



URGENT: MEDICAL DEVICE CORRECTION
Damon Q2 L3R .022 +13/+5/0 Hi TQ Hook

January 6, 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 Damon Q2 L3R .022 +13/+5/0 Hi TQ Hook. Affected part number is listed in table below.

| Product | Part Number | Lot Numbers |
|---------------------------------------|-------------|------------------|
| Damon Q2 L3R .022 +13/+5/0 Hi TQ Hook | 491-9834 | <u>031902599</u> |

INTENDED USE:

Damon Q2 is the 8th generation bracket of the Damon System, which combines passive self-ligating brackets, light force archwire sequencing, and recommended treatment protocols to successfully finish orthodontic treatment cases. Damon Q2 is intended for single use only, and they contain nickel and chromium, which is not suitable for patients with known allergic sensitivity to those metals.

ISSUE:

Ormco identified that DQ 2 brackets PN 491-9834, Lot 031902599 was incorrectly labeled with a high 13 torque bracket but it has a +7° torque inside the package.

RISK:

The issue might not be immediately apparent to the clinician/assistant unless the user inspects the bracket closely before bonding. The patient may experience misaligned teeth and may necessitate wire bends or bracket repositioning to realign the teeth. There may be a delay of 3-6 months for resolution of incorrect tooth position as a result of the incorrect bracket being used.

RECOMMENDATION:

Ormco is **not** requesting removal of this product from your facility. You can continue to use the product in your inventory, however, please note PN 491-9834, Lot 031902599 has a +7° torque instead of +13° torque and we request that you over-label the product with the enclosed label.

Ormco requests you to:

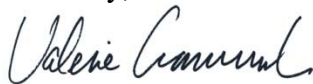
- (1) Call Ormco customer service at 1-800-854-1741 or email ormcocustcare@kavokerr.com to log any complaints related to this issue.
- (2) Ormco is requesting that you assess your patients coming in during follow-up visits to ensure treatment is progressing as planned.
- (3) Over-label affected product in inventory with the corrected label.
- (4) 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 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

Damon Q2 L3R .022 +13/+5/0 Hi TQ Hook Acknowledgement Form

| Product | Part Number | Lot Numbers |
|---------------------------------------|-------------|------------------|
| Damon Q2 L3R .022 +13/+5/0 Hi TQ Hook | 491-9834 | <u>031902599</u> |

I have read and understand the notification for the incorrect labeled Damon bracket?
 Yes No

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

If yes, please explain: _____

I have over-labeled the affected product in inventory
 Yes No, I do not have affected product

If yes, # of Affected product over-labeled _____

 Contact Person (Please Print)

 Facility

 Signature

 Date

 Phone number

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