

**McGRATH® MAC2 VIDEO LARYNGOSCOPE BLADE CLIP –
LIMITED BATCH RECALL**

4th November 2014

BACKGROUND & SUMMARY

Aircraft Medical Limited have issued a voluntary recall on select batches of McGRATH® MAC2 Video Laryngoscope Blades due to an error in the manufacturing process that makes it possible for the blade retaining clip to be difficult to engage and thereby increase the possibility of a blade becoming disconnected during intubation, specifically when the device is being retracted from the patients mouth.

All affected blades should be quarantined immediately to avoid accidental use and shall be replaced free of charge by the Company with blades that are in compliance.

Only blades that display the recorded batch numbers are affected as the root cause has been identified as a manufacturing error on one particular mould tool therefore no other batches or blade sizes will be affected and should continue to be used.

Affected products should be returned to Aircraft where they shall be decommissioned.

AFFECTED PRODUCTS

Product Nomenclature :	McGRATH® MAC2 Video Laryngoscope Blade
Product Part Number :	350-017-000
Affected Products :	LOT 14030501
	LOT 14061616
	LOT 14031814
	LOT 13042401
	LOT 13122301
	LOT 13121202

NATURE OF ISSUE

When a blade from an affected LOT is fitted to certain MAC handles it may be difficult to get the blade clip to engage onto the tooth on the handle. During our investigation we found this problem only occurred on some handles due to the normal manufacturing variability between handles. Where the problem does exist it is very apparent to the user.

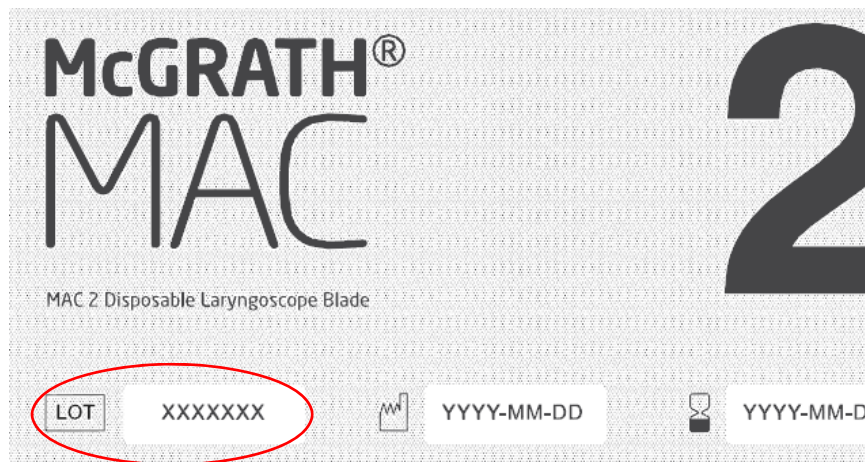
REQUIRED ACTION

All notified distributors shall check their own stock and their customers' stock for any blades that relate to the above LOT number, and arrange for any remaining stock to be removed from use. Note that it is possible that the blades have already been used without any problems.

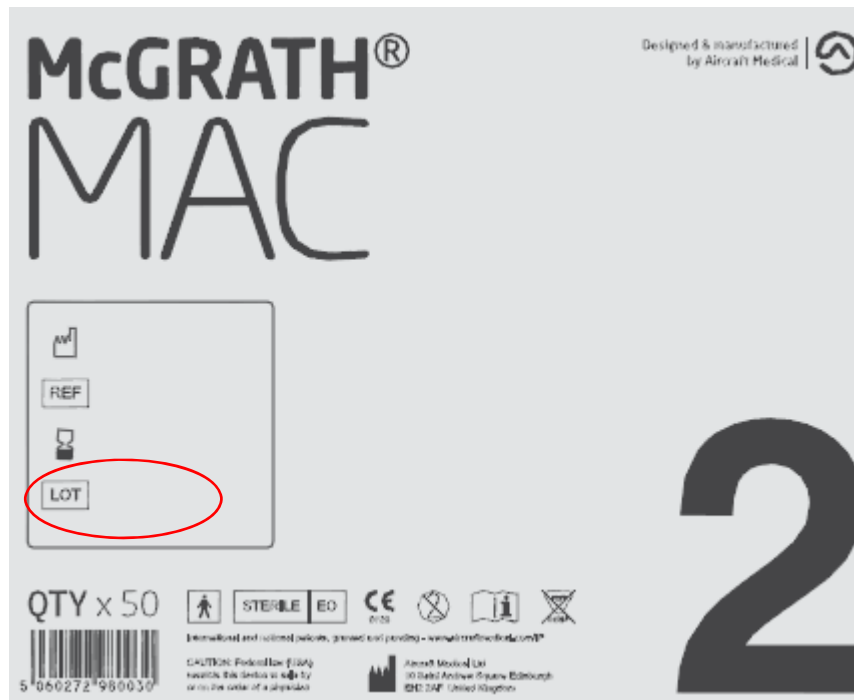
Aircraft Medical will replace any stock that is removed from circulation during November 2014.

IDENTIFICATION OF LOT NUMBER

On McGRATH® MAC2 Peel Pouch



On McGRATH® MAC2 Box



If you have any questions or concerns about this please contact Aircraft Medical please contact Andrew Carmichael, International Sales & Service Manager, ac@aircraftmedical.com (Tel: +44(0)7803 938371)

Jeremy Wheeler
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