

Ormco Communication to UK Damon Doctors Approached by the ASA Regarding Damon Claims on Practice Websites, 5-24-17

The U.K.'s Advertising Standards Authority (ASA) has, this week, upheld two complaints relating to advertising in respect of our Damon™ System braces. The ASA has determined that claims indicating that Damon braces provide faster and less painful treatment than traditional braces are not adequately supported by evidence. As a result, these claims are deemed to be misleading and should not be used.

As manufacturer of Damon System braces, we fundamentally disagree with the ASA's ruling and have committed significant resources throughout the process to counter the complaints. We have submitted numerous documents to the ASA to support these claimed benefits, including a number of in vivo and in vitro clinical studies, articles, Ormco's product technical files and Masters theses. A team from Ormco (including two expert Damon doctors/educators) also participated in a call with the ASA, explaining the relevance of the data provided and the justification for the claims. Notwithstanding the volume of evidence presented and the opinions expressed by our Damon experts, the ASA has concluded that the substantiation is inadequate on the basis that we were unable to present results from a randomized, blinded controlled trial. This being despite our vigorous attempts to explain to the ASA that such a trial would not be possible to design and run, in the context of orthodontic products. We also argued that the ASA concluding that our claims were not justified purely based on the absence of such trial data was contrary to the ASA's own guidance of claim substantiation, which clearly references that an advertiser can seek to rely on a variety of evidential sources to substantiate claims of this nature.

We are disappointed and frustrated that the ASA has decided to uphold the complaints and, by doing so, is discounting our evidence and opinions of experts in this field. We stand by all claims we make comparing our Damon braces with traditional braces, such claims being based on over 20 years of experience and development. We want to make it very clear that Ormco took every step possible to defend the ASA's challenge.

However, as a result of the ASA's ruling, we now need to recommend to you that you should cease using any promotional materials for our product which specifically reference a faster or less painful treatment process compared with traditional braces. The two complaints which have been ruled on by the ASA were made against orthodontic practices using these claims on their website. As manufacturer, we agreed to assist both practices to respond to the complaints. As a result of the rulings, the ASA might consider bringing further complaints against any doctors using similar claims for Damon braces. Equally, there is a possibility that the individual who submitted the original challenge could choose to highlight examples of continuing usage of the claims on other doctors' websites. As a matter of courtesy, we are recommending to all our valued customers in the U.K. that at this time, they remove all such claims to avoid the risk of facing a similar ASA investigation. Of course, ultimately this will be a decision for each doctor advertising Damon braces. Please note that this ruling extends to website and printed materials that are accessible by consumers in the U.K.

While we disagree with the ASA's decision, the complaint process does not present us with a viable route to challenge the ruling. We shall, therefore, focus our attention on new claims for Damon braces which support the benefits of our system compared with others on the market. We will, of course, update you when we have new marketing claims which can be made in conjunction with the existing materials you are already using and which are not affected by the ASA's ruling.

Please let us know if you have any questions.