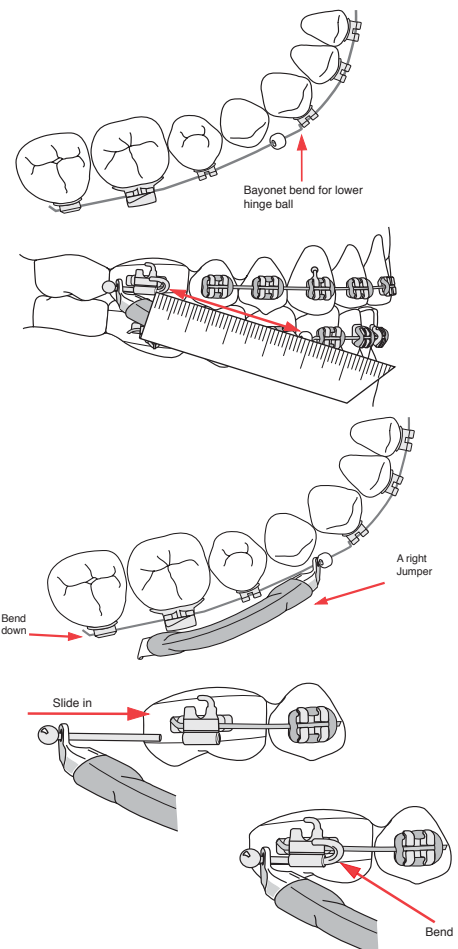
To get the right length, have the patient bite in their retruded or centric bite and measure from the mesial of the head-gear tube to the distal of the lower ball stop, then add 12mm (4mm for the tube, 4mm of free play, and 4mm of built-in activation). Some patients may require different length Jumpers on the left or right side.

### **Do not overactivate Jumper.**

3. Then slide the right and left Jumpers onto the lower arch wire and ligate it into the mouth. Elastic modules are fine, except for the bicuspid brackets -- they should be tied with ligature wire for extra strength. Bend the distal end of the wire down past the 7|7 to prevent anterior movement or tie it back.

4. You are now ready to attach the Jumper to the upper molar tubes. Slide the upper ball pin through the distal end of the Jumper and then through the molar head-gear tube from the distal. This ball pin wire can then be bent into a hook to secure it. (The front half of this wire has been annealed to facilitate bending.) Be sure to leave 4mm free play between the upper ball pin and the distal end of the buccal tube.

5. The Jumpers are now completely installed! You can adjust or balance their forces by pulling the ball pin through the tube and bending



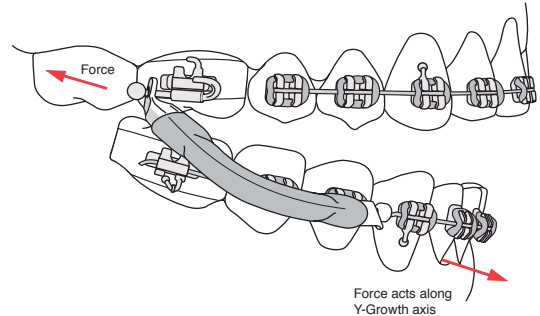
it as you would to activate a closing loop arch. If more activation is needed, slide the lower ball distally and place a crimpable stop anterior to the ball or replace the Jumper with the next longer size.

6. As the condition corrects over the next few months, the appliance can be reactivated to keep pressure on the lower jaw. If there is a unilateral problem, more pressure can be placed on that side. You can actually measure the force by instructing the patient to bite in their retruded bite and then manually pushing the lower Jumper distally off its hinge ball. (8 ounces is typical.)

## 16. REMOVAL

To remove the Jumpers, simply reverse the installation procedure. Straighten the upper ball pin and slide it out of the headgear tube. Then remove the lower arch wire and slide the Jumpers off. You can then rebond the 4|4 brackets and get back into lighter wires to continue your lower arch treatment. The openness in the posterior will settle down in a few months.

Six months of active Jumper treatment can produce tremendous changes. It is normal to remove them then and have the patient use light Class II elastics to maintain the rapid correction. If patient cooperation is nil, the Jumpers can be left in passively for retention.



## 17. 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.

## 18. 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.

## 19. 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.

## 20. REGULATORY INFORMATION

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

 American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • [www.americanortho.com](http://www.americanortho.com)

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See [www.americanortho.com](http://www.americanortho.com) for Symbol Glossary

MADE IN USA

~~STERILE~~ NOT STERILIZED



INSTRUCTIONS FOR USE



SINGLE USE



CONTAINS CHROMIUM AND/OR NICKEL

**CE 0843**

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.**