

## PHASE I:

Prospective  
Multi-Site  
Observational  
Assessment  
of Rotational  
Control in a Novel  
Self-Ligating  
Appliance System

### STUDY INVESTIGATORS:

- 10 Licensed orthodontists in private practice skilled in PSL therapy.

### STUDY OBJECTIVES:

- Phase I: To validate the clinical efficacy of rotational control of the novel PSL Damon Ultima System.
- Phase II: To validate the clinical efficacy of torque control of the novel PSL Damon Ultima System.

### METHODS:

- **Began:** October 2019
- **Patients Enrolled:** 133
- **Clinical Sites:** 8
- **Class Type Distribution:** Class I | 48% Class II | 37% Class III | 15%
- **Inclusion Criteria**
  - o Consecutive cases. Minimum of 10; Maximum of 50.
  - o Patients in permanent dentition from first molar to first molar irrespective of age, gender or race.
  - o Exceptions: Those requiring orthographic surgery or TAD-assisted tooth movement.
- **Records**
  - o Full photographic records (wires in) at the start of each appointment.
  - o Digital scans and clinician reporting form at the end of each appointment.
  - o 2nd full set of photographs after each wire change (wires in).
  - o Full photographic records, CBCT scans at the start and finish of treatment.

### TREATMENT PROGRESS:

- Patients seen at 4-week intervals for study consistency.
  - o The Ultima Study appointment interval does not reflect the standard Damon Ultima System recommended appointment interval.
- After initial leveling and aligning with round CuNiTi wires, Damon Ultima™ .014" x .0275" round-sided, rectangular CuNiTi Archwires were engaged in the novel parallelogram slot of the Damon Ultima™ Bracket.

### ASSESSMENT:

- After concluding the .014" x .0275" Damon Ultima Archwire (CuNiTi) phase, each clinician made rotational correction assessments.

### PHASE I INTERIM RESULTS DATE: 07/15/2020

- By engaging the buccal-lingual depth of the PSL bracket slot, the Damon Ultima .014" x .0275" round-sided, rectangular CuNiTi wires effectively achieved correction of first-order tooth rotations (**Figure 1**).

### PHASE I INTERIM CONCLUSIONS:

- By engaging the buccal-lingual depth of the PSL bracket slot, the Damon Ultima .014" x .0275" round-sided, rectangular CuNiTi wires effectively achieved correction of first-order tooth rotations.
  - o Note: After all rotations are corrected, the wire/bracket interface returns to a passive state while maintaining the desired rotational alignments throughout the remainder of treatment with the .0275" dimension wires (**Figure 1**).
- Predictably achieving first-order control earlier in treatment, with minimal wire or bracket position adjustments, increases clinical efficiency and has the potential to reduce treatment time in patients treated with this PSL appliance system.

### ROTATIONAL CONTROL WITH BUCCAL-LINGUAL WIRE/SLOT ENGAGEMENT VIA THE DAMON ULTIMA SYSTEM



**Figure 1.** By engaging the buccal-lingual depth of the parallelogram-shaped Damon Ultima Bracket slot, the .014" x .0275" round-sided, rectangular Damon Ultima Archwire restricts first-order freedom (wire play) for earlier and effective rotational control.