

19 June 2020

NCR200617-1

Urgent Field Safety Notice

CIMPAX ELECTRODE Conization 13x20mm

REF C31-18-121 - Batch 182402

Dear Customer and End-user,

Description:

The purpose of this Field Safety Notice is to inform you, that we by a mistake have packed the wrong model conization electrodes into boxes with reference code C31-18-121, Batch 182402.

The wrong model conization electrodes packed in to this batch are the smaller size 10x15 mm cone. Correct size according to label should have been 13x20 mm cone.



C31-18-120

Conization electrode 10x15mm/120mm



C31-18-121

Conization electrode 13x20mm/120mm



Potential risk:

Use of an affected device could potentially lead to undertreatment of the patient which might potentially require additional treatment.

Action to be taken by the user:

End-users are required to return affected devices to their distributor who is required to return the affected devices to the manufacturer.

Please do not hesitate to contact us if you have any further questions.

Best regards,

A handwritten signature in blue ink, appearing to read 'Michael Busch-Madsen', written in a cursive style.

Michael Busch-Madsen
Vice President
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