



URGENT: Medical Device Field Action Notification

01/MAY/2018

Quality Assurance Dep.

Alpha-Bio Tec

7 Hatnufa St. P.O.B 3936, Kiryat Arye

Petach Tikva 4951025, Israel

Dear Madam/Sir

This is to inform you of a product Field Action Notification involving:

Milling Drill D1.5mm, Catalog number 65050, All Lots.

This Field Action Notification has been initiated due to an issue with the design of this product.

Use of this product may cause, temporary or reversible impairment.

Please identify your customers and notify them at once of this product field action by forwarding them this field action notification letter.

All relevant available products that may or may not been used are to be disposed as soon as possible. New drills will be send with no need to send back the old ones.

Please update us vs email or phone about disposal of the products.

Your assistance is appreciated and necessary to prevent patient harm.

This field action is being made with the knowledge of the relevant authorities.

If you have any questions, contact QA Manager via mail: aviel.grumberg@Alpha-Bio.net

01-May-2018