IMPORTANT FIELD SAFETY NOTICE

Double Ended Ligature Tucker

Date: 15th April 2021

Dear Valued Customer,

We are writing to inform you of a product recall affecting a **Double Ended Ligature Tucker, Product Code: DB05-0311, Lot Number: 14757**.

Information on Affected Devices:
DB Orthodontics Limited (hereafter 'DB Orthodontics') has received reports that the tips on this batch of instruments appear weaker than usual; and that some tips have consequently broken during use.

The instruments are used to tuck and direct ligatures under the archwire or bracket wings or to push archwires or auxiliaries into position during routine orthodontic procedures.

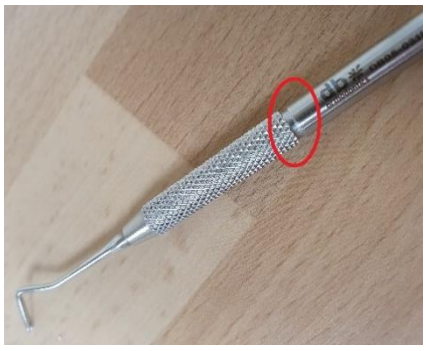
We are therefore asking you to identify and destroy these instruments with **Lot Number: 14757**. Please also destroy any stock that you hold of the effected instruments with this Lot number.

Hazard giving rise to the Field Safety Corrective Action:
If the tip is to break during use; there is a possibility the patient could swallow the tip of the instruments.

Background on the Issue:
Five (5) complaints have been received; from five (5) different customers relating to the Double Ended Ligature Tucker, Product Code: DB05-0311 Lot Number: 14757.

A total of two hundred and thirty four (234) Double Ended Ligature Tucker, Product Code: DB05-0311 Lot Number: 14757 have been sold to date.

Lot 14757 can be identified by an indent on the handle of the instrument as shown in the image below:



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Action to be taken:

Identify and destroy the affected devices.

Contact DB Orthodontics Quality department and inform them of the quantity that you have had to destroy – returns@dbortho.com

DB Orthodontics will issue a Replacement or Credit Note for the devices destroyed.

Please take this action immediately.
The Medicines and Healthcare products Regulatory Agency (MHRA) has received a copy of this safety information.

This notice needs to be passed onto all of those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer; and the national Competent Authority if appropriate, as this provides important feedback.

Please do not hesitate to contact us if you have any questions regarding this matter.

Yours Sincerely,

Victoria Coppack
Director
DB Orthodontics Limited

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