

URGENT Field Safety Notice (FSN)

Reference: FSCA 2024-001

Dated: 20 June 2024

Affected Product

Name Laryngoscope LED handles, green system (reusable)

Sender

Starkling e.K.
 SRN **DE-MF-000012725**
 Rudolf-Diesel-Str. 18
 78576 Emmingen-Liptingen, Germany

Attention

All users and distributors of the product including, but not limited to, clinicians in operating rooms, intensive care, emergency department, obstetric units and anesthetic departments, rescue & emergency services, paramedics, managers, nurses, and support staff.

Identification of affected devices

The tradename “STARKLING”, the product number and the lot number can be found on both the outer box and on the LED handle / Spare LED (device).

Only devices with the below product number and lot number are affected and included in this recall.

Starkling Product Number	Lot Number	Starkling Product Number	Lot Number
NL6000	220515-308	NL6001	220515-309
NL6000	220529-101	NL6001	220918-101
NL6000	220707-001	NL6001	220925-201
NL6000	220904-600	NL6001	230129-301
NL6000	221009-101	NL6001	230226-502
NL6000	230115-201	NL6001	230416-102

Starkling Product Number	Lot Number	Starkling Product Number	Lot Number
NL6000	230129-201	NL6001	230730-102
NL6000	230226-501	NL6001	230827-703
NL6000	230312-401	NL6001	240121-971
NL6000	230416-101	NL6001	240423-004
NL6000	230514-101	NL6826	210601-002
NL6000	230702-101	NL6826	220814-201
NL6000	230730-101	NL6826	220814-202
NL6000	230807-024	NL6826	221010-001
NL6000	230827-702	NL6826	230216-032
NL6000	231203-203	NL6826	230216-033
NL6000	240107-102	NL6826	230320-006
NL6000	240114-401	NL6826	231224-101
NL6000	240506-014	NL6826	231217-216
NL6000	240522-001	NL6826	240114-402

Description of the problem

Starkling LED laryngoscope handles have been found not to illuminate.

- Starkling e.K. has been made aware that the LED handles / Spare LEDs (devices) extinguish within 60 seconds of continuous illumination when used with some commercially available batteries and are permanently damaged as a result.
- This may pose a potential risk for new patients, if this happens during intubation.
- There is no risk involved for patients who have already been treated with this device previously.
- According to the instructions for use, it is necessary to check the function of all laryngoscope handles at least after each reprocessing cycle by illuminating them. It is common practice to perform function tests daily and after each battery change by visual inspection. It is also common practice to have backup devices ready when performing intubations!

- If the handle does not light up, goes out or is only dimly lit during the function check, it is recommended that the backup device is also subjected to a functional check for 60 seconds to avoid a delay in treatment and/or difficult/unsuccessful intubation in an emergency.

Advise on action to be taken

1. If you have purchased any of these devices, please locate and quarantine the devices with lot numbers listed in the table above. The tradename “STARKLING”, the product number and lot number can be found on both the outer box and on the LED handle / Spare LED (device).
2. Please ensure this Field Safety Notice (FSN) has been communicated to all users.
3. If you have any devices as listed, please complete and return the Acknowledgment and Response Form (last 2 pages) of this notice to Starkling e.K. indicating the quantities for each lot. Arrangements for return, subsequent credit/replacement and/or spare parts replacement of these devices will then be given.
4. Even if you have no affected devices, you are still requested to complete and return the Acknowledgment and Response Form (last 2 pages) of this notice to Starkling e.K. indicating Zero stock.

Transmission of this Urgent Field Safety Notice (FSN)

Please ensure in your organization that all users (including those listed in the “Attention” section above) of the above products and other people to be informed are aware of this Urgent Field Safety Notice (FSN).

If you have supplied (or transferred) the affected products to third parties or other organizations, please forward a copy of this information to them or inform the contact person listed below.

Please keep this information at least until the action has been completed.

I confirm that this notice has been notified to the appropriate regulatory authority.

Starkling e.K would like to apologize for any inconvenience this matter may cause you. If you have any questions, please contact your local Starkling e.K. medical representative/distributor or email us at info@starkling.de

Contact Person

Mr. Khurram Iqbal
Starkling e.K.
Tel +49 (7465) 3119927
Mobile +49 (175) 3361951
Fax +49 (7465) 3119928

Signed 20 June 2024

URGENT Medical Device Field Safety Notice (FSN)

Acknowledgement & Response Form

Starkling Part Number	Lot Number	Quantity Quarantined (pieces)	Starkling Part Number	Lot Number	Quantity Quarantined (pieces)
NL6000	220515-308		NL6001	220515-309	
NL6000	220529-101		NL6001	220918-101	
NL6000	220707-001		NL6001	220925-201	
NL6000	220904-600		NL6001	230129-301	
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NL6000	240506-014		NL6826	231217-216	
NL6000	240522-001		NL6826	240114-402	

- I acknowledge that I have received the Field Safety Notice (FSN) and confirm that I have read and understood its contents.
- The information and necessary measures were brought to the attention of all relevant users and implemented.

URGENT Medical Device Field Safety Notice (FSN) Acknowledgement & Response Form

- I have the following quantities that are in quarantine (see table above), these are ready for collection, return or repair.

Tick if applicable.

- I have noticed that we do not have any of the LOT numbers listed.

Tick if applicable.

Customer Name _____ Position _____

Facility Name _____

Facility Address _____

Tel _____ Email _____

Date _____ Signature _____

By completing this form, you agree to the data protection policy at <https://starkling.de/privacy-policy/>

**Please complete this form latest by 10 July 2024 and
return by email to info@starkling.de or by Fax to +49 (7465) 3119928**

For Starkling e.K. Internal Use Only	
Comments	
Reviewed By	Dated