

Persoonsgegevens

Wimsheim, August 2023

Urgent Medical Device Field Correction (for Bone profiler J5003.3350)

Dear Customer,

The purpose of this notification letter is to advise you that Altatec is voluntarily performing a field correction of item reference number **J5003.3350** [product description: Bone Profiler, Ø 5.0mm for Ø 3.3mm].

Our records reflect a distribution of this item to you. Therefore, we are submitting this field correction notification as awareness of the issue described below.

DESCRIPTION OF ISSUE

A physical examination of item number J5003.3350 revealed the sleeve is too tight to pass the profiler over the corresponding guiding pin.

The nonconforming condition does not represent a hazard to patient safety. Hence, no special patient remediation measures or other actions need to be taken.

RISK to PATIENT HEALTH

No reports of adverse events have been received related to the identified nonconformance. **There is no risk for patients, user or others** as the drill will not pass through the guiding pin towards the bone.

The immediate patient impact could be a **delay in treatment** if an alternative drill is not available.

Please discard the listed lot numbers of the product in accordance with your local regulations.

The following lot numbers are affected: 0010125131 and 0010130452.

We will send you a replacement bone profiler upon request.

Please confirm receipt of this notice to Raphael.brausch@altatec.de per E-Mail.

We regret any inconvenience that might have caused.

With best regards,
ALTATEC GmbH

Persoonsgegevens

Persoonsgegevens

Persoonsgegevens