

Clarity™ SL Self-Ligating Appliance System

Instructions For Use



Warnings

- Due to the hardness of ceramic brackets, bonding brackets in occlusion should be avoided to prevent wearing of enamel surfaces during all phases of treatment.
- Instruct patients not to chew or bite on hard substances such as hard candy, ice, carrots, etc. Careful and thorough patient instruction is a key to avoiding appliance or enamel damage.
- Bonding of ceramic brackets to compromised teeth (i.e., with large restorations, peg laterals or preexisting conditions) can increase the risk of tooth damage.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.
- The archwire slot liner and clips of Clarity™ SL Self-Ligating Brackets contain nickel and chromium. A small percentage of the population is known to be allergic to nickel and/or chromium. If an allergic reaction occurs, direct patient to consult physician.
- Debonding of Clarity SL brackets can be done using a Unitek™ Self-Ligating Bracket Debonding Instrument, REF 804-170. No other existing ceramic debonding instrument is recommended to debond Clarity SL brackets. Doing so may result in fractured tie-wings or tooth damage.

Cautions

- Archwires should be inserted into the Clarity SL bracket using the SmartClip™ Appliance Wire Insertion Instrument, REF 804-152 (0.022 slot) or REF 804-153 (0.018 slot).
- Archwires should be disengaged from the Clarity SL bracket using the SmartClip Appliance Wire Disengagement Instrument, REF 804-160.
- If a bracket fractures during treatment or debonding, use a diamond burr to carefully remove the ceramic fragments. Failure to follow the correct debonding procedure may lead to tooth damage.

Notes

- Clarity SL brackets are for single use only. Due to its vertical debonding slot design, these brackets collapse during debonding and cannot be reused or recycled.
- Avoid lodging dental instruments under or around the ceramic protrusion and cap that hold the self-ligating clips. Excessive force on this feature may result in bracket failure and should be avoided.
- Use of an instrument other than the SmartClip Appliance Wire Disengagement Instrument, REF 804-160, to disengage archwires from the Clarity SL bracket may place abnormally high pressure on the opposing cap/protrusions causing damage to the bracket and should be avoided.
- Use care when flossing. Floss can become lodged between the bracket and the Nitinol clip. Use of excessive force to remove the floss can lead to damage to the ceramic protrusion/cap.

Bracket Identification

Clarity SL brackets are identifiable by a color coded recessed distal gingival dot.

Bracket Bonding

Remove adhesive flash at bonding to minimize staining of the adhesive and reduce the risk of bracket breakage during the debonding procedure. Clarity SL brackets feature mechanical retention on the bonding base. No special primers or pretreatments are necessary. Clarity SL brackets can be used with traditional direct or indirect bonding methods. No change in bonding technique is necessary. For bonding procedures please follow the adhesive manufacturer's recommendations. When placing Clarity SL brackets, it is suggested that the bracket be placed in a sliding motion, occlusal to gingival, forcing excess adhesive to the incisal edge of the bracket for easier clean-up. Care must be taken when cleaning up adhesive flash around the protrusion so as not to disturb the final positioning before adhesive curing.

Archwire Insertion Instructions

Using the SmartClip Appliance Wire Insertion Instrument, REF 804-152 (0.022 slot) or 804-153 (0.018 slot).

Technique using SINGLE POINT END:

- 1) Align archwire over clip opening and bracket slot.
- 2) Position instrument on archwire on either mesial or distal side of bracket.
- 3) Torque the archwire if necessary.
- 4) Push instrument gently while providing lingual support to the teeth.

Note: Repeat procedure for each bracket.

Technique using TORQUING KEY END:

- 1) Align archwire over clip opening and bracket slot.
- 2) Position instrument on archwire so that torquing key straddles the bracket.
- 3) Torque the archwire if necessary.
- 4) Push instrument gently while providing lingual support to the teeth.

Note: Repeat procedure for each bracket.

Note: Refer to REF 011-616 for further instructions of use for the SmartClip Appliance Wire Insertion Instrument.

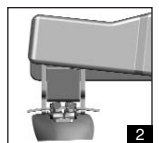
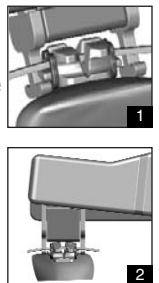
Archwire Disengagement Instructions

Using the SmartClip Appliance Wire Disengagement Instrument, REF 804-160.

Disengagement

Caution: Avoid lodging the hooks of the SmartClip Appliance Wire Disengagement Instrument under the protrusion of the Clarity SL Bracket (Figure 1). The hooks should clear the protrusions on both the mesial and distal sides of the bracket (Figure 2). Failure to locate the Wire Disengagement Instrument correctly can result in cap/protrusion and clip damage or bond failure.

- 1) Approach archwire with disengagement instrument from occlusal or gingival side.
- 2) Place instrument hooks under archwire keeping the bracket between the instrument hooks.
- 3) Squeeze handles.



Note: Repeat procedure for each bracket.

Note: Refer to REF 011-618 for instructions for use of the SmartClip Appliance Wire Disengagement Instrument.

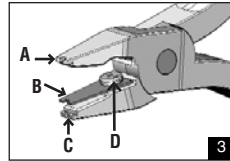
Clarity SL Self-Ligating Bracket Debonding Procedure

Using the Unitek™ Self-Ligating Bracket Debonding Instrument to debond the Clarity™ SL Self-Ligating Bracket and the SmartClip™ Self-Ligating Bracket:

Clarity SL Self-Ligating Brackets and SmartClip Brackets may be debonded either with the archwire engaged in the archwire slots or with the archwire removed.

Instrument Descriptor (Figure 3):

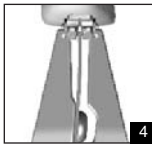
- A. Archwire Slot
- B. Nitinol Insert
- C. Bracket Gripping Shelf
- D. Screw holding Nitinol Insert in place



- 1) Remove adhesive flash around base of bracket to be debonded.

Note: Failure to remove flash around bracket base, especially on the mesial-distal sides, may result in incomplete debonding.

- 2) Place the Nitinol Insert of the debonding instrument vertically into the center of the self-ligating bracket, perpendicular to the archwire slot. **Be sure that the ledges of the instrument are symmetrically positioned against the labial surfaces of the bracket.** (Figure 4)



- 3) Squeeze instrument handles until the Clarity SL bracket collapses or the SmartClip bracket deforms. Gently rock the bracket in the mesial or distal direction to completely separate the bracket from the enamel. (Figure 5)



Bracket Rebonding Procedure

In the case of a spontaneous bond failure, it may be necessary to rebond a bracket. The following steps are recommended:

1. Carefully inspect the bracket for any damage. Brackets that have fractured through the vertical debonding slot cannot be rebonded and must be replaced. In certain cases, the bracket tie-wings might have fractured but due to the metal liner in the archwire slot, the bracket tie-wings will remain attached to the bracket body. If a tie-wing is cracked, replace the bracket. Brackets that have fractured through the mesial or distal protrusions (which support the self-ligating clips) cannot be rebonded and must be replaced.
2. Remove any excess adhesive. Extra care must be taken to prevent chipping or breaking of the bracket. Use a hand scaler to remove any excess flash from around the edges of the bracket. Take extra care when removing adhesive near the self-ligating clips and ceramic protrusions. **Do not use a burr. Do not attempt to scrape adhesive from the base of the bracket or attempt to micro-etch the adhesive as this may damage the bracket's bonding surface.**
3. If the bracket has been contaminated (e.g., moisture), rinse the bracket in isopropyl alcohol or acetone and allow to dry.
4. Prepare the tooth surface and bond the bracket using the procedure as described by the adhesive manufacturer.

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