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Urgent Field Safety Notice

McGRATH™ MAC 2 Disposable Laryngoscope Blade

Recall

Item Code	Product GTIN	Description	Lot Number
350-017-000	10884521816336	McGrath™ MAC 2 Disposable Laryngoscope Blade	22082207
			22083101
350-084-000	10884521824386	McGrath™ MAC 2 Disposable Laryngoscope Blade	22102001

August 2023

Medtronic Reference: FA1356
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager, Director of Respiratory Care:
The purpose of this letter is to advise you that Medtronic is initiating a recall for specific production lots of McGRATH™ MAC 2 disposable laryngoscope blades. This recall follows receipt of six (6) complaints of poor picture quality and foggy and/or blurred images on the McGRATH™ MAC 2 video laryngoscope screen during use of these blades. The reports indicated a delay to treatment while an alternate device was located and/or oral tissue injury due to multiple intubation attempts. You are receiving this letter because Medtronic records indicate that potentially affected devices were shipped to your facility

Issue Description:

Our investigation of these customer reports identified a manufacturing issue which resulted in an ineffective application of the anti-fog agent on the blades. An ineffective application of the anti-fog coating can result in condensation accumulating on the blade during use, resulting in the image on the video laryngoscope screen being blurred or obscured.

Risk to Health:
A blurred or obscured video laryngoscope image during use may result in the intubation process being prolonged, resulting in the potential for hypoxia and/ or respiratory failure although no reports of these occurrences have been received by Medtronic. Additionally, a blurred or obscured image appearing on the video laryngoscope screen may result in multiple intubation attempts, potentially increasing the risk of oral tissue injury and or bleeding.

Patient Management:
A McGRATH™ MAC 2 disposable video laryngoscope blade affected by this issue would be evident to the practitioner at the beginning of laryngoscopy, once the blade is placed into the patient's mouth; in this event a replacement blade would be needed to complete the intubation procedure. There are no additional patient management recommendations that should be employed for patients where potentially affected blades were previously used.

Actions to be taken:

- Quarantine all unused product from the affected lots of McGRATH™ MAC 2 disposable laryngoscope blades. See attachment A for guidance on identifying potentially affected devices.

- Return all unused product from the affected lots in your inventory to Medtronic as described on the Customer Confirmation Form.

- Please complete and return the enclosed Customer Acknowledgement Form even if you **do not** have unused inventory.

- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product from the specified lots has been transferred or distributed.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Representative

Sincerely,
Medtronic (Schweiz) AG

Enclosures:

Attachment A: Identifying Affected Devices
Customer Acknowledgement Form

Attachment A:

IDENTIFYING POTENTIALLY AFFECTED DEVICES

Locate product information on product labels in your inventory