
August 20, 2014

Important Product Information!


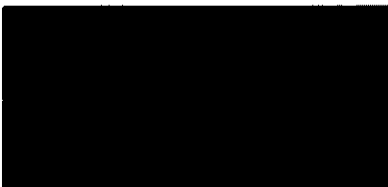
Elos Medtech has found that article no. AB-ZSV3515150, batch 93138 and article no. AB-ZSV4515150, batch 93139 and article no. AB-ZSV5515150, batch 93140 of abutment blanks for the Zimmer Screw-Vent® connection have been manufactured with a geometry which does not meet our specifications. This error is an unfortunate combination of multiple, unforeseen factors that allowed these batches to pass our strict quality control. There is a potential risk that this error in some cases may lead to a situation where the abutment is not fully seated in the implant i.e. resulting in a gap between abutment and implant.

The opinion of our clinical advisor (please see attached) is that a gap at the abutment/implant interface could cause infection of the gingiva, which as long term effect could lead to necrosis of the bone supporting the associated endosseous implant (peri-implantitis) and thus cause implant failure. Consequently, Elos Medtech recommends that all affected batches are returned and that abutments already placed in patients are replaced.

You are kindly requested to inform quantities remaining in stock and quantities placed in patients.

Whilst we apologize the inconvenience caused by this situation, we kindly ask you to rest assured that product quality and patient safety remain our highest priority.

Best regards,


Head of Research & Development
Head of Sales