Urgent Medical Device Field Action

MAY-06-2022 | REF-605552 | Rev B

Subject: VOLISTA paint chipping

Products affected:
Volista StandOp cupolas which has been manufactured until 31-Dec-2020.

Dear Customer,

Maquet SAS/Getinge is initiating a voluntary Medical Device Correction for the VOLISTA StandOp Surgical Lights due to the potential for paint chipping to occur on the component (reference ARD568801164) located on the fork of the Volista StandOp Cupolas.

VOLISTA surgical lights are intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnostics and treatment.

Maquet SAS has received 18 complaints for a paint chipping issue on the component (ARD568801164) located on the fork of the Volista StandOp cupolas. There have been no reports of adverse events related to this issue.

Identification of the issue:

Under certain conditions, it was found that the paint could chip on a specific part of the fork. Therefore, there is a risk that paint particles may detach and fall in the operating field. The location where the potential for chipping to occur is shown circled in red in Figure 1 below:

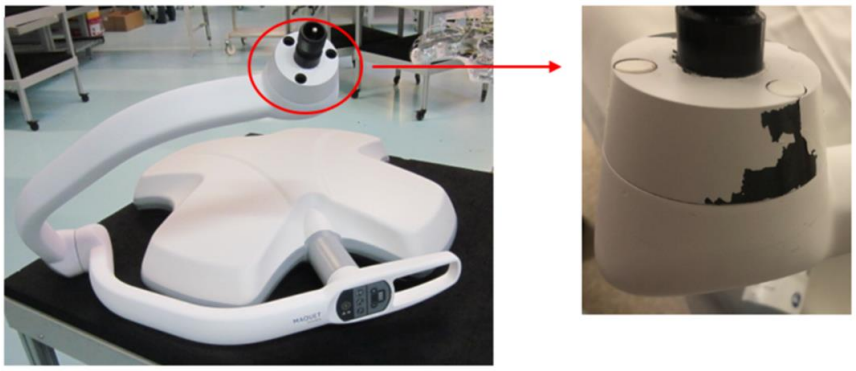


FIGURE 1

Risk to Health:

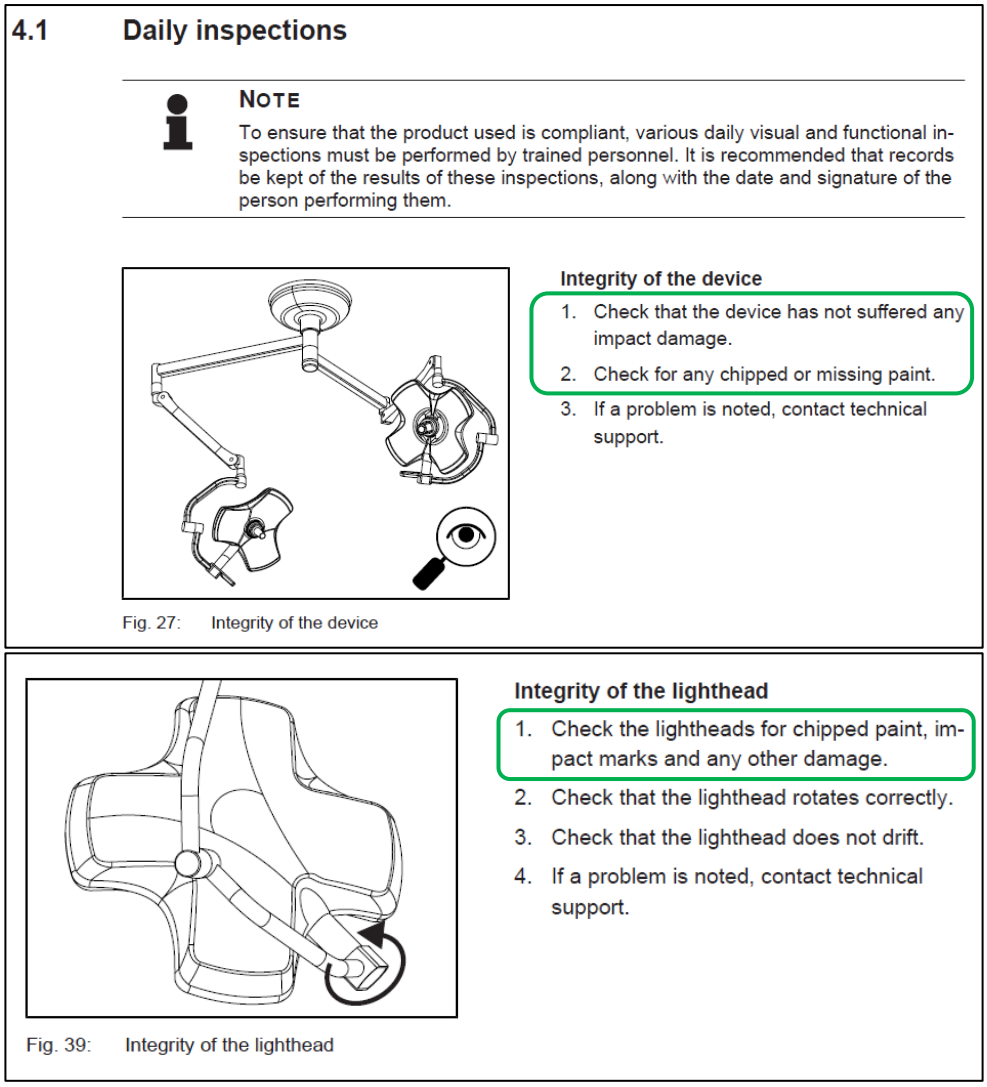
In the worst case scenario, infection, organ irritation, hypersensitivity reaction, and tissue granuloma may result if particles fall during surgical operation into the patient body or in the operating field.

Action to be taken by Customer:

Our records indicate that you have received one or more affected Volista StandOp Surgical Lights. Please identify your affected units using the reference numbers on page 4 and follow the instructions below:

1. Please ensure that all the VOLISTA System users at your facility are aware of this notice and forward as needed to all current and potential users at your facility.

2. Continue to perform daily inspections as instructed in the IFU which include checking for may chipped or missing paint. See Figure 2 below for IFU Reference.



4.1 Daily inspections

NOTE

To ensure that the product used is compliant, various daily visual and functional inspections must be performed by trained personnel. It is recommended that records be kept of the results of these inspections, along with the date and signature of the person performing them.

Fig. 27: Integrity of the device

Fig. 39: Integrity of the lighthead

FIGURE 2

If you observe paint chipping or detachment, Getinge recommends that you stop using the VOLISTA StandOP Surgical Lights and contact your Getinge service representative to schedule an appointment to replace the part free of charge.
To ensure that the whole scope of the surgical lights affected by this recall is covered, it is requested that if chipped or missing paint is observed through April 2025 you contact your Getinge service representative to have the part replaced.

Actions to be taken by Getinge:

Getinge service representatives will inspect component ARD568801164 during periodic maintenance and will replace the component if the issue is observed through April 2025. The component will also be replaced if Getinge service is contacted by a customer for the observation of paint chipped or missing on the component.

This voluntary recall only affects the products listed on page 1; no other products are affected by this voluntary recall.

We apologize for any inconvenience this may cause and we remain permanently at your disposal to remediate any issue you may experience.

Sincerely,

Sebastien LE PAGE
Technical Department Manager

Pascal JAY
Quality Regulatory Compliance Director

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Please acknowledge receipt of this communication by returning a copy or a scan copy to:

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