



URGENT: MEDICAL DEVICE CORRECTION SNAPLINK BUCCAL TUBES

January 16, 2020

Dear Customer,

The purpose of this letter is to advise you that Ormco Corporation (hereafter referred as Ormco) is providing a voluntary correction for lower Snaplink Buccal Tubes. Affected part numbers are listed in table below.

Product Name	Part Numbers
Snaplink Buccal Tube, 18° 0° 12°	438-2190, 438-2191. All lots of product distributed since 2015

INTENDED USE:

Snaplink, is intended for use for the orthodontic movement of teeth. It is used temporarily and are removed after orthodontic treatment has been completed.

ISSUE:

Ormco received an increase in complaints relating to lower Snaplink buccal tube slide doors not staying closed. We received 140 complaints from 2015 to Sep 2019, with no reported patient injuries. The incidence of this issue appears to be low. Approximately <0.1% of the Snaplink Buccal Tubes experience this issue due to an interaction between the Snaplink slide and the pin that enables the door to stay open or closed.

RISK:

In the event of functional failure, broken/damaged Snaplink may cause the tooth to rotate, possibly delay treatment and inconvenience the patient and clinician. If a patient or clinician does not notice this issue, it may extend treatment by approximately 1-3 months, depending on the patients visit schedule. If you experience this failure, please follow the recommendations below.

RECOMMENDATION:

Ormco is **not** requesting removal of Snaplink, from your facility. You can continue to use the product in your inventory. If you experience Snaplink buccal tube slide doors not staying closed, Ormco requests you to:

- (1) Call Ormco customer service at 1-800-854-1741 or email **ormcocustcare@kavokerr.com** to log any complaints related to this issue.
- (2) For patients who had Snaplink lowers placed, check the patient records and determine if you need an additional patient visit to check the integrity of the door to ensure it remains closed.
- (3) Instruct patients to check bracket after each brush to ensure bracket door remains closed. If door appears open, instruct patients to contact your office to schedule an appointment.

- (4) If the bracket door does not stay closed, use a double over tie, per typical orthodontic practices (Refer to pictures below) or remove the Snaplink and replace it with a new device. If the Snaplink is removed, please contact customer care (1-800-854-1741) for the product to be returned.
- (5) **Complete the enclosed acknowledgement form and email the form to ormcocustcare@kavokerr.com within 10 business days.**

Please accept our apologies for any inconvenience this may have caused. If you have any questions or require additional information, please contact our customer care department at 1-800-854-1741, between the hours of 7am to 5pm (PST) or send an email to ormcocustcare@kavokerr.com

Adverse reactions or quality problems experienced with the use of this product may be reported to Ormco customer care, FDA or appropriate International Ministry of Health:

- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) or
- Call FDA 1-888-INFO-FDA (1-888-463-6332).

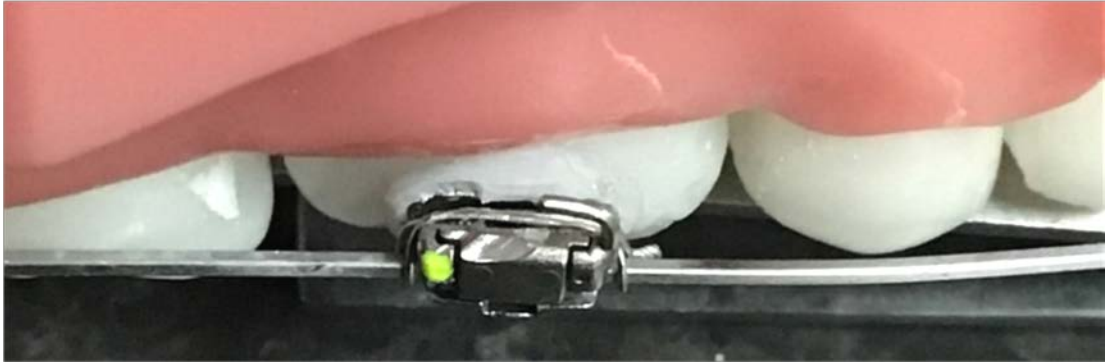
Sincerely,



Valerie Cimmarusti
Vice President, Regulatory, Quality and Clinical

Attachments: Acknowledgement Form

Pictures of Typical Orthodontic double-over tie:



SNAPLINK BUCCAL TUBES Acknowledgement Form

Product Name	Part Numbers
Snaplink Buccal Tube, 18° 0° 12°	438-2190, 438-2191 distributed since 2015.

I have read and understand the notification for the Snaplink Buccal Tubes and if I provided the Snaplink to another dental professional, I will forward the notice
 Yes No

Were there any adverse events and/or complaints of injury associated with the product? Yes No

If yes, please explain: _____

Were there any affected devices removed from the patient? Yes No

If yes, total # of devices affected and returned to Ormco _____

 Contact Person (Please Print)

 Facility

 Signature

 Date

 Phone number

If you have questions or need help please call customer care at 1-800-854-1741, between the hours of 7am to 5pm (PST) or send an email to ormcocustcare@kavokerr.com.