
Urgent Medical Device Field Action



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Subject: VOLISTA paint chipping

Products affected:

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

Dear Customer,

The purpose of this letter is to inform you about a potential issue found in the VOLISTA light head. Our records indicate that your facility has received one or more of these devices.

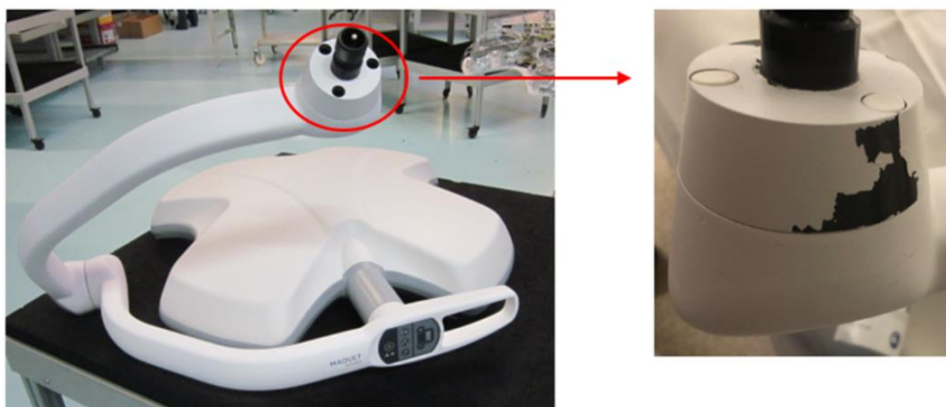
Normal use and Indications

Under normal circumstances 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.

The following has been discovered

Under certain conditions, it was established that the paint could chip on a specific part of the fork. Therefore, there is a risk probability that paint particles may detached and fall in the operating field.

- The paint peeling is located on a specific part of the fork, as shown on the pictures below:



Potential hazards

This issue may result at worst in a potential infection if particles fall during surgical operation in the patient body or in the operating field.

Action

For remediating to this possible paint chipping, we require your contribution in paying attention to your device, and then if you experience the paint chipping on the affected part, to follow the instruction for our service support to replace the part with one with improved paint adhesion.

Therefore,

- Before using the device, and as already recommended in our Instruction for use, please inspect the fork as below

4.1 Daily inspections

i 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.

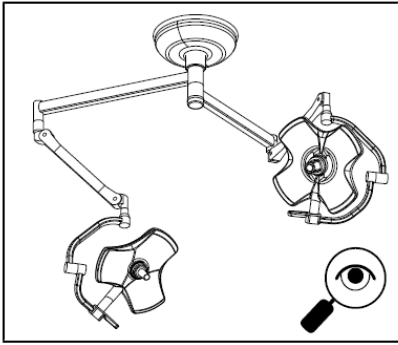


Fig. 27: Integrity of the device

Integrity of the device

1. Check that the device has not suffered any impact damage.
2. Check for any chipped or missing paint.
3. If a problem is noted, contact technical support.

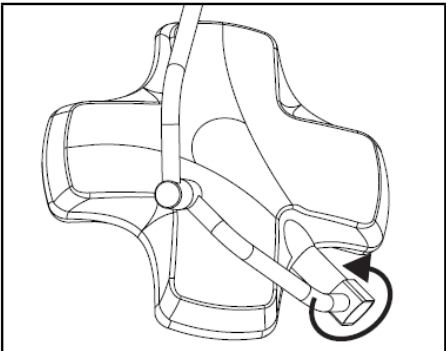


Fig. 39: Integrity of the lighthouse

Integrity of the lighthouse

1. Check the lighthouses for chipped paint, impact marks and any other damage.
2. Check that the lighthouse rotates correctly.
3. Check that the lighthouse does not drift.
4. If a problem is noted, contact technical support.

- Should you detect a paint peeling on this part of the fork, please evaluate if you should stop using your Volista and contact systematically your Getinge representative.

The Getinge Representative and our Service Support will proceed with the replacement in the shortest time-interval.

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

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Local Quality Manager

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

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