

1. IDENTIFICATION OF THE COMPANY

Company Name
 American Orthodontics
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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

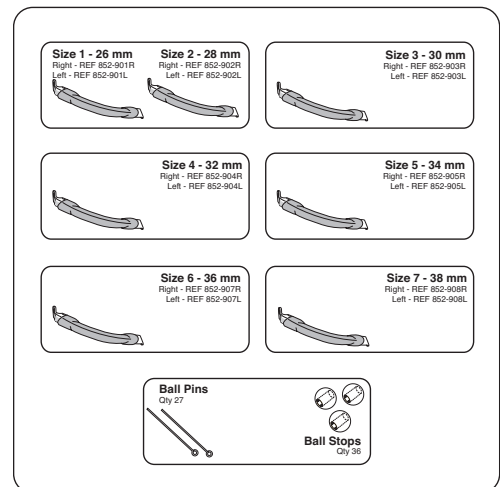
CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

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

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 profile 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.



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. 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.

10. 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.

11. ARCH WIRES

The largest stainless steel rectangular wire possible.

1. Upper Arch: The action of the Jumper tends to intrude, tip, distalize 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: Ideally, lower second molars should be banded. Place lingual crown torque in the lower incisor area to prevent anterior tipping, or use -10° torqued lower incisor brackets.

12. INSTALLATION

1. Fabricate a sectional wire with ball stop and slide on the lower arch. Do not crimp connections or permanently attach at this stop.
2. Have the patient close in their central / haitakafj occlusion.
3. With the patient closed, measure the distance (in inches) from the mesial end of the head gear tube of the upper first molar to the distal end of the ball stop on the sectional wire. Add 12mm to this distance and select the corresponding size jumper.
4. Remove the sectional and slide the lower end cap of the jumper on it, taking care that the long flat surface of the flange contacts the ball stop.
5. Replace the sectional and, now crimp the connections closed, securing the sectional in place.
6. With either a hemostat or needle holder, grasp a ball pin at the ball end.
7. Insert the ball pin through the distal (flat) end of the upper flange of the jumper and carry the assembly to the distal end of the head gear tube.
8. Slide the pin completely through the head gear tube. Hold the ball against the tube with your forefinger. Release the instrument holding the pin.
9. Grasp the mesial end of the pin with a bird beak pliers. Release your forefinger from the pin. Turn the end to lock the pin and Jumper in place, allowing the pin to extend distally from the head gear tube approximately 4 inches.

NOTES

1. If the measurement falls between jumper sizes, select the longer jumper module.
2. It is not unusual to record different measurements from right to left on the same patient.

13. QUESTIONS AND ANSWERS

Q: How long do I leave them in?

A: A normal treatment sequence following placement of the braces is to level the case and work up to your largest rectangular arches. This stage may take six months. You can then place the Jumpers for the next phase of treatment – to correct the occlusion and coordinate the anterior/posterior relationship. This stage also takes approximately six months. Nice overjet corrections will occur simply because the Jumper is a fixed force. The orthodontist now has one year left in which to detail the case. The Jumpers can be left in passively for a few extra months to retain the bite corrections or they can be removed and very light Class II elastics can be used for retention.

Q: What about extraction cases?

A: The Jumper can actually be used as an upper cuspid retainer. This will pit twelve anchored lower teeth against two upper cuspids and thus place very little stress on lower teeth. When sliding the upper ball pin through the molar tubes, bend the annealed front part into a hook. You can then attach a spring, a memory chain or simply tie the Jumper to the cuspid and let the lower arch retract the cuspids.

Q: Can the upper incisors be retracted en masse?

A: Yes. The jumper can be linked directly to a hook on the upper arch wire thereby pitting six upper teeth against twelve anchored lower teeth. This ratio does place more labial pressure on the lower incisors, but this is often beneficial in an extraction case to preserve the profile and support the incisors near the A-Po plane.

Q: Is it important to “use” the new bite?

A: A vital part of normal facial growth is “facial exercise”. Chewing gum is excellent in this regard. A few loose brackets is a small price to pay for the enormous benefits of lip seal, nasal breathing, and teeth together swallowing that spontaneously occur when a person is chewing gum. Form follows function.

Q: Is there any way to avoid putting stress on the lower arch?

A: The only way is to use the entire lower arch as an anchor and pit two upper teeth at a time against it.

Q: Are there any alternatives to removing 4|4 brackets?

A: Yes. Sectionals, either fixed or removable, can be used for attachment in the lower arch.

14. 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.

15. 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.

16. 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.


17. 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.




18. 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.

19. REGULATORY INFORMATION

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