



SCORPION

Urgent Field Safety Notice

CLUB-30K Scorpion tips

May 16, 2014

This letter is to inform you of a voluntary product recall being conducted by Scorpion. It concerns the **CLUB-30K** magnetostrictive scaling tips distributed by Swallow Dental Supplies Limited, batch numbers starting with **21A20A** and **21B20B**.

Our records indicate that you may have received one or more of these products. We have determined that there could be a weakness area at the junction of the tip point and the body of the tip, near the handle, which could lead to a breaking during the use. There could be a risk for the patient safety if the breakage appears in the mouth where the broken piece could hurt the mouth parts, or be swallowed or inhaled. To date no incident related to this issue have been reported. However, Scorpion is taking a conservative approach in addressing the issue and requesting return of the potentially affected products.

Please return the CLUB-30K tips concerned to Swallow Dental Supplies Limited.

The Medicines and Healthcare products Regulatory Agency is aware of this recall.

Scorpion has implemented design changes to eliminate this issue and has begun production of new batches of CLUB-30K tips which will be sent for replacement as soon as possible.

Scorpion is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you.

Thank you for your continued support.
Yours sincerely

Stephane GIGAULT
Manager
sgigault@scorpion.fr



Scorpion

4, rue Enrico Fermi - 63540 ROMAGNAT
Tel/Fax : +33 4 73 78 20 87
ISO 9001 - ISO 13485

