

29. April 2015

FIELD SAFETY CORRECTIVE ACTION AND FIELD SAFETY NOTICE

Dear Customer,

Unfortunately a misfortune happened at one of our suppliers and we would like to inform you about this case.

A certain amount of Camlog Screw Line Implants with part number K1042.4311 and lot number 0030054130 have been labelled incorrectly on the inner part of the package as well as on the patient labels. The expiration date was printed with transposed digits.

Instead of Use by: 2019-09 some of the products have been labelled with Use by: 2109-09. Although multiple internal and external quality inspections are executed this mistake did happen. The outside package shows the correct expiration date on the label, therefore the problem is not detectable if the package is originally closed.

The wrong Use by date on the inner label does not expose any risk to patients, user or others, as the medical device itself is safe and effective and confirm to the product specifications. Nevertheless it is our claim and policy to correct this mistake and we ask you to return to us all of the products with the lot number mentioned above.

Should you already have used the product we would like to ask you to correct the Use by date of the implant in the appropriate patient label.

We apologize for any inconvenience and we want to assure to you that our broad Quality Management activities will be utilized to prevent this from recurrence.

With best regards,

Jean-Marie Wyss
General Manager

Safety Officer (MD)