

General Guidelines

Prescription only

CAUTION: Federal law restricts this device to sale by or on the order of a qualified dentist or physician.

Impressions

Only accurate impressions with hydrophilic PVS impression material or digitally scanned 3D captured models are acceptable. Impression trays may be disposable plastic rigid trays with a tray adhesive used or perforated metal trays. *Alginate impressions or poured models from dentists must not be accepted.*

Models

Stone models are required if PVS impressions are sent. The durability of the model must be strong and must have a base of approximately 7mm. The models will be mounted to an articulator after splint fabrication.

Bite Registration

A blue bite registration material must be used for stability. **A wax bite is not sufficient.** The bite method should be used on a bite fork with a George gauge, SOMGauge™ or the like. The dentist should send the bite fork wrapped carefully to the lab or captured digital bite. The minimum vertical opening is 6mm in the posterior and 7mm of inter-incisal clearance. The desired protrusion of the mandibular advancement initially is 40-50% of maximum protrusive.

Articulation

Models should be mounted on a mini-S type magnetic articulator for easy removal from the articulator. The Slide® connectors will come pre-loaded into a custom jig, which the lab will use for aligning and mounting them to the splints. *Any mounting of the connectors without the use of the supplied jig will void any warranties and is not licensed for manufacturing for this device.*

Materials and Components

- Bonding Resin: Cold Cure Acrylic PMMA (polymethyl methacrylate) powder and liquid
- Splints: KeySplint Soft® is the **ONLY** resin that maybe used for 3D printing.
- Device: The Slide® connectors **ONLY** from LeBlanc Dental Products, Inc.

Practical Considerations

Inspect for Damage

Inspect the Slide® connectors and components for signs of damage before assembly. Contact manufacturer if discrepancies are found with any of the kit components.

Dentition

A full complement of teeth to the first molar is required for the fabrication of the Slide®. This insures sufficient room for the placement of the rail connectors on the upper arch splint at the most posterior disto-lingual portion of the splint.

Vertical Opening

At least 7 mm of inter-incisal clearance is suggested in order for the Slide® connectors to fit between the upper and lower splints. If the connectors do not fit at the time of fabrication, contact the prescribing dentist. It is the responsibility of the prescribing dentist to deliver a quality bite that is 40- 50% protrusive and at the correct vertical.

Steps for Laboratory Fabrication



Steps for Creating Splints

Use the digital impression files to 3D print the models in the sleep apnea protrusive bite sent by the scan from the dentist, and then, 3D print the upper and lower splints. **Printed models are required for fabrication.** Splints should have a thickness of 1.5-2mm; however, the occlusal area may be trimmed down to 1mm to fit the Slide[®] parts without compromising the physical properties of the splint. All sharp embrasures between the teeth on the splints should be removed for ease of removal from the mouth by the patient. If necessary, remove the facial portion of the upper anterior teeth from canine to canine to the incisal edge so that the upper splint is not too tight.

Add an anterior support guide (ASG) on the lower splint for additional strength and stability of the posterior connectors. It provides a tripod effect to support the device. Design the ASG, a triangular-rounded block shaped component of dimensions 5 x 10mm to the front of the lower splint (See figure below). The ASG should be slanted from lingual to buccal to allow for more tongue space.



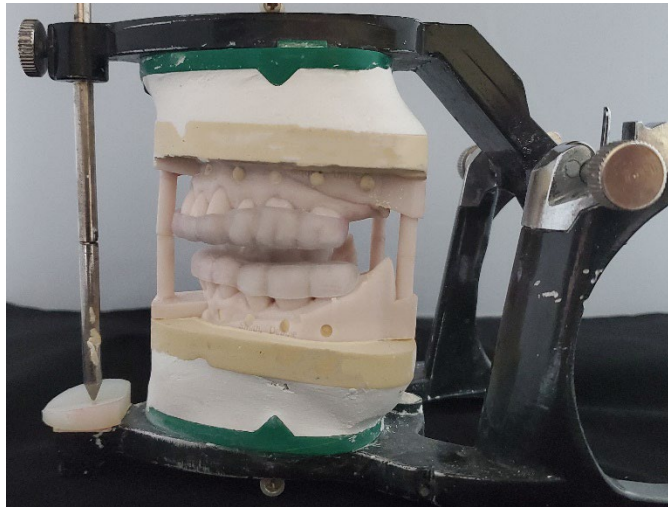
If the dentist has sent PVS impressions of the upper and lower arches, digitally scan the models after pouring them up in stone. Next, mount the stone models with the sleep apnea protrusive bite sent by the dentist. Finally, 3D print the upper and lower splints. The required product for 3D printing is KeySplint Soft[®] resin only.

Steps to Perform Final Slide[®] Assembly

Mounting

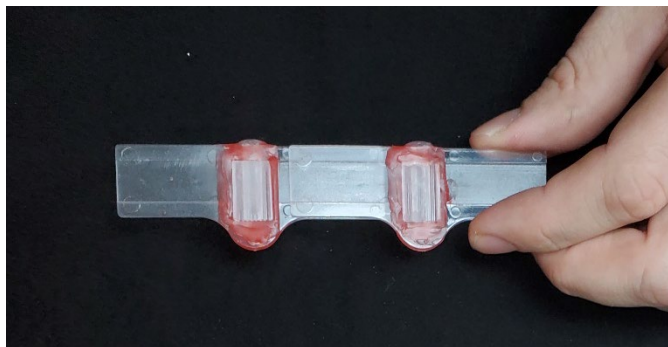
Mount models to the articulator with the 3D printed models or stone models with the protrusive bite.

Ensure that the supplied connectors inserted in the disposable jig will have enough clearance to be mounted in the posterior area (>4mm). If not, spot reduce the splint to allow clearance for connectors. If that does not solve the clearance issue, you will need to contact the prescribing dentist.



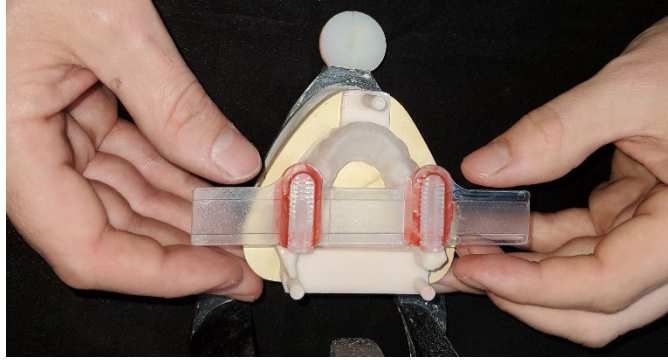
Block Out The Jig

Use blocking material, such as a hard wax, to block out the jig around the upper (longer rail) and lower (shorter slider) connectors to insure cold cure acrylic does not bond to the jig. Do not use setting wax, soft wax, or wax with heavy dies as this could lead to device discoloration. If required, remove the Rail and Groove to ensure the small gap around the connectors are completely blocked out.



Positioning the Connectors

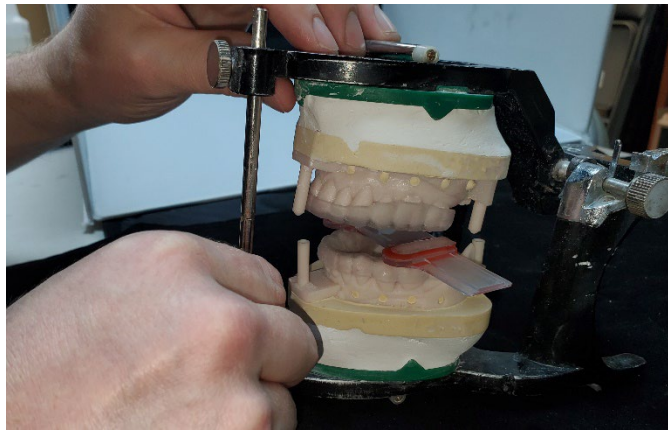
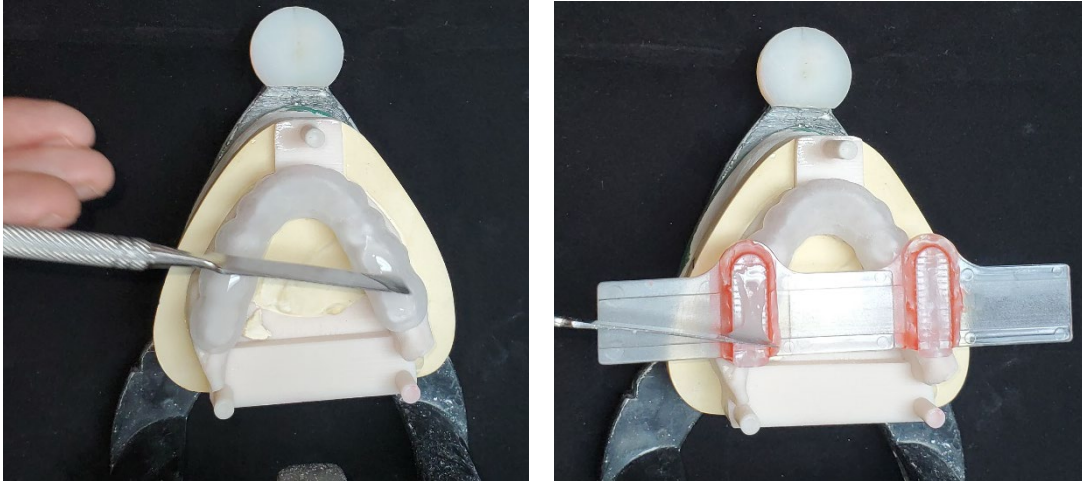
Orient the jig such that the short sliding connector is towards the mandible and the longer rail is towards the maxilla. Position the jig in between the upper and lower splints mounted in the articulator; adjust the width of the jig to accommodate different jaw widths. If required, spot glue the Jigs together at the desired width to prevent shifting.



Maximize the surface area over the posterior teeth of the splint. Try to position the inside corners of the connectors on the disto-lingual of the last tooth on the lower splint. This will maximize the surface area. You may get some of the connector extending out of the ridge on the buccal in the bicuspid area. That is fine. It will be polished and finished to the curvature of the splint. In addition, an indexed jig on the lower tongue space on the lower model tongue space can be made by mixing a putty and pushing the jig into the desired position. This insures that the jig is secure during the placement of the cold cure acrylic.

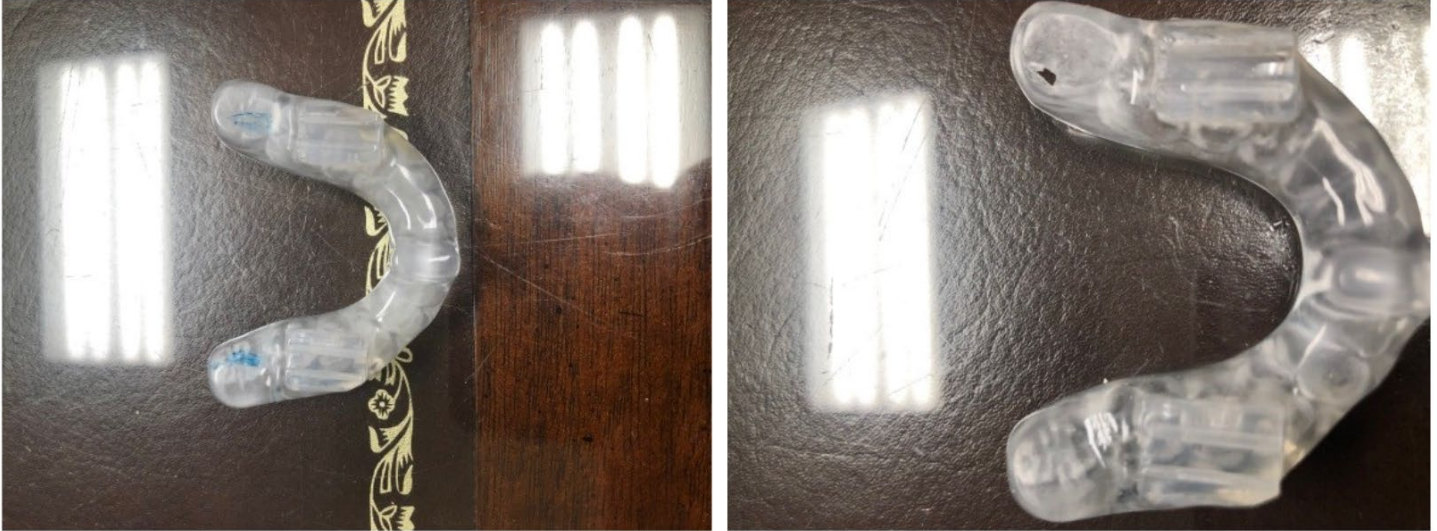
Attaching the Connectors

Mix a small amount of the cold cure acrylic resin together in a small mixing cup. Start by placing the cold cure on the lower splint and carefully place the jig with the connectors in the desired position mentioned earlier. *Ensure the orientation of the jig is such that the short sliding connector is towards the mandible and the longer rail is towards the maxilla.* Try to position the connectors equidistance between the upper and lower mounted splints. Next, place a small amount of the cold cure to the connector and close the articulator to bond it to the upper splint. Use care to not get acrylic in the grooves of the jig, as it will cure to the splints along with the connectors.



Trimming and Clean Up

After the connectors set, separate the connectors from the Jig. Slide upper and lower splints apart. Add extra acrylic to the connectors to fill in any gaps and cure again. Make sure that any interferences are removed so that the upper rail easily slides into the lower groove. If necessary, use articulating paper (see photos) to mark the binding areas and trim the acrylic distal to the lower groove connectors. Occasionally, a small window through the splint may occur from the adjustment, but the retention of the device will not be affected as long as there is a distal wrap of the most posterior tooth. Finish polishing with pumice and rag wheel. After polishing the splint, rinse with water to ensure device is free of any debris from the polishing process. The fabrication is complete. Check for any rough edges or spurs from the connectors.



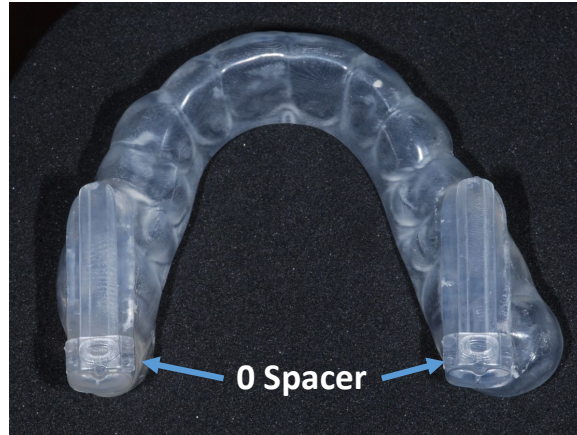
Inspect for Damage

Inspect the Slide[®] connectors for signs of damage before assembly. Contact manufacturer if discrepancies are found with any of the kit components.



Pack and Ship

Place one "O Spacer" on each side of the device and slide the appliance together. Spacers are located in the folded holder within the kit next to the storage case.



Place Slide® in the protective case provided with the kit. Add any models to the Slide® packaging, leveraging empty space reserved under the tray. Pack the kit in a padded envelope, apply a label, and ship to the prescribing dentist.

Symbols

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|------------|-------------------------|----------------|------------------------------|--|-------------------------------|--|--------------------------|--|--------------------|
| REF | Catalogue Number | Rx Only | Prescription Use Only | | Single Patient, Multiple Uses | | Keep Away From Rain | | Non-sterile Device |
| LOT | Batch Code (Lot Number) | | Consult Instructions for Use | | Date of Manufacture | | Upper Temperature Limits | | |

Distributed by: LeBlanc Dental Products, Inc.
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PATENT PENDING

Recognition

Special thank you to B&R Dental Laboratory San Antonio, TX & DSG®Davis Dental Laboratory Wyoming, MI for providing support in device development and assisting in creating these assembly instructions. Photos provided by B&R Dental Laboratory team.