Ormco Your Practice. Our Priority.

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	031902599

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 +7º 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 +7º torque instead of +13º torque and we request that you over-label the product with the enclosed label.

Ormco requests you to:

(1) Call Ormco customer service at 1-800-854-1741or 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

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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	031902599

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.