



URGENT FIELD SAFETY NOTICE

Stage-1 Part ISS141K
MR 18-001
12 February 2018
Field Safety Corrective Action (FSCA)

Dear Customer,

Keystone Dental has initiated a Field Safety Corrective Action (FSCA) for certain lots of the Disposable Tissue Punch, 4.5mm, product code ISS141K, lot# 33945 and 34987. These tissue punches may potentially have a damaged cutting edge. The cutting edge of the tissue punch may contain small dents and nicks resulting in a potentially dull tissue punch.

Keystone Dental has performed a thorough review and determined there are minor health hazards associated with this issue. Use of a tissue punch with these nicks and dents may require more time and pressure to cut through soft tissue and in a worst-case scenario, protruding corners or edges could result in minor tears of the soft tissue. In this worst-case scenario, the tearing may cause slightly more discomfort and swelling of the soft tissue than usual during the healing phase. Typical procedures to mitigate normal post-operative pain and swelling during the healing phase can be used and no additional remediation is required.

Keystone Dental records show that the following orders were shipped to you by Keystone Dental's European Distributor, OT Medical.

Order Number	Product Code	Lot Number	Quantity

These lots were the only affected product and all other inventory you may have can be used without issue. Any product remaining in inventory can be returned to Keystone Dental and replacement product will be sent to you. Please also confirm whether any of the product was used for our records.

Please note that the National Competent Authority has been notified. This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

Please be assured that we have taken the necessary steps to avoid this error in the future and we sincerely apologize for the inconvenience this incident might have caused you.

Sincerely,



Keystone Dental, Inc.